C/2024/3878

28.6.2024

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 May 2024 to 31 May 2024

(Decisions taken pursuant to Article 34 of Directive 2001/83/EC [1], Article 38 of Directive 2001/82/EC [2]or Article 5 of Regulation (EU) 2019/6 of the European Parliament and of the Council [3])

(C/2024/3878)

— Issuing, maintenance or modification of a national marketing authorisation

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorisation	Member State concerned	Date of notification
16.5.2024	Micrazym and associated names	porcine pancreas enzymes	See Annex II	See Annex II	17.05.2024
24.5.2024	Synapse Labs Pvt. Ltd.	Medicinal products for human use which have been authorised or are pending approval based on studies performed at Synapse Labs Pvt. Ltd.	See Annex III	See Annex III	24.5.2024

— Refusal of a national marketing authorisation

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorisation	Member State concerned	Date of notification
10.5.2024	Ibuprofen NVT and associated names	ibuprofen	See Annex I	See Annex I	13.5.2024

— Suspension of a national marketing authorisation

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorisation	Member State concerned	Date of notification
10.5.2024	Ibuprofen NVT and associated names	ibuprofen	See Annex I	See Annex I	13.5.2024
24.5.2024	Synapse Labs Pvt. Ltd.	Medicinal products for human use which have been authorised or are pending approval based on studies performed at Synapse Labs Pvt. Ltd.	See Annex III	See Annex III	24.5.2024

[1] OJ L 311, 28.11.2001, p. 67.
[2] OJ L 311, 28.11.2001, p. 1.
[3] OJ L 4, 7.1.2019, p. 43.

ANNEX I

List of medicinal products and presentations

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Estonia	NVT UAB Sodu G. 1 Kauno R. Sav. Linksmakalnio K. Kaunas County 53290 Lithuania		Ibuprofen NVT	ibuprofen 400 mg	Capsule, soft	Oral use
France	Laboratoire Biogaran 15 Boulevard Charles De Gaulle 92700 Colombes France		Ibuprofene Biogaran Conseil 400 mg, capsule molle.	ibuprofen 400 mg	Capsule, soft	Oral use
Latvia	UAB 'NVT' Sodų st. 1, Linksmakalnio v., Kaunas r. LT-53290 Lithuania		Ibuprofen NVT 400 mg mīkstās kapsulas	ibuprofen 400 mg	Capsule, soft	Oral use
Lithuania	JSC 'NVT' Sodų st. 1, Linksmakalnio v., Kaunas r. LT-53290 Lithuania		Ibuprofen NVT 400 mg minkštosios kapsulės	ibuprofen 400 mg	Capsule, soft	Oral use
Poland	Ranbaxy (Poland) Sp. z o. o ul. Idzikowskiego 16, 00-710 Warszawa.		Paduden Express Forte - for 400mg	ibuprofen 400 mg	Capsule, soft	Oral use
Romania	Terapia SA Str. Fabricii nr. 124, Cluj Napoca 400632 Romania		PADUDEN Express Forte 400 mg capsule moi	ibuprofen 400 mg	Capsule, soft	Oral use
Spain		Laboratorios Liconsa S.A. C/Dulcinea s/n, Alcalá de Henares, Madrid 28805 Spain	Ibuprofeno Liconsa 400 mg cápsulas blandas	ibuprofen 400 mg	Capsule, soft	Oral use

ANNEX II

List of medicinal products and presentations

Member State EU/EEA	Applicant	Invented name	Strength	Pharmaceutical form	Route of administration
Austria	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Micrazym 10 000 Einheiten magensaftresistente Hartkapseln	10 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Austria	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Micrazym 25 000 Einheiten magensaftresistente Hartkapseln	25 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Belgium	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Ankreta 10 000 unités gélules gastrorésistantes	10 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Belgium	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Ankreta 25 000 unités gélules gastrorésistantes	25 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Cyprus	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Micrazym 10 000 Μονάδες γαστροανθεκτικά καψάκια, σκληρά	10 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Cyprus	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Micrazym 25 000 Μονάδες γαστροανθεκτικά καψάκια, σκληρά	25 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Czech Republic	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Mekrazym	10 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Czech Republic	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Mekrazym	25 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use

Member State EU/EEA	Applicant	Invented name	Strength	Pharmaceutical form	Route of administration
Denmark	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Micrazym 10 000 Enheder hårde enterokapsler	10 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Denmark	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Micrazym 25 000 Enheder hårde enterokapsler	25 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Finland	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Micrazym 10 000 Yksikköä enterokapseli, kova	10 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Finland	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Micrazym 25 000 Yksikköä enterokapseli, kova	25 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Germany	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Pankreatin Klinge 10 000 Einheiten magensaftresistente Hartkapseln	10 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Germany	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Pankreatin Klinge 25 000 Einheiten magensaftresistente Hartkapseln	25 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Ireland	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Micrazym, 10 000 Units gastro-resistant capsules, hard	10 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Ireland	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Micrazym, 25 000 Units gastro-resistant capsules, hard	25 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Luxembourg	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Ankreta 10 000 unités gélules gastrorésistantes	10 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use

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Member State EU/EEA	Applicant	Invented name	Strength	Pharmaceutical form	Route of administration
Luxembourg	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Ankreta 25 000 unités gélules gastrorésistantes	25 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
The Netherlands	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Micrazym, 10 000 Ph. Eur. Units, maagsapresistente capsules, hard	10 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
The Netherlands	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Micrazym, 25 000 Ph. Eur. Units, maagsapresistente capsules, hard	25 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Norway	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Micrazym	10 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Norway	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Micrazym	25 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Slovak Republic	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Micrazym 10 000 jednotiek tvrdé gastrorezistentné kapsuly	10 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Slovak Republic	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Micrazym 25 000 jednotiek tvrdé gastrorezistentné kapsuly	25 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Spain	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Mekrazym 10 000 U cápsulas duras gastrorresistentes	10 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Spain	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Mekrazym 25 000 U cápsulas duras gastrorresistentes	25 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use

Member State EU/EEA	Applicant	Invented name	Strength	Pharmaceutical form	Route of administration
Sweden	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Alimentease	10 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use
Sweden	AVVA Pharmaceuticals Ltd. 23A Spyrou Kyprianou, 4001, Limassol, Cyprus	Alimentease	25 000 Ph. Eur. units	gastro-resistant capsules, hard	Oral use

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ANNEX III

List of nationally authorised medicinal products and marketing authorisation applications

ANNEX IIIA.

Medicinal products for which the marketing authorisations are recommended for maintenance and marketing authorisation applications for which bioequivalence vis-à-vis the EU reference medicinal product has been established

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Austria		Bluefish	Sunitinib Bluefish 12,5 mg Hartkapseln	Sunitinib	12,5 mg	Capsule, hard	Oral use
Austria		Bluefish	Sunitinib Bluefish 25 mg Hartkapseln	Sunitinib	25 mg	Capsule, hard	Oral use
Austria		Bluefish	Sunitinib Bluefish 50 mg Hartkapseln	Sunitinib	50 mg	Capsule, hard	Oral use
Austria	+pharma arzneimittel gmbh		Sitagliptin +pharma 100 mg Filmtabletten	Sitagliptin	100 mg	Film-coated tablet	Oral use
Austria	+pharma arzneimittel gmbh		Sitagliptin +pharma 25 mg Filmtabletten	Sitagliptin	25 mg	Film-coated tablet	Oral use
Austria	+pharma arzneimittel gmbh		Sitagliptin +pharma 50 mg Filmtabletten	Sitagliptin	50 mg	Film-coated tablet	Oral use
Austria	Genericon Pharma GmbH		Sitagliptin Genericon 100 mg Filmtabletten	Sitagliptin	100 mg	Film-coated tablet	Oral use
Austria	Genericon Pharma GmbH		Sitagliptin Genericon 25 mg Filmtabletten	Sitagliptin	25 mg	Film-coated tablet	Oral use
Austria	Genericon Pharma GmbH		Sitagliptin Genericon 50 mg Filmtabletten	Sitagliptin	50 mg	Film-coated tablet	Oral use
Austria	Sandoz GmbH		Sitagliptin Sandoz GmbH 100 mg – Filmtabletten	Sitagliptin	100 mg	Film-coated tablet	Oral use
Austria	Sandoz GmbH		Sitagliptin Sandoz GmbH 25 mg – Filmtabletten	Sitagliptin	25 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Austria	Sandoz GmbH		Sitagliptin Sandoz GmbH 50 mg – Filmtabletten	Sitagliptin	50 mg	Film-coated tablet	Oral use
Austria	+pharma arznei-mittel gmbh		Sitagliptin/Metforminhydro-chlorid +pharma 50 mg/1 000 mg Filmtabletten	Sitagliptin/ met-formin	50 mg / 1 000 mg	Film-coated tablet	Oral use
Austria	Genericon Pharma GmbH		Sitagliptin/Metforminhydro-chlorid Genericon 50 mg/1 000 mg Filmtabletten	Sitagliptin/ met-formin	50 mg / 1 000 mg	Film-coated tablet	Oral use
Austria	Sandoz GmbH		Sitagliptin/Metformin Sandoz GmbH 50 mg/1 000 mg – Filmta-bletten	Sitagliptin/ met-formin	50 mg / 1 000 mg	Film-coated tablet	Oral use
Belgium	Sandoz GmbH		Sitagliptin Sandoz GmbH - 100 mg - Film-coated tablet	Sitagliptin	100 mg	Film-coated tablet	Oral use
Belgium	Sandoz GmbH		Sitagliptin Sandoz GmbH - 25 mg - Film-coated tablet	Sitagliptin	25 mg	Film-coated tablet	Oral use
Belgium	Sandoz GmbH		Sitagliptin Sandoz GmbH - 50 mg - Film-coated tablet	Sitagliptin	50 mg	Film-coated tablet	Oral use
Belgium	Sandoz GmbH		Sitagliptin/Metformin Sandoz GmbH - 50 mg - 1 000 mg - Film-coated tablet	Sitagliptin/ met-formin	50 mg / 1 000 mg	Film-coated tablet	Oral use
Croatia		Belupo lijekovi i kozmetika d.d.	Gitas 100 mg filmom obložene tablete	Sitagliptin	100 mg	Film-coated tablet	Oral use
Croatia		Belupo lijekovi i kozmetika d.d.	Gitas 25 mg filmom obložene tablete	Sitagliptin	25 mg	Film-coated tablet	Oral use
Croatia		Belupo lijekovi i kozmetika d.d.	Gitas 50 mg filmom obložene tablete	Sitagliptin	50 mg	Film-coated tablet	Oral use
Croatia	Belupo lijekovi i kozmetika, d.d.		Condias Combi 50 mg/1 000 mg filmom obložene tablete	Sitagliptin/ met-formin	50 mg/ 1 000 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Croatia	Genericon Pharma GmbH		Sitagliptin/metforminklorid Genericon 50 mg/1 000 mg filmom obložene tablete	Sitagliptin/ metformin	50 mg / 1 000 mg	Film-coated tablet	Oral use
Croatia	Farmex d.o.o.		Nibufar 12,5 mg tvrde kapsule	Sunitinib	12,5 mg	Capsule, hard	Oral use
Croatia	Farmex d.o.o.		Nibufar 25 mg tvrde kapsule	Sunitinib	25 mg	Capsule, hard	Oral use
Croatia	Farmex d.o.o.		Nibufar 50 mg tvrde kapsule	Sunitinib	50 mg	Capsule, hard	Oral use
Cyprus	Win Medica S.A.		Retaform tablet, prolonged-release 1 000 mg	Metformin	1 000 mg	Prolonged-release tablet	Oral use
Cyprus	Win Medica S.A.		Retaform tablet, prolonged-release 500 mg	Metformin	500 mg	Prolonged-release tablet	Oral use
Cyprus	Win Medica S.A.		Retaform tablet, prolonged-release 750 mg	Metformin	750 mg	Prolonged-release tablet	Oral use
Cyprus		Sapiens Pharmaceuticals Ltd	Sunitinib Sapiens capsule, hard 12.5 mg	Sunitinib	12,5 mg	Capsule, hard	Oral use
Cyprus		Sapiens Pharmaceuticals Ltd	Sunitinib Sapiens capsule, hard 25 mg	Sunitinib	25 mg	Capsule, hard	Oral use
Cyprus		Sapiens Pharmaceuticals Ltd	Sunitinib Sapiens capsule, hard 37.5 mg	Sunitinib	37,5 mg	Capsule, hard	Oral use
Cyprus		Sapiens Pharmaceuticals Ltd	Sunitinib Sapiens capsule, hard 50 mg	Sunitinib	50 mg	Capsule, hard	Oral use
Czech Republic	Novatin Limited		Zexitor	Metformin	1 000 mg	Prolonged-release tablet	Oral use
Czech Republic	Novatin Limited		Zexitor	Metformin	500 mg	Prolonged-release tablet	Oral use
Czech Republic	Novatin Limited		Zexitor	Metformin	750 mg	Prolonged-release tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Czech Republic	+pharma arznei-mittel gmbh		Sitagliptin/Metformin +pharma	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Czech Republic		Belupo Lijekovi I Kozmetika d.d.	Condias	Sitagliptin	100 mg	Film-coated tablet	Oral use
Czech Republic		Belupo Lijekovi I Kozmetika d.d.	Condias	Sitagliptin	25 mg	Film-coated tablet	Oral use
Czech Republic		Belupo Lijekovi I Kozmetika d.d.	Condias	Sitagliptin	50 mg	Film-coated tablet	Oral use
Czech Republic	+pharma arznei-mittel gmbh		Sitagliptin +pharma	Sitagliptin	100 mg	Film-coated tablet	Oral use
Czech Republic	+pharma arznei-mittel gmbh		Sitagliptin +pharma	Sitagliptin	25 mg	Film-coated tablet	Oral use
Czech Republic	+pharma arznei-mittel gmbh		Sitagliptin +pharma	Sitagliptin	50 mg	Film-coated tablet	Oral use
Czech Republic	Heaton k.s.		Anau	Sitagliptin	100 mg	Film-coated tablet	Oral use
Czech Republic	Sandoz GmbH		Sitagliptin Sandoz GmbH	Sitagliptin	100 mg	Film-coated tablet	Oral use
Czech Republic	Belupo Lijekovi I Kozmetika d.d.		Condias Combi	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Czech Republic	Heaton k.s.		Sipactimet	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Czech Republic	Sandoz GmbH		Sitagliptin/Metformin Sandoz GmbH	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Estonia	Sandoz Pharmaceuticals d.d.		Sitagliptin Sandoz	Sitagliptin	100 mg	Film-coated tablet	Oral use
Estonia	Sandoz Pharmaceuticals d.d.		Sitagliptin Sandoz	Sitagliptin	25 mg	Film-coated tablet	Oral use
Estonia	Sandoz Pharmaceuticals d.d.		Sitagliptin Sandoz	Sitagliptin	50 mg	Film-coated tablet	Oral use
Estonia	Sandoz d.d.		Sitagliptin/ Metformin Hydrochloride Sandoz	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Finland	Hexal A/S		Sitagliptin Hexal	Sitagliptin	100 mg	Film-coated tablet	Oral use
Finland	Hexal A/S		Sitagliptin Hexal	Sitagliptin	25 mg	Film-coated tablet	Oral use
Finland	Hexal A/S		Sitagliptin Hexal	Sitagliptin	50 mg	Film-coated tablet	Oral use
Finland	Hexal A/S		Sitagliptin/Metformin Hexal	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
France	Evolupharm		Sitagliptine Evolugen 100 mg, comprimé pelliculé	Sitagliptin	100 mg	Film-coated tablet	Oral use
France	Evolupharm		Sitagliptine Evolugen 50 mg, comprimé pelliculé	Sitagliptin	50 mg	Film-coated tablet	Oral use
France	Sandoz		Sitagliptine GNR 100 mg, comprimé pelliculé	Sitagliptin	100 mg	Film-coated tablet	Oral use
France	Sandoz		Sitagliptine GNR 50 mg, comprimé pelliculé	Sitagliptin	50 mg	Film-coated tablet	Oral use
France	Biogaran		Sitagliptine/Metformine BGR 50 mg/1 000 mg, comprimé pelliculé	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
France	Evolupharm		Sitagliptine/Metformine Evolugen 50 mg/1 000 mg, comprimé pelliculé	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
France	Sandoz		Sitagliptine/Metformine GNR 50 mg/1 000 mg, comprimé pelliculé	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Germany	Bluefish Pharmaceuticals AB		Sutinib Bluefish 12,5 mg Hartkapseln	Sunitinib	12,5 mg	Capsule, hard	Oral use
Germany	Bluefish Pharmaceuticals AB		Sutinib Bluefish 25 mg Hartkapseln	Sunitinib	25 mg	Capsule, hard	Oral use
Germany	Bluefish Pharmaceuticals AB		Sutinib Bluefish 50 mg Hartkapseln	Sunitinib	50 mg	Capsule, hard	Oral use
Germany	1 A Pharma GmbH		Sitagliptin - 1 A Pharma 100 mg Filmtabletten	Sitagliptin	100 mg	Film-coated tablet	Oral use
Germany	1 A Pharma GmbH		Sitagliptin - 1 A Pharma 25 mg Filmtabletten	Sitagliptin	25 mg	Film-coated tablet	Oral use
Germany	1 A Pharma GmbH		Sitagliptin - 1 A Pharma 50 mg Filmtabletten	Sitagliptin	50 mg	Film-coated tablet	Oral use
Germany	1 A Pharma GmbH		Sitagliptin/Metformin - 1 A Pharma 50 mg/1 000 mg Filmtabletten	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Germany	Hexal AG		Sitagliptin HEXAL 100 mg Filmtabletten	Sitagliptin	100 mg	Film-coated tablet	Oral use
Germany	Hexal AG		Sitagliptin HEXAL 25 mg Filmtabletten	Sitagliptin	25 mg	Film-coated tablet	Oral use
Germany	Hexal AG		Sitagliptin HEXAL 50 mg Filmtabletten	Sitagliptin	50 mg	Film-coated tablet	Oral use
Germany	Hexal AG		Sitagliptin Metformin HEXAL 50 mg/1 000 mg Filmtabletten	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Greece	Win Medica S.A.		Retaform	Metformin	1 000 mg	Prolonged-release tablet	Oral use
Greece	Win Medica S.A.		Retaform	Metformin	500 mg	Prolonged-release tablet	Oral use
Greece	Win Medica S.A.		Retaform	Metformin	750 mg	Prolonged-release tablet	Oral use
Greece	Genepharm S.A.		Egotux	Sunitinib	12,5 mg	Capsule, hard	Oral use
Greece	Genepharm S.A.		Egotux	Sunitinib	25 mg	Capsule, hard	Oral use
Greece	Genepharm S.A.		Egotux	Sunitinib	37,5 mg	Capsule, hard	Oral use
Greece	Genepharm S.A.		Egotux	Sunitinib	50 mg	Capsule, hard	Oral use
Greece	Sandoz Pharmaceuticals d.d.		Sitagliptin Sandoz 100 mg	Sitagliptin	100 mg	Film-coated tablet	Oral use
Greece	Sandoz Pharmaceuticals d.d.		Sitagliptin Sandoz 25 mg	Sitagliptin	25 mg	Film-coated tablet	Oral use
Greece	Sandoz Pharmaceuticals d.d.		Sitagliptin Sandoz 50 mg	Sitagliptin	50 mg	Film-coated tablet	Oral use
Greece	Sandoz d.d.		Sitagliptin+ Metformin Sandoz	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Hungary	1 A Pharma GmbH		SITAGLIPTIN 1 A PHARMA 100 mg filmtabletta	Sitagliptin	100 mg	Film-coated tablet	Oral use
Hungary	1 A Pharma GmbH		SITAGLIPTIN 1 A PHARMA 25 mg filmtabletta	Sitagliptin	25 mg	Film-coated tablet	Oral use
Hungary	1 A Pharma GmbH		SITAGLIPTIN 1 A PHARMA 50 mg filmtabletta	Sitagliptin	50 mg	Film-coated tablet	Oral use
Hungary	Pharmevid s.r.o.		Sunitinib Pharmevid	Sunitinib	12.5 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Hungary	Pharmevid s.r.o.		Sunitinib Pharmevid	Sunitinib	25 mg	Capsule, hard	Oral use
Hungary	Pharmevid s.r.o.		Sunitinib Pharmevid	Sunitinib	50 mg	Capsule, hard	Oral use
Hungary	1 A Pharma GmbH		SITAGLIPTIN/METFORMIN 1 A PHARMA 50 mg/1 000 mg film-tabletta	Sitagliptin/ metformin	50 mg / 1 000 mg	Film-coated tablet	Oral use
Ireland	Pharmafile Limited		Nortriptyline	Nortriptyline	10 mg	Film-coated tablet	Oral use
Ireland	Pharmafile Limited		Nortriptyline	Nortriptyline	25 mg	Film-coated tablet	Oral use
Ireland	Bluefish Pharmaceuticals AB		Sunitinib Bluefish	Sunitinib	12,5 mg	Capsule, hard	Oral use
Ireland	Bluefish Pharmaceuticals AB		Sunitinib Bluefish	Sunitinib	25 mg	Capsule, hard	Oral use
Ireland	Bluefish Pharmaceuticals AB		Sunitinib Bluefish	Sunitinib	50 mg	Capsule, hard	Oral use
Italy	DOC Generici S.r.l.		Sitagliptin DOC Generici	Sitagliptin	100 mg	Film-coated tablet	Oral use
Italy	DOC Generici S.r.l.		Sitagliptin DOC Generici	Sitagliptin	25 mg	Film-coated tablet	Oral use
Italy	DOC Generici S.r.l.		Sitagliptin DOC Generici	Sitagliptin	50 mg	Film-coated tablet	Oral use
Italy	Sandoz GmbH		Sitagliptin Sandoz GmbH	Sitagliptin	100 mg	Film-coated tablet	Oral use
Italy	Sandoz GmbH		Sitagliptin Sandoz GmbH	Sitagliptin	25 mg	Film-coated tablet	Oral use
Italy	Sandoz GmbH		Sitagliptin Sandoz GmbH	Sitagliptin	50 mg	Film-coated tablet	Oral use
Italy	DOC Generici S.r.l.		Sitagliptin e metformina DOC Generici	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Italy	Sandoz GmbH		Sitagliptin e Metformina Sandoz GmbH	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Latvia	Sandoz d.d.		Sitagliptin Sandoz 100 mg film-coated tablets	Sitagliptin	100 mg	Film-coated tablet	Oral use
Latvia	Sandoz d.d.		Sitagliptin Sandoz 25 mg film-coated tablets	Sitagliptin	25 mg	Film-coated tablet	Oral use
Latvia	Sandoz d.d.		Sitagliptin Sandoz 50 mg film-coated tablets	Sitagliptin	50 mg	Film-coated tablet	Oral use
Latvia	Sandoz d.d.		Sitagliptin/Metformin hydrochloride Sandoz 50 mg/1 000 mg film-coated tablets	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Lithuania	Sandoz d.d.		Sitagliptin Sandoz 100 mg plėvele dengtos tabletės	Sitagliptin	100 mg	Film-coated tablet	Oral use
Lithuania	Sandoz d.d.		Sitagliptin Sandoz 25 mg plėvele dengtos tabletės	Sitagliptin	25 mg	Film-coated tablet	Oral use
Lithuania	Sandoz d.d.		Sitagliptin Sandoz 50 mg plėvele dengtos tabletės	Sitagliptin	50 mg	Film-coated tablet	Oral use
Lithuania	Sandoz d.d.		Sitagliptin/Metformin hydrochloride Sandoz 50 mg/1 000 mg plėvele dengtos tabletės	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Malta	Heaton k.s.		Anau 100 mg film-coated tablets	Sitagliptin	100 mg	Film-coated tablet	Oral use
Malta	Pharos Pharmaceutical Oriented Services Ltd.		Sitagliptin PharOS 100 mg film-coated tablets	Sitagliptin	100 mg	Film-coated tablet	Oral use
Malta	Pharos Pharmaceutical Oriented Services Ltd.		Sitagliptin PharOS 25 mg film-coated tablets	Sitagliptin	25 mg	Film-coated tablet	Oral use
Malta	Pharos Pharmaceutical Oriented Services Ltd.		Sitagliptin PharOS 50 mg film-coated tablets	Sitagliptin	50 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Malta	Heaton k.s.		Sipactimet 50 mg/1 000 mg film-coated tablets	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Malta	Pharos Pharmaceutical Oriented Services Ltd.		Sitagliptin / Metformin PharOS 50 mg/1 000 mg film-coated tablet	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Norway	Sandoz B.V.		Sitagliptin Hexal	Sitagliptin	100 mg	Film-coated tablet	Oral use
Norway	Sandoz B.V.		Sitagliptin Hexal	Sitagliptin	25 mg	Film-coated tablet	Oral use
Norway	Sandoz B.V.		Sitagliptin Hexal	Sitagliptin	50 mg	Film-coated tablet	Oral use
Poland		Bluefish Pharmaceuticals AB	Sunitinib Bluefish	Sunitinib	12,5 mg	Capsule, hard	Oral use
Poland		Bluefish Pharmaceuticals AB	Sunitinib Bluefish	Sunitinib	25 mg	Capsule, hard	Oral use
Poland		Bluefish Pharmaceuticals AB	Sunitinib Bluefish	Sunitinib	50 mg	Capsule, hard	Oral use
Poland	+pharma arzneimittel gmbh		Sitagliptin +pharma	Sitagliptin	100 mg	Film-coated tablet	Oral use
Poland	+pharma arzneimittel gmbh		Sitagliptin +pharma	Sitagliptin	25 mg	Film-coated tablet	Oral use
Poland	+pharma arzneimittel gmbh		Sitagliptin +pharma	Sitagliptin	50 mg	Film-coated tablet	Oral use
Poland	Sandoz GmbH		Sitagliptin Sandoz	Sitagliptin	100 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Poland	Sandoz GmbH		Sitagliptin Sandoz	Sitagliptin	50 mg	Film-coated tablet	Oral use
Poland	+pharma arznei-mittel gmbh		Sitagliptin + Metformin hydro-chloride +pharma	Sitagliptin/ met-formin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Poland	Sandoz GmbH		Sitagliptin + Metformin hydro-chloride Sandoz	Sitagliptin/ met-formin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Portugal	Bluefish Pharma-ceuticals AB		Sunitinib Bluefish	Sunitinib	12,5 mg	Capsule, hard	Oral use
Portugal	Bluefish Pharma-ceuticals AB		Sunitinib Bluefish	Sunitinib	25 mg	Capsule, hard	Oral use
Portugal	Bluefish Pharma-ceuticals AB		Sunitinib Bluefish	Sunitinib	50 mg	Capsule, hard	Oral use
Portugal	Sandoz Farmacêu-tica, Lda.		Sitagliptina Sandoz	Sitagliptin	100 mg	Film-coated tablet	Oral use
Portugal	Sandoz Farmacêu-tica, Lda.		Sitagliptina Sandoz	Sitagliptin	25 mg	Film-coated tablet	Oral use
Portugal	Sandoz Farmacêu-tica, Lda.		Sitagliptina Sandoz	Sitagliptin	50 mg	Film-coated tablet	Oral use
Portugal	Sandoz Farmacêu-tica, Lda.		Metformina+Sitagliptina Sandoz	Sitagliptin/ met-formin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Romania	Sandoz S.R.L.		Sitagliptina Sandoz 100 mg com-primate filmate	Sitagliptin	100 mg	Film-coated tablet	Oral use
Romania	SC Sandoz SRL, Romania		Sitagliptina Sandoz 100 mg com-primate filmate	Sitagliptin	100 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Romania	Sandoz S.R.L.		Sitagliptin/ Metformin Sandoz 50 mg/1 000 mg comprimate filmate	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Slovakia	Pharmevid s.r.o.		Sunitinib Pharmevid	Sunitinib	12.5 mg	Capsule, hard	Oral use
Slovakia	Pharmevid s.r.o.		Sunitinib Pharmevid	Sunitinib	25 mg	Capsule, hard	Oral use
Slovakia	Pharmevid s.r.o.		Sunitinib Pharmevid	Sunitinib	50 mg	Capsule, hard	Oral use
Slovakia	Heaton k.s.		Anau 100 mg filmom obalené tablety	Sitagliptin	100 mg	Film-coated tablet	Oral use
Slovakia	Sandoz GmbH,		Sitagliptin Sandoz 100 mg	Sitagliptin	100 mg	Film-coated tablet	Oral use
Slovakia	Sandoz GmbH,		Sitagliptin Sandoz 50 mg	Sitagliptin	50 mg	Film-coated tablet	Oral use
Slovakia	Heaton k.s.		Sipactimet 50 mg/1 000 mg filmom obalené tablety	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Slovakia	Sandoz GmbH		Sitagliptin/Metformin Sandoz 50 mg/1 000 mg filmom obalené tablety	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Spain	Sandoz Farmaceutica, S.A.		Sitagliptina Sandoz Farmaceutica 100 mg comprimidos recubiertos de pelicula EFG	Sitagliptin	100 mg	Film-coated tablet	Oral use
Spain	Sandoz Farmaceutica, S.A.		Sitagliptina Sandoz Farmaceutica 25 mg comprimidos recubiertos de pelicula EFG	Sitagliptin	25 mg	Film-coated tablet	Oral use
Spain	Sandoz Farmaceutica, S.A.		Sitagliptina Sandoz Farmaceutica 50 mg comprimidos recubiertos de pelicula EFG	Sitagliptin	50 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Spain	Sandoz Farmaceutica, S.A.		Sitagliptina/Metformina Sandoz Farmaceutica 50 mg/1 000 mg comprimidos recubiertos de película EFG	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Sweden	Bluefish Pharmaceuticals AB		Sunitinib Bluefish	Sunitinib	12,5 mg	Capsule, hard	Oral use
Sweden	Bluefish Pharmaceuticals AB		Sunitinib Bluefish	Sunitinib	25 mg	Capsule, hard	Oral use
Sweden	Bluefish Pharmaceuticals AB		Sunitinib Bluefish	Sunitinib	50 mg	Capsule, hard	Oral use
The Netherlands	Genepharm S.A.		Egotux 12,5 mg harde capsules	Sunitinib	12,5 mg	Capsule, hard	Oral use
The Netherlands	Genepharm S.A.		Egotux 25 mg harde capsules	Sunitinib	25 mg	Capsule, hard	Oral use
The Netherlands	Genepharm S.A.		Egotux 37,5 mg harde capsules	Sunitinib	37,5 mg	Capsule, hard	Oral use
The Netherlands	Genepharm S.A.		Egotux 50 mg harde capsules	Sunitinib	50 mg	Capsule, hard	Oral use
The Netherlands	Teva B.V.		Ursodeoxycholzuur Teva 300 mg, tabletten	Ursodeoxycholic acid	300 mg	Tablet	Oral use
The Netherlands	Teva B.V.		Ursodeoxycholzuur Teva 500 mg, tabletten	Ursodeoxycholic acid	500 mg	Tablet	Oral use
The Netherlands	DOC Generici S.r.l.		Sitagliptine DOC Generici, 100 mg filmomhulde tabletten	Sitagliptin	100 mg	Film-coated tablet	Oral use
The Netherlands	DOC Generici S.r.l.		Sitagliptine DOC Generici, 25 mg filmomhulde tabletten	Sitagliptin	25 mg	Film-coated tablet	Oral use
The Netherlands	DOC Generici S.r.l.		Sitagliptine DOC Generici, 50 mg filmomhulde tabletten	Sitagliptin	50 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	Heaton k.s.		Anau 100 mg filmomhulde tabletten	Sitagliptin	100 mg	Film-coated tablet	Oral use
The Netherlands	Maddox Pharma Swiss B.V.		Sitagla 100 mg filmomhulde tabletten	Sitagliptin	100 mg	Film-coated tablet	Oral use
The Netherlands	Maddox Pharma Swiss B.V.		Sitagla 25 mg filmomhulde tabletten	Sitagliptin	25 mg	Film-coated tablet	Oral use
The Netherlands	Maddox Pharma Swiss B.V.		Sitagla 50 mg filmomhulde tabletten	Sitagliptin	50 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine Sandoz 100 mg, filmomhulde tabletten	Sitagliptin	100 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine Sandoz 100 mg, filmomhulde tabletten	Sitagliptin	100 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine Sandoz 100 mg, filmomhulde tabletten	Sitagliptin	100 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine Sandoz 100 mg, filmomhulde tabletten	Sitagliptin	100 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine Sandoz 100 mg, filmomhulde tabletten	Sitagliptin	100 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine Sandoz 25 mg, filmomhulde tabletten	Sitagliptin	25 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine Sandoz 25 mg, filmomhulde tabletten	Sitagliptin	25 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine Sandoz 25 mg, filmomhulde tabletten	Sitagliptin	25 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	Sandoz B.V.		Sitagliptine Sandoz 25 mg, filmomhulde tabletten	Sitagliptin	25 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine Sandoz 25 mg, filmomhulde tabletten	Sitagliptin	25 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine Sandoz 50 mg, filmomhulde tabletten	Sitagliptin	50 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine Sandoz 50 mg, filmomhulde tabletten	Sitagliptin	50 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine Sandoz 50 mg, filmomhulde tabletten	Sitagliptin	50 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine Sandoz 50 mg, filmomhulde tabletten	Sitagliptin	50 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine Sandoz 50 mg, filmomhulde tabletten	Sitagliptin	50 mg	Film-coated tablet	Oral use
The Netherlands	DOC Generici S.r.l.		Sitagliptine/Metformine hydrochloride DOC Generici 50mg/ 1 000 mg, filmomhulde tabletten	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
The Netherlands	Genericon Pharma GmbH		Sitagliptine/Metformine hydrochloride Genericon 50 mg/1 000 mg filmomhulde tabletten	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
The Netherlands	Heaton k.s.		Sipactimet 50mg/1 000 mg, filmomhulde tabletten	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
The Netherlands	Maddox Pharma Swiss B.V.		Sitaglamet 50 mg/1 000 mg filmomhulde tabletten	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	Sandoz B.V.		Sitagliptine/Metformine HCl Sandoz 50mg/1 000 mg, filmomhulde tabletten	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine/Metformine HCl Sandoz 50mg/1 000 mg, filmomhulde tabletten	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine/Metformine HCl Sandoz 50mg/1 000 mg, filmomhulde tabletten	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine/Metformine HCl Sandoz 50mg/1 000 mg, filmomhulde tabletten	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine/Metformine HCl Sandoz 50mg/1 000 mg, filmomhulde tabletten	Sitagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Genus Pharmaceuticals Limited		Fesoterodine Fumarate Stada 4mg prolonged-release tablets	Fesoterodine	4 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)	Genus Pharmaceuticals Limited		Fesoterodine Fumarate Stada 8mg prolonged-release tablets	Fesoterodine	8 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)	Teva UK Limited		Ursodeoxycholic acid 150 mg tablets	Ursodeoxycholic acid	150 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Alissa Healthcare Research Limited		Nortriptyline 10 mg film-coated tablets	Nortriptyline	10 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Alissa Healthcare Research Limited		Nortriptyline 25 mg film-coated tablets	Nortriptyline	25 mg	Film-coated tablet	Oral use

ANNEX IIIB.

Medicinal products for which the marketing authorisations are recommended for suspension and marketing authorisation applications which do not satisfy the criteria for authorisation

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Austria	+pharma arznei-mittel gmbh		Sitagliptin/Metforminhydrochlorid +pharma 50 mg/850 mg Filmtabletten	Sitagliptin/ met-formin	50 mg / 850 mg	Film-coated tablet	Oral use
Austria	AOP Orphan Pharmaceuticals GmbH		Tadalafil AOP 20 mg Filmtabletten	Tadalafil	20 mg	Film-coated tablet	Oral use
Austria	Baxter B.V.		Propofol Baxter 1 % MCT Emulsion zur Injektion/Infusion	Propofol	10 mg/ml	Emulsion for injec-tion/ infusion	Intravenous use
Austria	Baxter B.V.		Propofol Baxter 2 % MCT Emulsion zur Injektion/Infusion	Propofol	20 mg/ml	Emulsion for injec-tion/ infusion	Intravenous use
Austria	G.L. Pharma GmbH		Sorafenib G.L. 400 mg-Filmtabletten	Sorafenib	400 mg	Film-coated tablet	Oral use
Austria	G.L. Pharma GmbH		Lanrektan 10 mg-Filmtabletten	Tadalafil	10 mg	Film-coated tablet	Oral use
Austria	G.L. Pharma GmbH		Talrektan 10 mg Filmtabletten	Tadalafil	10 mg	Film-coated tablet	Oral use
Austria	G.L. Pharma GmbH		Lanrektan 2,5 mg-Filmtabletten	Tadalafil	2,5 mg	Film-coated tablet	Oral use
Austria	G.L. Pharma GmbH		Talrektan 2,5 mg Filmtabletten	Tadalafil	2,5 mg	Film-coated tablet	Oral use
Austria	G.L. Pharma GmbH		Lanrektan 20 mg-Filmtabletten	Tadalafil	20 mg	Film-coated tablet	Oral use
Austria	G.L. Pharma GmbH		Talrektan 20 mg Filmtabletten	Tadalafil	20 mg	Film-coated tablet	Oral use
Austria	G.L. Pharma GmbH		Lanrektan 5 mg-Filmtabletten	Tadalafil	5 mg	Film-coated tablet	Oral use
Austria	G.L. Pharma GmbH		Talrektan 5 mg Filmtabletten	Tadalafil	5 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Austria	Genericon Pharma GmbH		Sitagliptin/Metforminhydrochlorid Genericon 50 mg/850 mg Filmtabletten	Sitagliptin/ metformin	50 mg / 850 mg	Film-coated tablet	Oral use
Austria	Holsten Pharma		Amlodipin/Valsartan/HCT Rivopharm 10 mg/160 mg/12,5 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 160 mg / 12,5 mg	Film-coated tablet	Oral use
Austria	Holsten Pharma		Amlodipin/Valsartan/HCT Rivopharm 10 mg/160 mg/25 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 160 mg / 25 mg	Film-coated tablet	Oral use
Austria	Holsten Pharma		Amlodipin/Valsartan/HCT Rivopharm 10 mg/320 mg/25 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 320 mg / 25 mg	Film-coated tablet	Oral use
Austria	Holsten Pharma		Amlodipin/Valsartan/HCT Rivopharm 5 mg/160 mg/12,5 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg / 160 mg / 12,5 mg	Film-coated tablet	Oral use
Austria	Holsten Pharma		Amlodipin/Valsartan/HCT Rivopharm 5 mg/160 mg/25 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg / 160 mg / 25 mg	Film-coated tablet	Oral use
Austria	Opella Healthcare Austria GmbH		Racecadotril Opella Healthcare 100 mg Hartkapsel	Racecadotril	100 mg	Capsule, hard	Oral use
Austria	Pharmaselect International Beteiligungs GmbH		Colchanova 0,5 mg Tabletten	Colchicine	0,5 mg	Tablet	Oral use
Austria	Pharmaselect International Beteiligungs GmbH		Colchanova 1 mg Tabletten	Colchicine	1 mg	Tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Austria	Sandoz GmbH		Darunavir Sandoz 800 mg – Filmtabletten	Darunavir	800 mg	Film-coated tablet	Oral use
Austria	Sandoz GmbH		Padviram 600 mg/200 mg/245 mg - Filmtabletten	Efavirenz/ emtricitabine/ tenofovir	600 mg / 200 mg / 245 mg	Film-coated tablet	Oral use
Austria	Sandoz GmbH		Sitagliptin/Metformin Sandoz GmbH 50 mg/850 mg – Filmtabletten	Sitagliptin/ metformin	50 mg / 850 mg	Film-coated tablet	Oral use
Austria	Sandoz GmbH		Sorafenib Sandoz 400 mg - Filmtabletten	Sorafenib	400 mg	Film-coated tablet	Oral use
Austria	Stada Arzneimittel		Abacavir/Lamivudin Stada 600 mg/300 mg Filmtabletten	Abacavir/ lamivudine	600 mg / 300 mg	Film-coated tablet	Oral use
Austria	Stada Arzneimittel		Darunavir STADA 800 mg Filmtabletten	Darunavir	800 mg	Film-coated tablet	Oral use
Austria	Stada Arzneimittel		Deferasirox STADA 900 mg Filmtabletten	Deferasirox	900 mg	Film-coated tablet	Oral use
Austria	Stada Arzneimittel		Efatriten 600 mg/200 mg/245 mg Filmtabletten	Efavirenz	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
Austria	Stada Arzneimittel		Lacosamid STADA 100 mg Filmtabletten	Lacosamide	100 mg	Film-coated tablet	Oral use
Austria	Stada Arzneimittel		Lacosamid STADA 150 mg Filmtabletten	Lacosamide	150 mg	Film-coated tablet	Oral use
Austria	Stada Arzneimittel		Lacosamid STADA 200 mg Filmtabletten	Lacosamide	200 mg	Film-coated tablet	Oral use
Austria	Stada Arzneimittel		Lacosamid STADA 50 mg Filmtabletten	Lacosamide	50 mg	Film-coated tablet	Oral use
Austria	Stada Arzneimittel		Posaconazol STADA 40 mg/ml Suspension zum Einnehmen	Posaconazole	40 mg/ml	Oral suspension	Oral use
Austria		Devatis GmbH	Eltrombopag Devatis 12,5 mg Filmtabletten	Eltrombopag	12,5 mg	Film-coated tablet	Oral use
Austria		Devatis GmbH	Eltrombopag Devatis 25 mg Filmtabletten	Eltrombopag	25 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Austria		Devatis GmbH	Eltrombopag Devatis 50 mg Filmtabletten	Eltrombopag	50 mg	Film-coated tablet	Oral use
Austria		Devatis GmbH	Eltrombopag Devatis 75 mg Filmtabletten	Eltrombopag	75 mg	Film-coated tablet	Oral use
Austria		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 150 mg Hartkapseln	Nilotinib	150 mg	Capsule, hard	Oral use
Austria		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris 150 mg Hartkapseln	Nilotinib	150 mg	Capsule, hard	Oral use
Austria		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Zentiva 150 mg Hartkapseln	Nilotinib	150 mg	Capsule, hard	Oral use
Austria		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 200 mg Hartkapseln	Nilotinib	200 mg	Capsule, hard	Oral use
Austria		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris 200 mg Hartkapseln	Nilotinib	200 mg	Capsule, hard	Oral use
Austria		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Zentiva 200 mg Hartkapseln	Nilotinib	200 mg	Capsule, hard	Oral use
Austria		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 50 mg Hartkapseln	Nilotinib	50 mg	Capsule, hard	Oral use
Austria		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris 50 mg Hartkapseln	Nilotinib	50 mg	Capsule, hard	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Belgium	Aurobindo N.V.		Leflunomide AB - 10 mg - Film-coated tablet	Leflunomide	10 mg	Film-coated tablet	Oral use
Belgium	Aurobindo N.V.		Olanzapina Aurobindo xx mg	Olanzapine	10 mg	Orodispersible tablet	Oral use
Belgium	Aurobindo N.V.		Olanzapine AB 5 mg tabletten	Olanzapine	5 mg	Tablet	Oral use
Belgium	Aurobindo N.V.		Olanzapine AB 10 mg tabletten	Olanzapine	10 mg	Tablet	Oral use
Belgium	Aurobindo N.V.		Olanzapina Aurobindo xx mg	Olanzapine	15 mg	Orodispersible tablet	Oral use
Belgium	Aurobindo N.V.		Olanzapine AB 15 mg tabletten	Olanzapine	15 mg	Tablet	Oral use
Belgium	Aurobindo N.V.		Olanzapine AB 2.5 mg tabletten	Olanzapine	2,5 mg	Tablet	Oral use
Belgium	Aurobindo N.V.		Olanzapina Aurobindo xx mg	Olanzapine	20 mg	Orodispersible tablet	Oral use
Belgium	Aurobindo N.V.		Olanzapine AB 20 mg tabletten	Olanzapine	20 mg	Tablet	Oral use
Belgium	Aurobindo N.V.		Olanzapin AB 5 mg orodispergeerbare tabletten	Olanzapine	5 mg	Orodispersible tablet	Oral use
Belgium	Aurobindo N.V.		Olanzapine AB 7.5 mg tabletten	Olanzapine	7,5 mg	Tablet	Oral use
Belgium	Aurobindo Pharma B.V.		Bosentan AB - 125 mg - Film-coated tablet	Bosentan	125 mg	Film-coated tablet	Oral use
Belgium	Aurobindo Pharma B.V.		Bosentan AB - 62.5 mg - Film-coated tablet	Bosentan	62,5 mg	Film-coated tablet	Oral use
Belgium	Brown & Burk IR Limited		Lymecycline Brown & Burk	Lymecycline	300 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Belgium	EG (Eurogenerics) NV		Erlotinib EG - 100 mg - Film-coated tablet	Erlotinib	100 mg	Film-coated tablet	Oral use
Belgium	EG (Eurogenerics) NV		Erlotinib EG - 150 mg - Film-coated tablet	Erlotinib	150 mg	Film-coated tablet	Oral use
Belgium	EG (Eurogenerics) NV		Erlotinib EG - 25 mg - Film-coated tablet	Erlotinib	25 mg	Film-coated tablet	Oral use
Belgium	EG (Eurogenerics) NV		Erlotinib EG - 50 mg - Film-coated tablet	Erlotinib	50 mg	Film-coated tablet	Oral use
Belgium	EG (Eurogenerics) NV		Lacosamide EG - 100 mg - Film-coated tablet	Lacosamide	100 mg	Film-coated tablet	Oral use
Belgium	EG (Eurogenerics) NV		Lacosamide EG - 150 mg - Film-coated tablet	Lacosamide	150 mg	Film-coated tablet	Oral use
Belgium	EG (Eurogenerics) NV		Lacosamide EG - 200 mg - Film-coated tablet	Lacosamide	200 mg	Film-coated tablet	Oral use
Belgium	EG (Eurogenerics) NV		Lacosamide EG - 50 mg - Film-coated tablet	Lacosamide	50 mg	Film-coated tablet	Oral use
Belgium	EG (Eurogenerics) NV		Sorafenib Eurogenerics - 400 mg - Film-coated tablet	Sorafenib	400 mg	Film-coated tablet	Oral use
Belgium	EG (Eurogenerics) NV		Tadalafil Eurogenerics - 10 mg - Film-coated tablet	Tadalafil	10 mg	Film-coated tablet	Oral use
Belgium	EG (Eurogenerics) NV		Tadalafil Eurogenerics - 2.5 mg - Film-coated tablet	Tadalafil	2,5 mg	Film-coated tablet	Oral use
Belgium	EG (Eurogenerics) NV		Tadalafil Eurogenerics - 20 mg - Film-coated tablet	Tadalafil	20 mg	Film-coated tablet	Oral use
Belgium	EG (Eurogenerics) NV		Tadalafil Eurogenerics - 5 mg - Film-coated tablet	Tadalafil	5 mg	Film-coated tablet	Oral use
Belgium	Pharmaselect International Beteiligungs GmbH		Colchicin Pharmaselect - 0.5 mg - Tablet	Colchicine	0,5 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Belgium	Pharmaselect International Beteiligungs GmbH		Colchicin Pharmaselect - 1 mg - Tablet	Colchicine	1 mg	Film-coated tablet	Oral use
Belgium	Sandoz - SA-NV - Belgium		Darunavir Sandoz - 600 mg - Film-coated tablet	Darunavir	600 mg	Film-coated tablet	Oral use
Belgium	Sandoz - SA-NV - Belgium		Darunavir Sandoz - 800 mg - Film-coated tablet	Darunavir	800 mg	Film-coated tablet	Oral use
Belgium	Sandoz - SA-NV - Belgium		Erlotinib Sandoz - 100 mg - Film-coated tablet	Erlotinib	100 mg	Film-coated tablet	Oral use
Belgium	Sandoz - SA-NV - Belgium		Erlotinib Sandoz - 150 mg - Film-coated tablet	Erlotinib	150 mg	Film-coated tablet	Oral use
Belgium	Sandoz - SA-NV - Belgium		Erlotinib Sandoz - 25 mg - Film-coated tablet	Erlotinib	25 mg	Film-coated tablet	Oral use
Belgium	Sandoz - SA-NV - Belgium		Sorafenib Sandoz - 400 mg - Film-coated tablet	Sorafenib	400 mg	Film-coated tablet	Oral use
Belgium	Sandoz GmbH		Sitagliptin/Metformin Sandoz GmbH - 50 mg - 850 mg - Film-coated tablet	Sitagliptin/ metformin	50 mg / 850 mg	Film-coated tablet	Oral use
Belgium		Generis Farmacêutica, S.A.	Teriflunomide AB - 14 mg - Film-coated tablet	Teriflunomide	14 mg	Film-coated tablet	Oral use
Belgium		Generis Farmacêutica, S.A.	Trazodona Generis Phar	Trazodone	100 mg	Film-coated tablet	Oral use
Belgium		Kappler Pharma Consult GmbH	Betahistin 'Kappler'	Betahistine	16 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Belgium		Kappler Pharma Consult GmbH	Betahistin 'Kappler'	Betahistine	24 mg	Tablet	Oral use
Belgium		Kappler Pharma Consult GmbH	Betahistin 'Kappler'	Betahistine	8 mg	Tablet	Oral use
Belgium		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 150 mg, harde capsules	Nilotinib	150 mg	Capsule, hard	Oral use
Belgium		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 200 mg, harde capsules	Nilotinib	200 mg	Capsule, hard	Oral use
Belgium		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 50 mg, harde capsules	Nilotinib	50 mg	Capsule, hard	Oral use
Belgium		Viatris Limited	Nilotinib Viatris 150 mg, harde capsules	Nilotinib	150 mg	Capsule, hard	Oral use
Belgium		Viatris Limited	Nilotinib Viatris 200 mg, harde capsules	Nilotinib	200 mg	Capsule, hard	Oral use
Belgium		Viatris Limited	Nilotinib Viatris 50 mg, harde capsules	Nilotinib	50 mg	Capsule, hard	Oral use
Bulgaria	Alkaloid - INT d.o.o.		Amlodipine/Valsartan/Hydrochlorothiazide Alkaloid-INT	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 160 mg / 12,5 mg	Film-coated tablet	Oral use
Bulgaria	Alkaloid - INT d.o.o.		Amlodipine/Valsartan/Hydrochlorothiazide Alkaloid-INT	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 160 mg / 25 mg	Film-coated tablet	Oral use
Bulgaria	Alkaloid - INT d.o.o.		Amlodipine/Valsartan/Hydrochlorothiazide Alkaloid-INT	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 160 mg / 25 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Bulgaria	Alkaloid - INT d.o.o.		Amlodipine/Valsartan/Hydrochlorothiazide Alkaloid-INT	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 320 mg / 25 mg	Film-coated tablet	Oral use
Bulgaria	Alkaloid - INT d.o.o.		Amlodipine/Valsartan/Hydrochlorothiazide Alkaloid-INT	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg / 160 mg / 12,5 mg	Film-coated tablet	Oral use
Bulgaria	Alkaloid - INT d.o.o.		Lacosamide Alkaloid-INT	Lacosamide	100 mg	Film-coated tablet	Oral use
Bulgaria	Alkaloid - INT d.o.o.		Lacosamide Alkaloid-INT	Lacosamide	150 mg	Film-coated tablet	Oral use
Bulgaria	Alkaloid - INT d.o.o.		Lacosamide Alkaloid-INT	Lacosamide	200 mg	Film-coated tablet	Oral use
Bulgaria	Alkaloid - INT d.o.o.		Lacosamide Alkaloid-INT	Lacosamide	50 mg	Film-coated tablet	Oral use
Bulgaria	G.L. Pharma GmbH		Gerocilan	Tadalafil	10 mg	Film-coated tablet	Oral use
Bulgaria	G.L. Pharma GmbH		Gerocilan	Tadalafil	2,5 mg	Film-coated tablet	Oral use
Bulgaria	G.L. Pharma GmbH		Gerocilan	Tadalafil	20 mg	Film-coated tablet	Oral use
Bulgaria	G.L. Pharma GmbH		Gerocilan	Tadalafil	5 mg	Film-coated tablet	Oral use
Bulgaria	Pharmacons AD		Amvalcon-Co	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg / 160 mg / 12,5 mg	Film-coated tablet	Oral use
Bulgaria	Pharmacons AD		Olanzacon	Olanzapine	10 mg	Tablet	Oral use
Bulgaria	Pharmacons AD		Tadalacon	Tadalafil	10 mg	Film-coated tablet	Oral use
Bulgaria	Pharmacons AD		Tadalacon	Tadalafil	20 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Bulgaria	Pharmacons AD		Vildacon-Met	Vildagliptin/ metformin	50 mg / 1 000 mg	Film-coated tablet	Oral use
Bulgaria	RIA Generics Limited		Colchicine Ria	Colchicine	0,5 mg	Tablet	Oral use
Bulgaria	RIA Generics Limited		Colchicine Ria	Colchicine	1 mg	Tablet	Oral use
Bulgaria	Sandoz d.d.		Erlotinib Sandoz	Erlotinib	100 mg	Film-coated tablet	Oral use
Bulgaria	Sandoz d.d.		Erlotinib Sandoz	Erlotinib	150 mg	Film-coated tablet	Oral use
Bulgaria	Teva B.V.		Deferasirox Teva	Deferasirox	900 mg	Film-coated tablet	Oral use
Bulgaria	Zentiva k.s.		Asbima HCT	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 160 mg / 12,5 mg	Film-coated tablet	Oral use
Bulgaria	Zentiva k.s.		Asbima HCT	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg / 160 mg / 12,5 mg	Film-coated tablet	Oral use
Bulgaria		Pharmascience International Limited	Nilotinib Pharmascience	Nilotinib	150 mg	Capsule, hard	Oral use
Bulgaria		Pharmascience International Limited	Nilotinib Pharmascience	Nilotinib	200 mg	Capsule, hard	Oral use
Bulgaria		Viatris Limited	Nilotinib Viatris	Nilotinib	150 mg	Capsule, hard	Oral use
Bulgaria		Viatris Limited	Nilotinib Viatris	Nilotinib	200 mg	Capsule, hard	Oral use
Bulgaria		Zentiva k.s.	Nilotinib Zentiva	Nilotinib	150 mg	Capsule, hard	Oral use
Bulgaria		Zentiva k.s.	Nilotinib Zentiva	Nilotinib	200 mg	Capsule, hard	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Croatia	Alkaloid - INT d.o.o.		Awerkano 10 mg/160 mg/12,5 mg filmom obložene tablete	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 160 mg / 12,5 mg	Film-coated tablet	Oral use
Croatia	Alkaloid - INT d.o.o.		Awerkano 10 mg/160 mg/25 mg filmom obložene tablete	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 160 mg / 25 mg	Film-coated tablet	Oral use
Croatia	Alkaloid - INT d.o.o.		Awerkano 10 mg/320 mg/25 mg filmom obložene tablete	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 320 mg / 25 mg	Film-coated tablet	Oral use
Croatia	Alkaloid - INT d.o.o.		Awerkano 5 mg/160 mg/12,5 mg filmom obložene tablete	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg / 160 mg / 12,5 mg	Film-coated tablet	Oral use
Croatia	Alkaloid - INT d.o.o.		Awerkano 5 mg/160 mg/25 mg filmom obložene tablete	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg / 160 mg / 25 mg	Film-coated tablet	Oral use
Croatia	Alkaloid - INT d.o.o.		Losmorid 100 mg filmom obložene tablete	Lacosamide	100 mg	Film-coated tablet	Oral use
Croatia	Alkaloid - INT d.o.o.		Losmorid 150 mg filmom obložene tablete	Lacosamide	150 mg	Film-coated tablet	Oral use
Croatia	Alkaloid - INT d.o.o.		Losmorid 200 mg filmom obložene tablete	Lacosamide	200 mg	Film-coated tablet	Oral use
Croatia	Alkaloid - INT d.o.o.		Losmorid 50 mg filmom obložene tablete	Lacosamide	50 mg	Film-coated tablet	Oral use
Croatia	AOP Orphan Pharmaceuticals GmbH		Tadalafil AOP 20 mg filmom obložene tablete	Tadalafil	20 mg	Film-coated tablet	Oral use
Croatia	Belupo lijekovi i kozmetika, d.d.		Midza 100 mg filmom obložene tablete	Lacosamide	100 mg	Film-coated tablet	Oral use
Croatia	Belupo lijekovi i kozmetika, d.d.		Midza 150 mg filmom obložene tablete	Lacosamide	150 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Croatia	Belupo lijekovi i kozmetika, d.d.		Midza 200 mg filmom obložene tablete	Lacosamide	200 mg	Film-coated tablet	Oral use
Croatia	Belupo lijekovi i kozmetika, d.d.		Midza 50 mg filmom obložene tablete	Lacosamide	50 mg	Film-coated tablet	Oral use
Croatia	Belupo lijekovi i kozmetika, d.d.		Condias Combi 50 mg/850 mg filmom obložene tablete	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Croatia	Genepharm S.A.		Amlodipin/valsartan/hidroklorotiazid Genepharm 10 mg/160 mg/12,5 mg filmom obložene tablete	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 160 mg / 12,5 mg	Film-coated tablet	Oral use
Croatia	Genepharm S.A.		Amlodipin/valsartan/hidroklorotiazid Genepharm 10 mg/160 mg/25 mg filmom obložene tablete	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 160 mg / 25 mg	Film-coated tablet	Oral use
Croatia	Genepharm S.A.		Amlodipin/valsartan/hidroklorotiazid Genepharm 10 mg/320 mg/25 mg filmom obložene tablete	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 320 mg / 25 mg	Film-coated tablet	Oral use
Croatia	Genepharm S.A.		Amlodipin/valsartan/hidroklorotiazid Genepharm 5 mg/160 mg/12,5 mg filmom obložene tablete	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg / 160 mg / 12,5 mg	Film-coated tablet	Oral use
Croatia	Genepharm S.A.		Amlodipin/valsartan/hidroklorotiazid Genepharm 5 mg/160 mg/25 mg filmom obložene tablete	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg / 160 mg / 25 mg	Film-coated tablet	Oral use
Croatia	Genericon Pharma GmbH		Sitagliptin/metforminklorid Genericon 50 mg/850 mg filmom obložene tablete	Sitagliptin/ metformin	50 mg / 850 mg	Film-coated tablet	Oral use
Croatia	Jadran Galenski laboratorij d.d.		Magnolicomb HCT 10mg/160mg/12,5mg filmom obložene tablete	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 160 mg / 12,5 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Croatia	Jadran Galenski laboratorij d.d.		Magnolicomb HCT 5mg/160mg/25mg filmom obložene tablete	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg / 160 mg / 25 mg	Film-coated tablet	Oral use
Croatia	Jadran Galenski laboratorij d.d.		Magnolicomb HCT 5mg/160mg/12,5mg filmom obložene tablete	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg / 160 mg / 12,5 mg	Film-coated tablet	Oral use
Croatia	Mylan Pharmaceuticals Limited		Erlotinib Mylan 150 mg filmom obložene tablete	Erlotinib	150 mg	Film-coated tablet	Oral use
Croatia	PharmaS d.o.o.		Erlotinib PharmaS 150 mg filmom obložene tablete	Erlotinib	150 mg	Film-coated tablet	Oral use
Croatia	Pharmaselect International Beteiligungs GmbH		Colcamexx 0,5 mg tablete	Colchicine	0,5 mg	Tablet	Oral use
Croatia	Pharmaselect International Beteiligungs GmbH		Colcamexx 1 mg tablete	Colchicine	1 mg	Tablet	Oral use
Croatia	Remedica Ltd		Erlotinib Remedica 150 mg filmom obložene tablete	Erlotinib	150 mg	Film-coated tablet	Oral use
Croatia	Sandoz d.o.o.		Darunavir Sandoz 800 mg filmom obložene tablete	Darunavir	800 mg	Film-coated tablet	Oral use
Croatia	Sandoz d.o.o.		Sorafenib Sandoz 400 mg filmom obložene tablete	Sorafenib	400 mg	Film-coated tablet	Oral use
Croatia	Stada d.o.o.		Emtenef 600 mg/200 mg/245 mg filmom obložene tablete	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
Croatia	Stada d.o.o.		Sorafenib Stada 400 mg filmom obložene tablete	Sorafenib	400 mg	Film-coated tablet	Oral use
Croatia	Umedica Netherlands B.V.		Deferasiroks Umedica 180 mg filmom obložene tablete	Deferasirox	180 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Croatia	Umedica Netherlands B.V.		Deferasiroks Umedica 360 mg filmom obložene tablete	Deferasirox	360 mg	Film-coated tablet	Oral use
Croatia	Umedica Netherlands B.V.		Deferasiroks Umedica 90 mg filmom obložene tablete	Deferasirox	90 mg	Film-coated tablet	Oral use
Croatia		Elpen Pharmaceutical Co. Inc.	Raupresil 375 mg tablete s produljenim oslobađanjem	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Croatia		Elpen Pharmaceutical Co. Inc.	Raupresil 500 mg tablete s produljenim oslobađanjem	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Croatia		Elpen Pharmaceutical Co. Inc.	Raupresil 750 mg tablete s produljenim oslobađanjem	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Croatia		Hexal AG	Ranzolva 375 mg tablete s produljenim oslobađanjem	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Croatia		Hexal AG	Ranzolva 500 mg tablete s produljenim oslobađanjem	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Croatia		Hexal AG	Ranzolva 750 mg tablete s produljenim oslobađanjem	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Croatia		Milstein C.V.	Pilokarpin hidroklorid 5 mg tablete	Pilocarpine	5 mg	Tablet	Oral use
Croatia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharmascience 150 mg tvrde kapsule	Nilotinib	150 mg	Capsule, hard	Oral use
Croatia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 150 mg tvrde kapsule	Nilotinib	150 mg	Capsule, hard	Oral use
Croatia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 150 mg tvrde kapsule	Nilotinib	150 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Croatia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharmascience 200 mg tvrde kapsule	Nilotinib	200 mg	Capsule, hard	Oral use
Croatia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 200 mg tvrde kapsule	Nilotinib	200 mg	Capsule, hard	Oral use
Croatia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 200 mg tvrde kapsule	Nilotinib	200 mg	Capsule, hard	Oral use
Croatia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 50 mg tvrde kapsule	Nilotinib	50 mg	Capsule, hard	Oral use
Croatia		Remedica Ltd.	ViaremBlu 100 mg filmom obložene tablete	Sildenafil	100 mg	Film-coated tablet	Oral use
Croatia		Remedica Ltd.	ViaremBlu 25 mg filmom obložene tablete	Sildenafil	25 mg	Film-coated tablet	Oral use
Croatia		Remedica Ltd.	ViaremBlu 50 mg filmom obložene tablete	Sildenafil	50 mg	Film-coated tablet	Oral use
Croatia		Zentiva k.s.	Nilotinib Zentiva 150 mg tvrde kapsule	Nilotinib	150 mg	Capsule, hard	Oral use
Croatia		Zentiva k.s.	Nilotinib Zentiva 200 mg tvrde kapsule	Nilotinib	200 mg	Capsule, hard	Oral use
Cyprus	Accord Healthcare S.L.U		Iviverz tablet, film-coated 600 mg/300 mg	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Cyprus	Aurobindo Pharma (Malta) Limited		Bosentan Aurobindo tablet, film-coated 125mg	Bosentan	125 mg	Film-coated tablet	Oral use
Cyprus	Aurobindo Pharma (Malta) Limited		Bosentan Aurobindo tablet, film-coated 62,5mg	Bosentan	62,5 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Cyprus	Aurobindo Pharma (Malta) Limited		Olanzapine Aurobindo 5 mg δισκία	Olanzapine	5 mg	Tablet	Oral use
Cyprus	Aurobindo Pharma (Malta) Limited		Olanzapine Aurobindo 10 mg δισκία	Olanzapine	10 mg	Tablet	Oral use
Cyprus	Elpen Pharmaceutical Co. Inc		Amlodipin/Valsartan/Hydrochlorthiazid 'Elpen'	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 160 mg / 25 mg	Film-coated tablet	Oral use
Cyprus	Elpen Pharmaceutical Co. Inc		Amlodipin/Valsartan/Hydrochlorthiazid 'Elpen'	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 320 mg / 25 mg	Film-coated tablet	Oral use
Cyprus	Elpen Pharmaceutical Co. Inc		Amlodipin/Valsartan/Hydrochlorthiazid 'Elpen'	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Cyprus	Elpen Pharmaceutical Co. Inc		Amlodipin/Valsartan/Hydrochlorthiazid 'Elpen'	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg / 160 mg / 12,5 mg	Film-coated tablet	Oral use
Cyprus	Elpen Pharmaceutical Co. Inc		Amlodipin/Valsartan/Hydrochlorthiazid 'Elpen'	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Cyprus	Elpen Pharmaceutical Co. Inc		Padlas tablet 50 mg	Vildagliptin	50 mg	Tablet	Oral use
Cyprus	Genepharm S.A.		Amlodipine/Valsartan/Hydrochlorothiazide Genepharm tablet, film-coated 10mg/160mg/12.5mg	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Cyprus	Genepharm S.A.		Amlodipine/Valsartan/Hydrochlorothiazide Genepharm tablet, film-coated 10mg/160mg/25mg	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Cyprus	Genepharm S.A.		Amlodipine/Valsartan/Hydrochlorothiazide Genepharm tablet, film-coated 10mg/320mg/12.5mg	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 320 mg/ 25 mg	Film-coated tablet	Oral use
Cyprus	Genepharm S.A.		Amlodipine/Valsartan/Hydrochlorothiazide Genepharm tablet, film-coated 5mg/160mg/12.5mg	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Cyprus	Genepharm S.A.		Amlodipine/Valsartan/Hydrochlorothiazide Genepharm tablet, film-coated 5mg/160mg/25mg	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Cyprus	Genepharm S.A.		Lacosamide/Genepharm tablet, film-coated 100 mg	Lacosamide	100 mg	Film-coated tablet	Oral use
Cyprus	Genepharm S.A.		Lacosamide/Genepharm tablet, film-coated 150 mg	Lacosamide	150 mg	Film-coated tablet	Oral use
Cyprus	Genepharm S.A.		Lacosamide/Genepharm tablet, film-coated 200 mg	Lacosamide	200 mg	Film-coated tablet	Oral use
Cyprus	Genepharm S.A.		Lacosamide/Genepharm tablet, film-coated 50 mg	Lacosamide	50 mg	Film-coated tablet	Oral use
Cyprus	Genepharm S.A.		Radicut tablet, film-coated 50 mg/850 mg	Vildagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Cyprus	Genepharm S.A.		Radicut tablet, film-coated 50 mg/1 000 mg	Vildagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Cyprus	Remedica Ltd		Kivala tablet, film-coated	Abacavir/ lamivudine	600 mg / 300 mg	Film-coated tablet	Oral use
Cyprus	Remedica Ltd		Atazanavir Remedica Capsule, hard 100mg	Atazanavir	100 mg	Capsule, hard	Oral use
Cyprus	Remedica Ltd		Atazanavir Remedica Capsule, hard 150mg	Atazanavir	150 mg	Capsule, hard	Oral use
Cyprus	Remedica Ltd		Atazanavir Remedica Capsule, hard 200mg	Atazanavir	200 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Cyprus	Remedica Ltd		Atazanavir Remedica Capsule, hard 300mg	Atazanavir	300 mg	Capsule, hard	Oral use
Cyprus	Remedica Ltd		Rezavir tablet, film-coated 150 mg	Darunavir	150 mg	Film-coated tablet	Oral use
Cyprus	Remedica Ltd		Rezavir tablet, film-coated 300 mg	Darunavir	300 mg	Film-coated tablet	Oral use
Cyprus	Remedica Ltd		Rezavir tablet, film-coated 400 mg	Darunavir	400 mg	Film-coated tablet	Oral use
Cyprus	Remedica Ltd		Rezavir tablet, film-coated 600 mg	Darunavir	600 mg	Film-coated tablet	Oral use
Cyprus	Remedica Ltd		Rezavir tablet, film-coated 75 mg	Darunavir	75 mg	Film-coated tablet	Oral use
Cyprus	Remedica Ltd		Rezavir tablet, film-coated 800 mg	Darunavir	800 mg	Film-coated tablet	Oral use
Cyprus	Remedica Ltd		Trinistem tablet, film-coated 600 mg/200 mg/245 mg	Efavirenz/ emtricitabine/ tenofovir	600 mg / 200 mg / 245 mg	Film-coated tablet	Oral use
Cyprus	Remedica Ltd		Erlotinib Remedica tablet, film-coated 100 mg	Erlotinib	100 mg	Film-coated tablet	Oral use
Cyprus	Remedica Ltd		Erlotinib Remedica tablet, film-coated 150 mg	Erlotinib	150 mg	Film-coated tablet	Oral use
Cyprus	Remedica Ltd		Erlotinib Remedica tablet, film-coated 25 mg	Erlotinib	25 mg	Film-coated tablet	Oral use
Cyprus	Remedica Ltd		Erlotinib Remedica tablet, film-coated 50 mg	Erlotinib	50 mg	Film-coated tablet	Oral use
Cyprus	Remedica Ltd		Laprem tablet, film-coated 250 mg	Lapatinib	250 mg	Film-coated tablet	Oral use
Cyprus	Remedica Ltd		Rexanib tablet, film-coated 400 mg	Sorafenib	400 mg	Film-coated tablet	Oral use
Cyprus	Sapiens Pharmaceuticals Ltd, Lemesos		Genement tablet, film-coated 20 mg	Tadalafil	20 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Cyprus	Sapiens Pharmaceuticals Ltd, Lemesos		Genement tablet, film-coated 5 mg	Tadalafil	5 mg	Film-coated tablet	Oral use
Cyprus	Viatris Limited		Tutecvi tablet 50 mg	Vildagliptin	50 mg	Tablet	Oral use
Cyprus	Win Medica S.A.		Combipress tablet, film-coated 10mg/150mg	Amlodipine/ irbesartan	10 mg/ 150 mg	Film-coated tablet	Oral use
Cyprus	Win Medica S.A.		Combipress tablet, film-coated 10mg/300mg	Amlodipine/ irbesartan	10 mg/ 300 mg	Film-coated tablet	Oral use
Cyprus	Win Medica S.A.		Combipress tablet, film-coated 5mg/150mg	Amlodipine/ irbesartan	5 mg/ 150 mg	Film-coated tablet	Oral use
Cyprus	Win Medica S.A.		Combipress tablet, film-coated 5mg/300mg	Amlodipine/ irbesartan	5 mg/ 300 mg	Film-coated tablet	Oral use
Cyprus		Elpen Pharmaceutical Co. Inc.	Ranolazine Elpen tablet, prolonged-release 375 mg	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Cyprus		Elpen Pharmaceutical Co. Inc.	Raxala tablet, prolonged-release 375 mg	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Cyprus		Elpen Pharmaceutical Co. Inc.	Ranolazine Elpen tablet, prolonged-release 500 mg	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Cyprus		Elpen Pharmaceutical Co. Inc.	Raxala tablet, prolonged-release 500 mg	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Cyprus		Elpen Pharmaceutical Co. Inc.	Ranolazine Elpen tablet, prolonged-release 750 mg	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Cyprus		Elpen Pharmaceutical Co. Inc.	Raxala tablet, prolonged-release 750 mg	Ranolazine	750 mg	Prolonged-release tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Cyprus		Pharos Pharmaceutical Oriented Services Ltd.	Padviram tablet, film-coated 600 mg/200 mg/245 mg	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
Cyprus		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos capsule, hard 150 mg	Nilotinib	150 mg	Capsule, hard	Oral use
Cyprus		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris capsule, hard 150 mg	Nilotinib	150 mg	Capsule, hard	Oral use
Cyprus		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos capsule, hard 200 mg	Nilotinib	200 mg	Capsule, hard	Oral use
Cyprus		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris capsule, hard 200 mg	Nilotinib	200 mg	Capsule, hard	Oral use
Cyprus		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos capsule, hard 50 mg	Nilotinib	50 mg	Capsule, hard	Oral use
Cyprus		Remedica Ltd.	Zestaval tablet 400 mg	Albendazole	400 mg	Tablet	Oral use
Cyprus		Remedica Ltd.	Viaremblu tablet, film-coated 100 mg	Sildenafil	100 mg	Film-coated tablet	Oral use
Cyprus		Remedica Ltd.	Viaremblu tablet, film-coated 25 mg	Sildenafil	25 mg	Film-coated tablet	Oral use
Cyprus		Remedica Ltd.	Viaremblu tablet, film-coated 50 mg	Sildenafil	50 mg	Film-coated tablet	Oral use
Cyprus		Sandoz Hungaria KFT.	Erlotinib Sandoz tablet, film-coated 150 mg	Erlotinib	150 mg	Film-coated tablet	Oral use
Cyprus		Sapiens Pharmaceuticals Ltd	Aglimon tablet 50mg	Vildagliptin	50 mg	Tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Czech Republic	+pharma arznei-mittel gmbh		Sitagliptin/Metformin +pharma	Sitagliptin/ met-formin	50 mg/ 850 mg	Film-coated tablet	Oral use
Czech Republic	AOP Orphan Pharmaceuticals GmbH		Tadalafil AOP	Tadalafil	20 mg	Film-coated tablet	Oral use
Czech Republic	ARDEZ Pharma, spol. s r.o.		Laramo	Lacosamide	100 mg	Film-coated tablet	Oral use
Czech Republic	ARDEZ Pharma, spol. s r.o.		Laramo	Lacosamide	150 mg	Film-coated tablet	Oral use
Czech Republic	ARDEZ Pharma, spol. s r.o.		Laramo	Lacosamide	200 mg	Film-coated tablet	Oral use
Czech Republic	ARDEZ Pharma, spol. s r.o.		Laramo	Lacosamide	50 mg	Film-coated tablet	Oral use
Czech Republic	Ardez Pharma, spol. s r.o.		Tadard	Tadalafil	20 mg	Film-coated tablet	Oral use
Czech Republic	Ardez Pharma, spol. s r.o.		Tadard	Tadalafil	5 mg	Film-coated tablet	Oral use
Czech Republic	Baxter B.V.		Anesia	Propofol	10 mg/ml	Emulsion for injec-tion/ infusion	Intravenous use
Czech Republic	Baxter B.V.		Anesia	Propofol	20 mg/ml	Emulsion for injec-tion/ infusion	Intravenous use
Czech Republic	Belupo Lijekovi I Kozmetika d.d.		Condias Combi	Sitagliptin/ met-formin	50 mg/ 850 mg	Film-coated tablet	Oral use
Czech Republic	Belupo lijekovi i kozmetika, d.d.		Midza	Lacosamide	100 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Czech Republic	Belupo lijekovi i kozmetika, d.d.		Midza	Lacosamide	150 mg	Film-coated tablet	Oral use
Czech Republic	Belupo lijekovi i kozmetika, d.d.		Midza	Lacosamide	200 mg	Film-coated tablet	Oral use
Czech Republic	Belupo lijekovi i kozmetika, d.d.		Midza	Lacosamide	50 mg	Film-coated tablet	Oral use
Czech Republic	Belupo lijekovi i kozmetika, d.d.		Tadalafil Belupo	Tadalafil	20 mg	Film-coated tablet	Oral use
Czech Republic	Dr. Max Pharma s.r.o.		Loperamid Dr.Max	Loperamide	2 mg	Capsule, hard	Oral use
Czech Republic	Farmak International Sp.z.o.o.		Tadalafil FMK	Tadalafil	10 mg	Film-coated tablet	Oral use
Czech Republic	Farmak International Sp.z.o.o.		Tadalafil FMK	Tadalafil	2,5 mg	Film-coated tablet	Oral use
Czech Republic	Farmak International Sp.z.o.o.		Tadalafil FMK	Tadalafil	20 mg	Film-coated tablet	Oral use
Czech Republic	Farmak International Sp.z.o.o.		Tadalafil FMK	Tadalafil	5 mg	Film-coated tablet	Oral use
Czech Republic	Heaton k.s.		Sipactimet	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Czech Republic	Neuraxpharm Bohemia s.r.o.		Arkvimma	Lacosamide	100 mg	Film-coated tablet	Oral use
Czech Republic	Neuraxpharm Bohemia s.r.o.		Arkvimma	Lacosamide	150 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Czech Republic	Neuraxpharm Bohemia s.r.o.		Arkvimma	Lacosamide	200 mg	Film-coated tablet	Oral use
Czech Republic	Neuraxpharm Bohemia s.r.o.		Arkvimma	Lacosamide	50 mg	Film-coated tablet	Oral use
Czech Republic	Neuraxpharm Bohemia s.r.o.		Azoneurax	Trazodone	150 mg	Modified-release tablet	Oral use
Czech Republic	Neuraxpharm Bohemia s.r.o.		Azoneurax	Trazodone	75 mg	Modified-release tablet	Oral use
Czech Republic	Opella Healthcare Czech s.r.o.		Enditril	Racecadotril	100 mg	Capsule, hard	Oral use
Czech Republic	Pharmaselect International Beteiligungs GmbH		Colchicine Pharmaselect	Colchicine	0,5 mg	Tablet	Oral use
Czech Republic	Pharmaselect International Beteiligungs GmbH		Colchicine Pharmaselect	Colchicine	1 mg	Tablet	Oral use
Czech Republic	Sandoz GmbH		Sitagliptin/Metformin Sandoz GmbH	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Czech Republic	Sandoz s.r.o.		Sorafenib Sandoz	Sorafenib	400 mg	Film-coated tablet	Oral use
Czech Republic	Stada Arzneimittel AG		Sorafenib Stada	Sorafenib	400 mg	Film-coated tablet	Oral use
Czech Republic	Umedica Netherlands B.V.		Pirfenidone Umedica	Pirfenidone	267 mg	Film-coated tablet	Oral use
Czech Republic	Umedica Netherlands B.V.		Pirfenidone Umedica	Pirfenidone	801 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Czech Republic	Umedica Netherlands B.V.		Ranolazine Umedica	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Czech Republic	Umedica Netherlands B.V.		Ranolazine Umedica	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Czech Republic	Umedica Netherlands B.V.		Ranolazine Umedica	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Czech Republic	Viatris Limited		Tutecvi	Vildagliptin	50 mg	Tablet	Oral use
Czech Republic	Vipharm S.A.		Anvildis	Vildagliptin	50 mg	Tablet	Oral use
Czech Republic	Win Medica S.A.		Combipres	Amlodipine/ irbesartan	10 mg/ 150 mg	Film-coated tablet	Oral use
Czech Republic	Win Medica S.A.		Combipres	Amlodipine/ irbesartan	10 mg/ 300 mg	Film-coated tablet	Oral use
Czech Republic	Win Medica S.A.		Combipres	Amlodipine/ irbesartan	5 mg/ 150 mg	Film-coated tablet	Oral use
Czech Republic	Win Medica S.A.		Combipres	Amlodipine/ irbesartan	5 mg/ 300 mg	Film-coated tablet	Oral use
Czech Republic		Kappler Pharma Consult GmbH	Betahistin Kappler	Betahistine	16 mg	Tablet	Oral use
Czech Republic		Kappler Pharma Consult GmbH	Betahistin Kappler	Betahistine	24 mg	Tablet	Oral use
Czech Republic		Kappler Pharma Consult GmbH	Betahistin Kappler	Betahistine	8 mg	Tablet	Oral use
Czech Republic		Medreg s.r.o.	Betahistine Medreg	Betahistine	16 mg	Tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Czech Republic		Medreg s.r.o.	Betahistine Medreg	Betahistine	24 mg	Tablet	Oral use
Czech Republic		Nutra Essential OTC, S.L.	Ibuprofen Nutra Essential	Ibuprofen	400 mg	Capsule, soft	Oral use
Czech Republic		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	150 mg	Capsule, hard	Oral use
Czech Republic		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris	Nilotinib	150 mg	Capsule, hard	Oral use
Czech Republic		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Zentiva	Nilotinib	150 mg	Capsule, hard	Oral use
Czech Republic		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	200 mg	Capsule, hard	Oral use
Czech Republic		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris	Nilotinib	200 mg	Capsule, hard	Oral use
Czech Republic		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Zentiva	Nilotinib	200 mg	Capsule, hard	Oral use
Czech Republic		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	50 mg	Capsule, hard	Oral use
Czech Republic		Rontis Hellas Medical And Pharmaceutical Products S.A.	Tadax	Tadalafil	10 mg	Chewable tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Czech Republic		Rontis Hellas Medical And Pharmaceutical Products S.A.	Tadax	Tadalafil	20 mg	Chewable tablet	Oral use
Czech Republic		Rontis Hellas Medical And Pharmaceutical Products S.A.	Tadax	Tadalafil	5 mg	Chewable tablet	Oral use
Denmark	2care4 Generics ApS		Lymelysal	Lymecycline	300 mg	Capsule, hard	Oral use
Denmark	Accord Healthcare B.V.		Abacavir/Lamivudine 'Accord'	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Denmark	Aurobindo Pharma (Malta) Limited		Leflunomid 'Aurobindo'	Leflunomide	10 mg	Film-coated tablet	Oral use
Denmark	Aurobindo Pharma (Malta) Limited		Leflunomid 'Aurobindo'	Leflunomide	15 mg	Film-coated tablet	Oral use
Denmark	Baxter B.V.		Profast	Propofol	10 mg/ml	Emulsion for injection/ infusion	Intravenous use
Denmark	Baxter B.V.		Profast	Propofol	20 mg/ml	Emulsion for injection/ infusion	Intravenous use
Denmark	Brown & Burk IR Limited		Lymecyclin 'Brown & Burk'	Lymecycline	300 mg	Capsule, hard	Oral use
Denmark	Elpen Pharmaceutical Co. Inc		Amlodipin/Valsartan/Hydrochlorthiazid 'Elpen'	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Denmark	Elpen Pharmaceutical Co. Inc		Amlodipin/Valsartan/Hydrochlorthiazid 'Elpen'	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Denmark	Elpen Pharmaceutical Co. Inc		Amlodipin/Valsartan/Hydrochlorthiazid 'Elpen'	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 320 mg/ 25 mg	Film-coated tablet	Oral use
Denmark	Elpen Pharmaceutical Co. Inc		Amlodipin/Valsartan/Hydrochlorthiazid 'Elpen'	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Denmark	Elpen Pharmaceutical Co. Inc		Amlodipin/Valsartan/Hydrochlorthiazid 'Elpen'	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Denmark	Morningside Healthcare (Malta) Ltd		Dinetrel	Amantadine	100 mg	Capsule, hard	Oral use
Denmark	Mylan AB		Erlotinib 'Mylan'	Erlotinib	100 mg	Film-coated tablet	Oral use
Denmark	Mylan AB		Erlotinib 'Mylan'	Erlotinib	150 mg	Film-coated tablet	Oral use
Denmark	Mylan AB		Erlotinib 'Mylan'	Erlotinib	25 mg	Film-coated tablet	Oral use
Denmark	Mylan AB		Vildagliptin Mylan	Vildagliptin	50 mg	Tablet	Oral use
Denmark	Newbury Pharmaceuticals AB		Lapatinib 'Newbury'	Lapatinib	250 mg	Film-coated tablet	Oral use
Denmark	Orifarm Generics A/S		Priminova	Phenoxymethylpenicillin	800mg	Film-coated tablet	Oral use
Denmark	Sandoz A/S		Darunavir 'Sandoz'	Darunavir	600 mg	Film-coated tablet	Oral use
Denmark	Sandoz A/S		Darunavir 'Sandoz'	Darunavir	800 mg	Film-coated tablet	Oral use
Denmark	Sandoz A/S		Padviram	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Denmark	Sandoz A/S		Erlotinib 'Sandoz'	Erlotinib	100 mg	Film-coated tablet	Oral use
Denmark	Sandoz A/S		Erlotinib 'Sandoz'	Erlotinib	150 mg	Film-coated tablet	Oral use
Denmark	Sandoz A/S		Erlotinib 'Sandoz'	Erlotinib	25 mg	Film-coated tablet	Oral use
Denmark	Stada Arzneimittel AG		Abacavir/Lamivudine 'Stada'	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Denmark	Stada Arzneimittel AG		Atazanavir 'Stada'	Atazanavir	150 mg	Capsule, hard	Oral use
Denmark	Stada Arzneimittel AG		Atazanavir 'Stada'	Atazanavir	200 mg	Capsule, hard	Oral use
Denmark	Stada Arzneimittel AG		Atazanavir 'Stada'	Atazanavir	300 mg	Capsule, hard	Oral use
Denmark	Stada Arzneimittel AG		Darunavir Stada	Darunavir	400 mg	Film-coated tablet	Oral use
Denmark	Stada Arzneimittel AG		Darunavir Stada	Darunavir	600 mg	Film-coated tablet	Oral use
Denmark	Stada Arzneimittel AG		Darunavir Stada	Darunavir	800 mg	Film-coated tablet	Oral use
Denmark	Stada Arzneimittel AG		Emtenef	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
Denmark	Stada Arzneimittel AG		Erlotinib 'Stada'	Erlotinib	100 mg	Film-coated tablet	Oral use
Denmark	Stada Arzneimittel AG		Erlotinib 'Stada'	Erlotinib	150 mg	Film-coated tablet	Oral use
Denmark	Stada Arzneimittel AG		Erlotinib 'Stada'	Erlotinib	25 mg	Film-coated tablet	Oral use
Denmark	Stada Arzneimittel AG		Lacosamide 'Stada'	Lacosamide	100 mg	Film-coated tablet	Oral use
Denmark	Stada Arzneimittel AG		Lacosamide 'Stada'	Lacosamide	150 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Denmark	Stada Arzneimittel AG		Lacosamide 'Stada'	Lacosamide	200 mg	Film-coated tablet	Oral use
Denmark	Stada Arzneimittel AG		Lacosamide 'Stada'	Lacosamide	50 mg	Film-coated tablet	Oral use
Denmark	Stada Arzneimittel AG		Posaconazole Stada	Posaconazole	40 mg/ml	Oral suspension	Oral use
Denmark	Stada Arzneimittel AG		Tadalafil "Stada	Tadalafil	10 mg	Film-coated tablet	Oral use
Denmark	Stada Arzneimittel AG		Tadalafil "Stada	Tadalafil	20 mg	Film-coated tablet	Oral use
Denmark	Stada Arzneimittel AG		Tadalafil "Stada	Tadalafil	5 mg	Film-coated tablet	Oral use
Denmark	Teva B.V.		Posaconazol 'Teva B.V.'	Posaconazole	40 mg/ ml	Oral suspension	Oral use
Denmark		2care4 Generics ApS	Bendatol	Albendazole	400 mg	Tablet	Oral use
Denmark		Kappler Pharma Consult GmbH	Betahistin 'Kappler'	Betahistine	16 mg	Tablet	Oral use
Denmark		Kappler Pharma Consult GmbH	Betahistin 'Kapplerpharma'	Betahistine	16 mg	Tablet	Oral use
Denmark		Kappler Pharma Consult GmbH	Betahistin 'Kappler'	Betahistine	24 mg	Tablet	Oral use
Denmark		Kappler Pharma Consult GmbH	Betahistin 'Kapplerpharma'	Betahistine	24 mg	Tablet	Oral use
Denmark		Kappler Pharma Consult GmbH	Betahistin 'Kappler'	Betahistine	8 mg	Tablet	Oral use
Denmark		Kappler Pharma Consult GmbH	Betahistin 'Kapplerpharma'	Betahistine	8 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Denmark		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib 'PharOS'	Nilotinib	150 mg	Capsule, hard	Oral use
Denmark		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib 'PharOS'	Nilotinib	150 mg	Capsule, hard	Oral use
Denmark		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib 'PharOS'	Nilotinib	200 mg	Capsule, hard	Oral use
Denmark		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib 'PharOS'	Nilotinib	200 mg	Capsule, hard	Oral use
Denmark		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib 'PharOS'	Nilotinib	50 mg	Capsule, hard	Oral use
Denmark		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib 'PharOS'	Nilotinib	50 mg	Capsule, hard	Oral use
Denmark		Sandoz A/S	Sorafenib 'Sandoz'	Sorafenib	400 mg	Film-coated tablet	Oral use
Denmark		Viatris Healthcare Limited	Nilotinib 'Viatris'	Nilotinib	150 mg	Capsule, hard	Oral use
Denmark		Viatris Healthcare Limited	Nilotinib 'Viatris'	Nilotinib	200 mg	Capsule, hard	Oral use
Denmark		Viatris Healthcare Limited	Nilotinib 'Viatris'	Nilotinib	50 mg	Capsule, hard	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Estonia	Accord Healthcare B.V.		Abacavir/Lamivudine Accord	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Estonia	Baxter B.V.		ANESIA	Propofol	10 mg/ml	Emulsion for injection/ infusion	Intravenous use
Estonia	Baxter B.V.		ANESIA	Propofol	20 mg/ ml	Emulsion for injection/ infusion	Intravenous use
Estonia	LV System Service, Latvia		Suphrex 12.5 mg hard capsules	Sunitinib	12,5 mg	Capsule, hard	Oral use
Estonia	LV System Service, Latvia		Suphrex 50 mg hard capsules	Sunitinib	50 mg	Capsule, hard	Oral use
Estonia	Mylan Ireland Limited		Posaconazole Mylan	Posaconazole	40 mg/ ml	Oral suspension	Oral use
Estonia	Mylan Pharmaceuticals Limited		Erlotinib 'Mylan'	Erlotinib	100 mg	Film-coated tablet	Oral use
Estonia	Mylan Pharmaceuticals Limited		Erlotinib 'Mylan'	Erlotinib	150 mg	Film-coated tablet	Oral use
Estonia	Sandoz d.d.		Sitagliptin/ Metformin Hydrochloride Sandoz	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Estonia	Sandoz Pharmaceuticals d.d.		Darunavir Sandoz	Darunavir	400 mg	Film-coated tablet	Oral use
Estonia	Sandoz Pharmaceuticals d.d.		Darunavir Sandoz	Darunavir	600 mg	Film-coated tablet	Oral use
Estonia	Sandoz Pharmaceuticals d.d.		Darunavir Sandoz	Darunavir	75 mg	Film-coated tablet	Oral use
Estonia	Sandoz Pharmaceuticals d.d.		Darunavir Sandoz	Darunavir	800 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Estonia	Sandoz Pharmaceuticals d.d.		PADVIRAM	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
Estonia	Sandoz Pharmaceuticals d.d.		Erlotinib 'Sandoz'	Erlotinib	100 mg	Film-coated tablet	Oral use
Estonia	Sandoz Pharmaceuticals d.d.		Erlotinib 'Sandoz'	Erlotinib	150 mg	Film-coated tablet	Oral use
Estonia	Sandoz Pharmaceuticals d.d.		ERLOTINIB SANDOZ	Erlotinib	25 mg	Film-coated tablet	Oral use
Estonia	Sandoz Pharmaceuticals d.d.		SORAFENIB SANDOZ	Sorafenib	400 mg	Film-coated tablet	Oral use
Estonia	SIA Elvim		Vildagliptin/ Metformin Elvim	Vildagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Estonia	SIA Elvim		Vildagliptin/ Metformin Elvim	Vildagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Estonia		Pharos Pharmaceutical Oriented Services Ltd.	NILOTINIB PHAROS	Nilotinib	150 mg	Capsule, hard	Oral use
Estonia		Pharos Pharmaceutical Oriented Services Ltd.	NILOTINIB PHAROS	Nilotinib	200 mg	Capsule, hard	Oral use
Estonia		Pharos Pharmaceutical Oriented Services Ltd.	NILOTINIB PHAROS	Nilotinib	50 mg	Capsule, hard	Oral use
Estonia		Remedica Ltd.	Viaremblu	Sildenafil	100 mg	Film-coated tablet	Oral use
Estonia		Remedica Ltd.	VIAREMBLU	Sildenafil	25 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Estonia		Remedica Ltd.	Viaremblu	Sildenafil	50 mg	Film-coated tablet	Oral use
Estonia		Sandoz Pharmaceuticals d.d.	Ranzolva	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Estonia		Sandoz Pharmaceuticals d.d.	Ranzolva	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Estonia		Sandoz Pharmaceuticals d.d.	Ranzolva	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Estonia		Viatris Limited	NILOTINIB VIATRIS	Nilotinib	200 mg	Capsule, hard	Oral use
Estonia		Zentiva k.s.	NILOTINIB ZENTIVA	Nilotinib	150 mg	Capsule, hard	Oral use
Estonia		Zentiva k.s.	NILOTINIB ZENTIVA	Nilotinib	200 mg	Capsule, hard	Oral use
Finland	Accord Healthcare B.V.		Abacavir/Lamivudine Accord	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Finland	AOP Orphan Pharmaceuticals GmbH		Tadalafil Aop	Tadalafil	20 mg	Film-coated tablet	Oral use
Finland	Baxter B.V.		Profast	Propofol	10 mg/ml	Emulsion for injection/ infusion	Intravenous use
Finland	Baxter B.V.		Profast	Propofol	20 mg/ ml	Emulsion for injection/ infusion	Intravenous use
Finland	Brown & Burk IR Limited		Lymecycline Brown & Burk	Lymecycline	300 mg	Capsule, hard	Oral use
Finland	Hexal A/S		Sitagliptin/Metformin Hexal	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Finland	Mylan AB		Amlodipine/Valsartan/Hydrochlorothiazide Mylan	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Finland	Mylan AB		Amlodipine/Valsartan/Hydrochlorothiazide Mylan	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Finland	Mylan AB		Amlodipine/Valsartan/Hydrochlorothiazide Mylan	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 320 mg/ 25 mg	Film-coated tablet	Oral use
Finland	Mylan AB		Amlodipine/Valsartan/Hydrochlorothiazide Mylan	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Finland	Mylan AB		Amlodipine/Valsartan/Hydrochlorothiazide Mylan	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Finland	Mylan AB		Vildagliptin Mylan	Vildagliptin	50 mg	Tablet	Oral use
Finland	Orion Corporation		Bosentan Orion	Bosentan	125 mg	Film-coated tablet	Oral use
Finland	Orion Corporation		Bosentan Orion	Bosentan	62,5 mg	Film-coated tablet	Oral use
Finland	Orion Corporation		Olanzapin Orion	Olanzapine	5 mg	Orodispersible tablet	Oral use
Finland	Orion Corporation		Olanzapin Orion 5 mg tabletit	Olanzapine	5 mg	Tablet	Oral use
Finland	Orion Corporation		Olanzapin Orion	Olanzapine	10 mg	Orodispersible tablet	Oral use
Finland	Orion Corporation		Olanzapin Orion 10 mg tabletit	Olanzapine	10 mg	Tablet	Oral use
Finland	Orion Corporation		Olanzapin Orion	Olanzapine	15 mg	Orodispersible tablet	Oral use
Finland	Orion Corporation		Olanzapin Orion 15 mg tabletit	Olanzapine	15 mg	Tablet	Oral use
Finland	Orion Corporation		Olanzapin Orion 2.5 mg tabletit	Olanzapine	2,5 mg	Tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Finland	Orion Corporation		Olanzapin Orion	Olanzapine	20 mg	Orodispersible tablet	Oral use
Finland	Orion Corporation		Olanzapin Orion 20 mg tabletit	Olanzapine	20 mg	Tablet	Oral use
Finland	Orion Corporation		Olanzapin Orion 7.5 mg tabletit	Olanzapine	7,5 mg	Tablet	Oral use
Finland	Sandoz A/S		Darunavir Sandoz	Darunavir	600 mg	Film-coated tablet	Oral use
Finland	Sandoz A/S		Darunavir Sandoz	Darunavir	800 mg	Film-coated tablet	Oral use
Finland	Sandoz A/S		Padviram	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
Finland	Stada Arzneimittel AG		Abacavir/Lamivudine Stada	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Finland	Stada Arzneimittel AG		Atazanavir Stada	Atazanavir	200 mg	Capsule, hard	Oral use
Finland	Stada Arzneimittel AG		Atazanavir Stada	Atazanavir	300 mg	Capsule, hard	Oral use
Finland	Stada Arzneimittel AG		Darunavir Stada	Darunavir	600 mg	Film-coated tablet	Oral use
Finland	Stada Arzneimittel AG		Darunavir Stada	Darunavir	800 mg	Film-coated tablet	Oral use
Finland	Stada Arzneimittel AG		Emtenef	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
Finland	Stada Arzneimittel AG		Erlotinib Stada	Erlotinib	100 mg	Film-coated tablet	Oral use
Finland	Stada Arzneimittel AG		Erlotinib Stada	Erlotinib	100 mg	Film-coated tablet	Oral use
Finland	Stada Arzneimittel AG		Erlotinib Stada	Erlotinib	150 mg	Film-coated tablet	Oral use
Finland	Stada Arzneimittel AG		Erlotinib Stada	Erlotinib	25 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Finland	Stada Arzneimittel AG		Lacosamide Stada	Lacosamide	100 mg	Film-coated tablet	Oral use
Finland	Stada Arzneimittel AG		Lacosamide Stada	Lacosamide	150 mg	Film-coated tablet	Oral use
Finland	Stada Arzneimittel AG		Lacosamide Stada	Lacosamide	200 mg	Film-coated tablet	Oral use
Finland	Stada Arzneimittel AG		Lacosamide Stada	Lacosamide	50 mg	Film-coated tablet	Oral use
Finland	Stada Arzneimittel AG		Posaconazole Stada	Posaconazole	40 mg/ml	Oral suspension	Oral use
Finland	Stada Arzneimittel AG		Tadalafil Stada	Tadalafil	10 mg	Film-coated tablet	Oral use
Finland	Stada Arzneimittel AG		Tadalafil Stada	Tadalafil	20 mg	Film-coated tablet	Oral use
Finland	Stada Arzneimittel AG		Tadalafil Stada	Tadalafil	5 mg	Film-coated tablet	Oral use
Finland		2care4 Generics ApS	Bendatol	Albendazole	400 mg	Tablet	Oral use
Finland		Kappler Pharma Consult GmbH	Betahistin Kappler	Betahistine	16 mg	Tablet	Oral use
Finland		Kappler Pharma Consult GmbH	Betahistin Kappler	Betahistine	24 mg	Tablet	Oral use
Finland		Kappler Pharma Consult GmbH	Betahistin Kappler	Betahistine	8 mg	Tablet	Oral use
Finland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	150 mg	Capsule, hard	Oral use
Finland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	200 mg	Capsule, hard	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Finland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	50 mg	Capsule, hard	Oral use
France	Almus France		Metformine Almus 500 mg, comprimé pelliculé	Metformin	500 mg	Film-coated tablet	Oral use
France	Almus France		Tramadol Almus 50 mg, gélule	Tramadol	50 mg	Capsule	Oral use
France	Arrow Génériques		Atazanavir Arrow 200 mg, gélule	Atazanavir	200 mg	Capsule	Oral use
France	Arrow Génériques		Atazanavir Arrow 300 mg, gélule	Atazanavir	300 mg	Capsule	Oral use
France	Arrow Génériques		Bosentan Arrow 125 mg, comprimé pelliculé	Bosentan	125 mg	Film-coated tablet	Oral use
France	Arrow Génériques		Bosentan Arrow 62,5 mg, comprimé pelliculé	Bosentan	62,5 mg	Film-coated tablet	Oral use
France	Arrow Génériques		Digoxine Arrow 0,125 mg, comprimé	Digoxin	0,125 mg	Tablet	Oral use
France	Arrow Génériques		Digoxine Arrow 0,25 mg, comprimé sécable	Digoxin	0,25 mg	Tablet	Oral use
France	Arrow Génériques		Leflunomide Arrow 10 mg, comprimé pelliculé	Leflunomide	10 mg	Film-coated tablet	Oral use
France	Arrow Génériques		Nevirapine Arrow LP 400 mg, comprimé à libération prolongée	Nevirapine	400 mg	Prolonged-release tablet	Oral use
France	Arrow Génériques		Olanzapina Arrow 10 mg comprimé orodispersible	Olanzapine	10 mg	Orodispersible tablet	Oral use
France	Arrow Génériques		Olanzapine ARROW 10 mg comprimé	Olanzapine	10 mg	Tablet	Oral use
France	Arrow Génériques		Olanzapina Arrow 15 mg comprimé orodispersible	Olanzapine	15 mg	Orodispersible tablet	Oral use
France	Arrow Génériques		Olanzapina Arrow 20 mg comprimé orodispersible	Olanzapine	20 mg	Orodispersible tablet	Oral use
France	Arrow Génériques		Olanzapina Arrow 5 mg comprimé orodispersible	Olanzapine	5 mg	Orodispersible tablet	Oral use
France	Arrow Génériques		Olanzapine ARROW 5 mg comprimé	Olanzapine	5 mg	Tablet	Oral use
France	Arrow Génériques		Olanzapine ARROW 7.5 mg comprimé	Olanzapine	7,5 mg	Tablet	Oral use
France	Arrow Génériques		Racecadotril Arrow 100 mg, gélule	Racecadotril	100 mg	Capsule	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
France	Baxter B.V.		Propofol Baxter 10 mg/ml, émulsion injectable/pour perfusion	Propofol	10 mg/ml	Emulsion for injection/ infusion	Intravenous use
France	Baxter B.V.		Propofol Baxter 20 mg/ml, émulsion injectable/pour perfusion	Propofol	20 mg/ ml	Emulsion for injection/ infusion	Intravenous use
France	Biogaran		Abacavir/Lamivudine Biogaran 600 mg/300 mg, comprimé pelliculé	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
France	Biogaran		Atazanavir Biogaran 150 mg, gélule	Atazanavir	150 mg	Capsule	Oral use
France	Biogaran		Atazanavir Biogaran 200 mg, gélule	Atazanavir	200 mg	Capsule	Oral use
France	Biogaran		Atazanavir Biogaran 300 mg, gélule	Atazanavir	300 mg	Capsule	Oral use
France	Biogaran		Darunavir Biogaran 600 mg, comprimé pelliculé	Darunavir	600 mg	Film-coated tablet	Oral use
France	Biogaran		Darunavir Biogaran 800 mg, comprimé pelliculé	Darunavir	800 mg	Film-coated tablet	Oral use
France	Biogaran		Efavirenz/Emtricitabine/Tenofovir Disoproxil Biogaran 600 mg/200 mg/245 mg, comprimé pelliculé	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
France	Biogaran		Erlotinib Biogaran 100 mg, comprimé pelliculé	Erlotinib	100 mg	Film-coated tablet	Oral use
France	Biogaran		Erlotinib Biogaran 150 mg, comprimé pelliculé	Erlotinib	150 mg	Film-coated tablet	Oral use
France	Biogaran		Erlotinib Biogaran 25 mg, comprimé pelliculé	Erlotinib	25 mg	Film-coated tablet	Oral use
France	Biogaran		Lapatinib Pharos 250 mg, comprimé pelliculé	Lapatinib	250 mg	Film-coated tablet	Oral use
France	EG LABO - Laboratoires Eurogenerics		Abacavir/ Lamivudine EG 600 mg/300 mg, comprimé pelliculé	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
France	EG LABO - Laboratoires Eurogenerics		Darunavir EG 150 mg, comprimé pelliculé	Darunavir	150 mg	Film-coated tablet	Oral use
France	EG LABO - Laboratoires Eurogenerics		Darunavir EG 300 mg, comprimé pelliculé	Darunavir	300 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
France	EG LABO - Laboratoires Eurogenerics		Darunavir EG 400 mg, comprimé pelliculé	Darunavir	400 mg	Film-coated tablet	Oral use
France	EG LABO - Laboratoires Eurogenerics		Darunavir EG 600 mg, comprimé pelliculé	Darunavir	600 mg	Film-coated tablet	Oral use
France	EG LABO - Laboratoires Eurogenerics		Darunavir EG 75 mg, comprimé pelliculé	Darunavir	75 mg	Film-coated tablet	Oral use
France	EG LABO - Laboratoires Eurogenerics		Darunavir EG 800 mg, comprimé pelliculé	Darunavir	800 mg	Film-coated tablet	Oral use
France	EG LABO - Laboratoires Eurogenerics		Efavirenz/Emtricitabine/Tenofovir Disoproxil EG 600 mg/200 mg/245 mg, comprimé pelliculé	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
France	EG LABO - Laboratoires Eurogenerics		Erlotinib EG 100 mg, comprimé pelliculé	Erlotinib	100 mg	Film-coated tablet	Oral use
France	EG LABO - Laboratoires Eurogenerics		Erlotinib EG 150 mg, comprimé pelliculé	Erlotinib	150 mg	Film-coated tablet	Oral use
France	EG LABO - Laboratoires Eurogenerics		Erlotinib EG 25 mg, comprimé pelliculé	Erlotinib	25 mg	Film-coated tablet	Oral use
France	EG LABO - Laboratoires Eurogenerics		Lacosamide EG 100 mg, comprimé pelliculé	Lacosamide	100 mg	Film-coated tablet	Oral use
France	EG LABO - Laboratoires Eurogenerics		Lacosamide EG 150 mg, comprimé pelliculé	Lacosamide	150 mg	Film-coated tablet	Oral use
France	EG LABO - Laboratoires Eurogenerics		Lacosamide EG 200 mg, comprimé pelliculé	Lacosamide	200 mg	Film-coated tablet	Oral use
France	EG LABO - Laboratoires Eurogenerics		Lacosamide EG 50 mg, comprimé pelliculé	Lacosamide	50 mg	Film-coated tablet	Oral use
France	EG LABO - Laboratoires Eurogenerics		Tadalafil EG 10 mg, comprimé pelliculé	Tadalafil	10 mg	Film-coated tablet	Oral use
France	EG LABO - Laboratoires Eurogenerics		Tadalafil EG 2,5 mg, comprimé pelliculé	Tadalafil	2,5 mg	Film-coated tablet	Oral use
France	EG LABO - Laboratoires Eurogenerics		Tadalafil EG 20 mg, comprimé pelliculé	Tadalafil	20 mg	Film-coated tablet	Oral use
France	EG LABO - Laboratoires Eurogenerics		Tadalafil EG 5 mg, comprimé pelliculé	Tadalafil	5 mg	Film-coated tablet	Oral use
France	Eugia Pharma (Malta) Limited		Anastrozole Arrow LAB 1 mg, comprimé pelliculé	Anastrozole	1 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
France	Laboratoires Majorelle		Kronalis 10 mg, comprimé pelliculé	Tadalafil	10 mg	Film-coated tablet	Oral use
France	Laboratoires Majorelle		Kronalis 2,5 mg, comprimé pelliculé	Tadalafil	2,5 mg	Film-coated tablet	Oral use
France	Laboratoires Majorelle		Kronalis 20 mg, comprimé pelliculé	Tadalafil	20 mg	Film-coated tablet	Oral use
France	Laboratoires Majorelle		Kronalis 5 mg, comprimé pelliculé	Tadalafil	5 mg	Film-coated tablet	Oral use
France	Sandoz		Atazanavir Sandoz 200 mg, gélule	Atazanavir	200 mg	Capsule	Oral use
France	Sandoz		Atazanavir Sandoz 300 mg, gélule	Atazanavir	300 mg	Capsule	Oral use
France	Sandoz		Darunavir Sandoz 400 mg, comprimé pelliculé	Darunavir	400 mg	Film-coated tablet	Oral use
France	Sandoz		Darunavir Sandoz 600 mg, comprimé pelliculé	Darunavir	600 mg	Film-coated tablet	Oral use
France	Sandoz		Darunavir Sandoz 800 mg, comprimé pelliculé	Darunavir	800 mg	Film-coated tablet	Oral use
France	Sandoz		Efavirenz/Emtricitabine/Tenofovir Disoproxil Sandoz 600 mg/200 mg/245 mg, comprimé pelliculé	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
France	Sandoz		Erlotinib Sando 100 mg, comprimé pelliculé	Erlotinib	100 mg	Film-coated tablet	Oral use
France	Sandoz		Erlotinib Sandoz 150 mg, comprimé pelliculé	Erlotinib	150 mg	Film-coated tablet	Oral use
France	Sandoz		Erlotinib Sandoz 25 mg, comprimé pelliculé	Erlotinib	25 mg	Film-coated tablet	Oral use
France	Teva Sante		Deferasirox Teva 900 mg, comprimé pelliculé	Deferasirox	900 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
France	Viatris Sante		Erlotinib Viatris 100 mg, comprimé pelliculé	Erlotinib	100 mg	Film-coated tablet	Oral use
France	Viatris Sante		Erlotinib Viatris 150 mg, comprimé pelliculé	Erlotinib	150 mg	Film-coated tablet	Oral use
France	Viatris Sante		Erlotinib Viatris 25 mg, comprimé pelliculé	Erlotinib	25 mg	Film-coated tablet	Oral use
France	Viatris Sante		Posaconazole Viatris 40 mg/mL, suspension buvable	Posaconazole	40 mg/ ml	Oral suspension	Oral use
France	Viatris Sante		Vildagliptin Viatris 50 mg, comprimé	Vildagliptin	50 mg	Film-coated tablet	Oral use
France	Zentiva France		Racecadotril Zentiva 100 mg, gélule	Racecadotril	100 mg	Capsule	Oral use
France		Arrow Génériques	Topiramate Arrow 15 mg, gélule	Topiramate	15 mg	Capsule	Oral use
France		Arrow Génériques	Topiramate Arrow 25 mg, gélule	Topiramate	25 mg	Capsule	Oral use
France		Arrow Génériques	Topiramate Arrow 50 mg, gélule	Topiramate	50 mg	Capsule	Oral use
France		Aurobindo Pharma (Malta) Limited	Dapaglifozine Metformine Arrow 5 mg/1 000 mg, comprimé pelliculé	Dapagliflozin/ metformin	5 mg/ 1 000 mg	Film-coated tablet	Oral use
France		Crescent Pharma International Limited	Midodrine Hydrochloride 2,5 mg, comprimé	Midodrine	2,5 mg	Tablet	Oral use
France		Crescent Pharma International Limited	Midodrine Hydrochloride 5 mg, comprimé	Midodrine	5 mg	Tablet	Oral use
France		Generis Farmacêutica, S.A.	Teriflunomide Arrow 14 mg, comprimé pelliculé	Teriflunomide	14 mg	Film-coated tablet	Oral use
France		Kappler Pharma Consult GmbH	Betahistine Kappler 24 mg, comprimé	Betahistine	24 mg	Tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
France		Kappler Pharma Consult GmbH	Betahistine Kappler 8 mg, comprimé	Betahistine	8 mg	Tablet	Oral use
France		Morningside Healthcare (Malta) Ltd.	Ponade 50 mg, comprimé	Dapsone	50 mg	Tablet	Oral use
France		Nutra Essential OTC, S.L.	Ibuprofene Winadol 400 mg, capsule molle	Ibuprofen	400 mg	Capsule, soft	Oral use
France		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 150 mg, gélules	Nilotinib	150 mg	Capsule	Oral use
France		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 150 mg, gélules	Nilotinib	150 mg	Capsule	Oral use
France		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris 150 mg, gélule	Nilotinib	150 mg	Capsule	Oral use
France		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 200 mg, gélules	Nilotinib	200 mg	Capsule	Oral use
France		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos200 mg, gélules	Nilotinib	200 mg	Capsule	Oral use
France		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris 200 mg, gélule	Nilotinib	200 mg	Capsule	Oral use
France		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 50 mg, gélules	Nilotinib	50 mg	Capsule	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
France		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 50 mg, gélules	Nilotinib	50 mg	Capsule	Oral use
France		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris 50 mg, gélule	Nilotinib	50 mg	Capsule	Oral use
Germany	1 A Pharma GmbH		Sitagliptin/Metformin - 1 A Pharma 50 mg/850 mg Filmtabletten	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Germany	Aliud Pharma GmbH		Darunavir AL 400 mg Filmtabletten	Darunavir	400 mg	Film-coated tablet	Oral use
Germany	Aliud Pharma GmbH		Darunavir AL 600 mg Filmtabletten	Darunavir	600 mg	Film-coated tablet	Oral use
Germany	Aliud Pharma GmbH		Darunavir AL 800 mg Filmtabletten	Darunavir	800 mg	Film-coated tablet	Oral use
Germany	Aliud Pharma GmbH		Deferasirox AL 900 mg Filmtabletten	Deferasirox	900 mg	Film-coated tablet	Oral use
Germany	Aliud Pharma GmbH		Lapatinib AL 250 mg Filmtabletten	Lapatinib	250 mg	Film-coated tablet	Oral use
Germany	Aliud Pharma GmbH		Posaconazol AL 40 mg/ml Suspension zum Einnehmen	Posaconazole	40 mg/ml	Oral suspension	Oral use
Germany	Aliud Pharma GmbH		Tadalafil AL 10 mg Filmtabletten	Tadalafil	10 mg	Film-coated tablet	Oral use
Germany	Aliud Pharma GmbH		Tadalafil AL 20 mg Filmtabletten	Tadalafil	20 mg	Film-coated tablet	Oral use
Germany	Aliud Pharma GmbH		Tadalafil PAH AL 20 mg Filmtabletten	Tadalafil	20 mg	Film-coated tablet	Oral use
Germany	Aliud Pharma GmbH		Tadalafil AL 5 mg Filmtabletten	Tadalafil	5 mg	Film-coated tablet	Oral use
Germany	Aliud Pharma GmbH		Abacavir/Lamivudin AL 600 mg/300 mg Filmtabletten	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Germany	Aliud Pharma GmbH		Atazanavir AL 150 mg Hartkapseln	Atazanavir	150 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany	Aliud Pharma GmbH		Atazanavir AL 200 mg Hartkapseln	Atazanavir	200 mg	Capsule, hard	Oral use
Germany	Aliud Pharma GmbH		Atazanavir AL 300 mg Hartkapseln	Atazanavir	300 mg	Capsule, hard	Oral use
Germany	Aliud Pharma GmbH		Efavirenz/ emtricitabine/ tenofovirdis AL 600 mg/200 mg/245 mg Filmtabletten	Efavirenz/ emtricitabine/ tenofovir	600 mg / 200 mg / 245 mg	Film-coated tablet	Oral use
Germany	Aliud Pharma GmbH		Lacosamid AL 100 mg Filmtabletten	Lacosamide	100 mg	Film-coated tablet	Oral use
Germany	Aliud Pharma GmbH		Lacosamid AL 150 mg Filmtabletten	Lacosamide	150 mg	Film-coated tablet	Oral use
Germany	Aliud Pharma GmbH		Lacosamid AL 200 mg Filmtabletten	Lacosamide	200 mg	Film-coated tablet	Oral use
Germany	Aliud Pharma GmbH		Lacosamid AL 50 mg Filmtabletten	Lacosamide	50 mg	Film-coated tablet	Oral use
Germany	Baxter B.V.		Propofol Baxter 10 mg/ml Emulsion zur Injektion/Infusion	Propofol	10 mg/ml	Emulsion for injection/ infusion	Intravenous use
Germany	Baxter B.V.		Propofol Baxter 10 mg/ml MCT Emulsion zur Injektion/Infusion	Propofol	10 mg/ml	Emulsion for injection/ infusion	Intravenous use
Germany	Baxter B.V.		Propofol Baxter 20 mg/ml Emulsion zur Injektion/Infusion	Propofol	20 mg/ ml	Emulsion for injection/ infusion	Intravenous use
Germany	Baxter B.V.		Propofol Baxter 20 mg/ml MCT Emulsion zur Injektion/Infusion	Propofol	20 mg/ml	Emulsion for injection/ infusion	Intravenous use
Germany	betapharm Arzneimittel GmbH		Abacavir/Lamivudin beta 600 mg/300 mg Filmtabletten	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Germany	betapharm Arzneimittel GmbH		Atazanavir beta 150 mg Hartkapseln	Atazanavir	150 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany	betapharm Arzneimittel GmbH		Atazanavir beta 200 mg Hartkapseln	Atazanavir	200 mg	Capsule, hard	Oral use
Germany	betapharm Arzneimittel GmbH		Atazanavir beta 300 mg Hartkapseln	Atazanavir	300 mg	Capsule, hard	Oral use
Germany	betapharm Arzneimittel GmbH		Efavirenz/Emtricitabin/Tenofovirdisoproxil beta 600 mg/200 mg/245 mg Filmtabletten	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
Germany	betapharm Arzneimittel GmbH		Posaconazol beta 40 mg/ml Suspension zum Einnehmen	Posaconazole	40 mg/ ml	Oral suspension	Oral use
Germany	Brillpharma (Ireland) Limited		Solifenacin Brillpharma 1mg/ml Lösung zum Einnehmen	Solifenacin	1 mg/ml	Oral solution	Oral use
Germany	C4 health GmbH		Metformin C4 health 1 000 mg Filmtabletten	Metformin	1 000 mg	Film-coated tablet	Oral use
Germany	C4 health GmbH		Metformin C4 health 500 mg Filmtabletten	Metformin	500 mg	Film-coated tablet	Oral use
Germany	C4 health GmbH		Metformin C4 health 850 mg Filmtabletten	Metformin	850 mg	Film-coated tablet	Oral use
Germany	Denk Pharma GmbH & Co. KG		Tadalafil Denk 10 mg Filmtabletten	Tadalafil	10 mg	Film-coated tablet	Oral use
Germany	Denk Pharma GmbH & Co. KG		Tadalafil Denk 2,5 mg Filmtabletten	Tadalafil	2,5 mg	Film-coated tablet	Oral use
Germany	Denk Pharma GmbH & Co. KG		Tadalafil Denk 20 mg Filmtabletten	Tadalafil	20 mg	Film-coated tablet	Oral use
Germany	Denk Pharma GmbH & Co. KG		Tadalafil Denk 5 mg Filmtabletten	Tadalafil	5 mg	Film-coated tablet	Oral use
Germany	Denk Pharma GmbH & Co. KG		Vildagliptin Denk 50 mg Tabletten	Vildagliptin	50 mg	Tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany	Elpen Pharmaceutical Co. Inc		Amlodipin/Valsartan/Hydrochlorothiazid ELPEN 10 mg/160 mg/12,5 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Germany	Elpen Pharmaceutical Co. Inc		Amlodipin/Valsartan/Hydrochlorothiazid ELPEN 10 mg/160 mg/25 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Germany	Elpen Pharmaceutical Co. Inc		Amlodipin/Valsartan/Hydrochlorothiazid ELPEN 10 mg/320 mg/25 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 320 mg/ 25 mg	Film-coated tablet	Oral use
Germany	Elpen Pharmaceutical Co. Inc		Amlodipin/Valsartan/Hydrochlorothiazid ELPEN 5 mg/160 mg/12,5 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Germany	Elpen Pharmaceutical Co. Inc		Amlodipin/Valsartan/Hydrochlorothiazid ELPEN 5 mg/160 mg/25 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Germany	Elpen Pharmaceutical Co. Inc		Vildagliptin ELPEN 50 mg Tabletten	Vildagliptin	50 mg	Film-coated tablet	Oral use
Germany	Eugia Pharma (Malta) Limited		Anastro Puren 1 mg Filmtabletten	Anastrozole	1 mg	Film-coated tablet	Oral use
Germany	Glenmark Arzneimittel GmbH		Posaconazol Glenmark 40 mg/ml Suspension zum Einnehmen	Posaconazole	40 mg	Oral suspension	Oral use
Germany	Glenmark Arzneimittel GmbH		Erlotinib Glenmark 100 mg Filmtabletten	Erlotinib	100 mg	Film-coated tablet	Oral use
Germany	Glenmark Arzneimittel GmbH		Erlotinib Glenmark 150 mg Filmtabletten	Erlotinib	150 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany	Glenmark Arzneimittel GmbH		Erlotinib Glenmark 25 mg Filmtabletten	Erlotinib	25 mg	Film-coated tablet	Oral use
Germany	Hexal AG		Atazanavir HEXAL 200 mg Hartkapseln	Atazanavir	200 mg	Capsule, hard	Oral use
Germany	Hexal AG		Atazanavir HEXAL 300 mg Hartkapseln	Atazanavir	300 mg	Capsule, hard	Oral use
Germany	Hexal AG		Darunavir HEXAL 600 mg Filmtabletten	Darunavir	600 mg	Film-coated tablet	Oral use
Germany	Hexal AG		Darunavir HEXAL 800 mg Filmtabletten	Darunavir	800 mg	Film-coated tablet	Oral use
Germany	Hexal AG		Padviram 600 mg/200 mg/245 mg Filmtabletten	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
Germany	Hexal AG		Erlotinib Hexal 100 mg Filmtabletten	Erlotinib	100 mg	Film-coated tablet	Oral use
Germany	Hexal AG		Erlotinib Hexal 150 mg Filmtabletten	Erlotinib	150 mg	Film-coated tablet	Oral use
Germany	Hexal AG		Erlotinib Hexal 25 mg Filmtabletten	Erlotinib	25 mg	Film-coated tablet	Oral use
Germany	Hexal AG		Sitagliptin Metformin HEXAL 50 mg/850 mg Filmtabletten	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Germany	Hexal AG		Sorafenib HEXAL 400 mg Filmtabletten	Sorafenib	400 mg	Film-coated tablet	Oral use
Germany	Holsten Pharma GmbH		Amlodipin/Valsartan/HCT Holsten 10 mg/160 mg/12,5 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Germany	Holsten Pharma GmbH		Amlodipin/Valsartan/HCT Holsten 10 mg/160 mg/25 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany	Holsten Pharma GmbH		Amlodipin/Valsartan/HCT Holsten 10 mg/320 mg/25 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 320 mg/ 25 mg	Film-coated tablet	Oral use
Germany	Holsten Pharma GmbH		Amlodipin/Valsartan/HCT Holsten 5 mg/160 mg/12,5 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Germany	Holsten Pharma GmbH		Amlodipin/Valsartan/HCT Holsten 5 mg/160 mg/25 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Germany	Klinge Pharma GmbH		Diaverde 100 mg Hartkapseln	Racecadotril	100 mg	Capsule, hard	Oral use
Germany	Milstein C.V.		Pilocarpinhydrochlorid Milstein 5 mg Filmtabletten	Pilocarpine	5 mg	Film-coated tablet	Oral use
Germany	Pharmaselect International Beteiligungs GmbH		Colchanova 0,5 mg Tabletten	Colchicine	0,5 mg	Tablet	Oral use
Germany	Pharmaselect International Beteiligungs GmbH		Colchanova 1 mg Tabletten	Colchicine	1 mg	Tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG		Olanzapin Aurobindo 5 mg Tabletten	Olanzapine	5 mg	Tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG		Olanzapin Aurobindo 10 mg Tabletten	Olanzapine	10 mg	Tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG		Olanzapin Aurobindo 15 mg Tabletten	Olanzapine	15 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany	PUREN Pharma GmbH & Co. KG		Olanzapin Aurobindo 2.5 mg Tabletten	Olanzapine	2,5 mg	Tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG		Olanzapin Aurobindo 20 mg Tabletten	Olanzapine	20 mg	Tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG		Olanzapin Aurobindo 7.5 mg Tabletten	Olanzapine	7,5 mg	Tablet	Oral use
Germany	Puren Pharma GmbH & Co. KG		Bosentan Puren 125 mg Filmtabletten	Bosentan	125 mg	Film-coated tablet	Oral use
Germany	Puren Pharma GmbH & Co. KG		Bosentan Puren 62,5 mg Filmtabletten	Bosentan	62,5 mg	Film-coated tablet	Oral use
Germany	Puren Pharma GmbH & Co. KG		Leflunomid Puren 10 mg Filmtabletten	Leflunomide	10 mg	Film-coated tablet	Oral use
Germany	Puren Pharma GmbH & Co. KG		Leflunomid Puren 15 mg Filmtabletten	Leflunomide	15 mg	Film-coated tablet	Oral use
Germany	Puren Pharma GmbH & Co. KG		Nevirapin Aurobindo 400 mg Retardtabletten	Nevirapine	400 mg	Prolonged-release tablet	Oral use
Germany	ratiopharm GmbH		Deferasirox-ratiopharm 900 mg Filmtabletten	Deferasirox	900 mg	Film-coated tablet	Oral use
Germany	ratiopharm GmbH		Posaconazol-ratiopharm 40 mg/ml Suspension zum Einnehmen	Posaconazole	40 mg/ ml	Oral suspension	Oral use
Germany	Stadapharm GmbH		Deferasirox Stada 900 mg Filmtabletten	Deferasirox	900 mg	Film-coated tablet	Oral use
Germany	Stadapharm GmbH		Erlotinib Stada 100 mg Filmtabletten	Erlotinib	100 mg	Film-coated tablet	Oral use
Germany	Stadapharm GmbH		Erlotinib Stada 150 mg Filmtabletten	Erlotinib	150 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany	Stadapharm GmbH		Erlotinib Stada 25 mg Filmtabletten	Erlotinib	25 mg	Film-coated tablet	Oral use
Germany	Stadapharm GmbH		Erlotinib Stada 50 mg Filmtabletten	Erlotinib	50 mg	Film-coated tablet	Oral use
Germany	Stadapharm GmbH		Lacosamid Stada 100 mg Filmtabletten	Lacosamide	100 mg	Film-coated tablet	Oral use
Germany	Stadapharm GmbH		Lacosamid Stada 150 mg Filmtabletten	Lacosamide	150 mg	Film-coated tablet	Oral use
Germany	Stadapharm GmbH		Lacosamid Stada 200 mg Filmtabletten	Lacosamide	200 mg	Film-coated tablet	Oral use
Germany	Stadapharm GmbH		Lacosamid Stada 50 mg Filmtabletten	Lacosamide	50 mg	Film-coated tablet	Oral use
Germany	Stadapharm GmbH		Lapatinib Stada 250 mg Filmtabletten	Lapatinib	250 mg	Film-coated tablet	Oral use
Germany	Stadapharm GmbH		Sorafenib Stada 400 mg Filmtabletten	Sorafenib	400 mg	Film-coated tablet	Oral use
Germany	Stadapharm GmbH		Tadalafil Stada 10 mg Filmtabletten	Tadalafil	10 mg	Film-coated tablet	Oral use
Germany	Stadapharm GmbH		Tadalafil Stada 20 mg Filmtabletten	Tadalafil	20 mg	Film-coated tablet	Oral use
Germany	Stadapharm GmbH		Tadalafil Stada 5 mg Filmtabletten	Tadalafil	5 mg	Film-coated tablet	Oral use
Germany	Umedica Netherlands B.V.		Atorvastatin Umedica 10 mg Filmtabletten	Atorvastatin	10 mg	Film-coated tablet	Oral use
Germany	Umedica Netherlands B.V.		Atorvastatin Umedica 20 mg Filmtabletten	Atorvastatin	20 mg	Film-coated tablet	Oral use
Germany	Umedica Netherlands B.V.		Atorvastatin Umedica 40 mg Filmtabletten	Atorvastatin	40 mg	Film-coated tablet	Oral use
Germany	Umedica Netherlands B.V.		Atorvastatin Umedica 80 mg Filmtabletten	Atorvastatin	80 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany	Umedica Netherlands B.V.		Carbamazepin Umedica 100 mg Tabletten	Carbamazepine	100 mg	Tablet	Oral use
Germany	Umedica Netherlands B.V.		Carbamazepin Umedica 200 mg Tabletten	Carbamazepine	200 mg	Tablet	Oral use
Germany	Umedica Netherlands B.V.		Carbamazepin Umedica 400 mg Tabletten	Carbamazepine	400 mg	Tablet	Oral use
Germany	Umedica Netherlands B.V.		Deferasirox Umedica 180 mg Filmtabletten	Deferasirox	180 mg	Film-coated tablet	Oral use
Germany	Umedica Netherlands B.V.		Deferasirox Umedica 360 mg Filmtabletten	Deferasirox	360 mg	Film-coated tablet	Oral use
Germany	Umedica Netherlands B.V.		Deferasirox Umedica 90 mg Filmtabletten	Deferasirox	90 mg	Film-coated tablet	Oral use
Germany	Umedica Netherlands B.V.		Pirfenidon Umedica 267 mg Filmtabletten	Pirfenidone	267 mg	Film-coated tablet	Oral use
Germany	Umedica Netherlands B.V.		Pirfenidon Umedica 801 mg Filmtabletten	Pirfenidone	801 mg	Film-coated tablet	Oral use
Germany	Umedica Netherlands B.V.		Ranolazin Umedica 375 mg Retardtabletten	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Germany	Umedica Netherlands B.V.		Ranolazin Umedica 500 mg Retardtabletten	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Germany	Umedica Netherlands B.V.		Ranolazin Umedica 750 mg Retardtabletten	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Germany	Umedica Netherlands B.V.		Sildenafil Umedica 20 mg Filmtabletten	Sildenafil	20 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany	Zentiva k.s.		Amlodipin/Valsartan/HCT Zentiva 10 mg/160 mg/12,5 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Germany	Zentiva k.s.		Amlodipin/Valsartan/HCT Zentiva 10 mg/160 mg/25 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Germany	Zentiva k.s.		Amlodipin/Valsartan/HCT Zentiva 10 mg/320 mg/25 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 320 mg/ 25 mg	Film-coated tablet	Oral use
Germany	Zentiva k.s.		Amlodipin/Valsartan/HCT Zentiva 5 mg/160 mg/12,5 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Germany	Zentiva k.s.		Amlodipin/Valsartan/HCT Zentiva 5 mg/160 mg/25 mg Filmtabletten	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Germany	Zentiva Pharma GmbH		Posaconazol Zentiva 40 mg/ml Suspension zum Einnehmen	Posaconazole	40 mg/ ml	Oral suspension	Oral use
Germany		2care4 Generics ApS	Bendatol	Albendazole	400 mg	Tablet	Oral use
Germany		Aurobindo Pharma (Malta) Limited	Dapagliflozin/ Metformin Aurobindo 5 mg/ 1 000 mg Filmtabletten	Dapagliflozin/ metformin	5 mg/ 1 000 mg	Film-coated tablet	Oral use
Germany		Aurobindo Pharma (Malta) Limited	Dapagliflozin/Metformin PUREN 5 mg 100 mg Filmtabletten	Dapagliflozin/ metformin	5 mg/ 1 000 mg	Film-coated tablet	Oral use
Germany		Aurobindo Pharma (Malta) Limited	Dapagliflozin/ Metformin Aurobindo 5 mg/ 850 mg Filmtabletten	Dapagliflozin/ metformin	5 mg/ 850 mg	Film-coated tablet	Oral use
Germany		Aurobindo Pharma (Malta) Limited	Dapagliflozin/Metformin PUREN 5 mg 850 mg Filmtabletten	Dapagliflozin/ metformin	5 mg/ 850 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany		Devatis GmbH	Eltrombopag Devatis 12,5 mg Filmtabletten	Eltrombopag	12,5 mg	Film-coated tablet	Oral use
Germany		Devatis GmbH	Eltrombopag Devatis 25 mg Filmtabletten	Eltrombopag	25 mg	Film-coated tablet	Oral use
Germany		Devatis GmbH	Eltrombopag Devatis 50 mg Filmtabletten	Eltrombopag	50 mg	Film-coated tablet	Oral use
Germany		Devatis GmbH	Eltrombopag Devatis 75 mg Filmtabletten	Eltrombopag	75 mg	Film-coated tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Ralaxa 375 mg Retardtabletten	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Ranange 375 mg Retardtabletten	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Ranolazin beta 375 mg Retardtabletten	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Ranolazin Heumann 375 mg Retardtabletten	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Ranolazine ELPEN 375 mg Retardtabletten	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Ranolpen 375 mg Retardtabletten	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Raupresil 375 mg Retardtabletten	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Rovalo 375 mg Retardtabletten	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Ralaxa 500 mg Retardtabletten	Ranolazine	500 mg	Prolonged-release tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany		Elpen Pharmaceutical Co. Inc.	Ranange 500 mg Retardtabletten	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Ranolazin beta 500 mg Retardtabletten	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Ranolazin Heumann 500 mg Retardtabletten	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Ranolazine ELPEN 500 mg Retardtabletten	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Ranolpen 500 mg Retardtabletten	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Raupresil 500 mg Retardtabletten	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Rovalo 500 mg Retardtabletten	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Ralaxa 750 mg Retardtabletten	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Ranange 750 mg Retardtabletten	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Ranolazin beta 750 mg Retardtabletten	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Ranolazin Heumann 750 mg Retardtabletten	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Ranolazine ELPEN 750 mg Retardtabletten	Ranolazine	750 mg	Prolonged-release tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany		Elpen Pharmaceutical Co. Inc.	Ranolpen 750 mg Retardtabletten	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Rovalo 750 mg Retardtabletten	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Germany		Elpen Pharmaceutical Co. Inc.	Raupresil 750 mg Retardtabletten	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Germany		Generis Farmacêutica, S.A.	Teriflunomid PUREN 14 mg Filmtabletten	Teriflunomide	14 mg	Film-coated tablet	Oral use
Germany		Generis Farmacêutica, S.A.	Trazodon PUREN 100 mg Filmtabletten	Trazodone	100 mg	Film-coated tablet	Oral use
Germany		Generis Phar, Unipessoal Lda	Teriflunomid Aurobindo 14 mg Filmtabletten	Teriflunomide	14 mg	Film-coated tablet	Oral use
Germany		Hexal Aktiengesellschaft	RanolaHexal 375 mg Retardtabletten	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Germany		Hexal Aktiengesellschaft	Ranzolva 375 mg Retardtabletten	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Germany		Hexal Aktiengesellschaft	RanolaHexal 500 mg Retardtabletten	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Germany		Hexal Aktiengesellschaft	Ranzolva 500 mg Retardtabletten	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Germany		Hexal Aktiengesellschaft	RanolaHexal 750 mg Retardtabletten	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Germany		Hexal Aktiengesellschaft	Ranzolva 750 mg Retardtabletten	Ranolazine	750 mg	Prolonged-release tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany		Hexal AG	Ranolazin - 1 A Pharma 375 mg Retardtabletten	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Germany		Hexal AG	Ranolazin - 1 A Pharma 500 mg Retardtabletten	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Germany		Hexal AG	Ranolazin - 1 A Pharma 750 mg Retardtabletten	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Germany		Kappler Pharma Consult GmbH	Betahistin Kappler 16 mg Tabletten	Betahistine	16 mg	Tablet	Oral use
Germany		Kappler Pharma Consult GmbH	Betahistin Kapplerpharma 16 mg Tabletten	Betahistine	16 mg	Tablet	Oral use
Germany		Kappler Pharma Consult GmbH	Betahistin Kappler 24 mg Tabletten	Betahistine	24 mg	Tablet	Oral use
Germany		Kappler Pharma Consult GmbH	Betahistin Kapplerpharma 24 mg Tabletten	Betahistine	24 mg	Tablet	Oral use
Germany		Kappler Pharma Consult GmbH	Betahistin Kappler 8 mg Tabletten	Betahistine	8 mg	Tablet	Oral use
Germany		Kappler Pharma Consult GmbH	Betahistin Kapplerpharma 8 mg Tabletten	Betahistine	8 mg	Tablet	Oral use
Germany		Morningside Healthcare (Malta) Ltd.	Mercaptopurine Morningside 10 mg Tabletten	Mercaptopurine	10 mg	Tablet	Oral use
Germany		Morningside Healthcare (Malta) Ltd.	Mercaptopurine Morningside 50 mg Tabletten	Mercaptopurine	50 mg	Tablet	Oral use
Germany		Neuraxpharm Bohemia s.r.o.	Trazodon neuraxpharm 150 mg Tabletten mit veränderter Wirkstoffreisetzung	Trazodone	150 mg	Modified-release tablet	Oral use
Germany		Neuraxpharm Bohemia s.r.o.	Trazodon neuraxpharm 75 mg Tabletten mit veränderter Wirkstofffreisetzung	Trazodone	75 mg	Modified-release tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany		Phagecon - Servicos e Consultoria Farmaceutica, Lda.	Trazodon Phagecon 150 mg Tabletten mit veränderter Wirkstofffreisetzung	Trazodone	150 mg	Modified-release tablet	Oral use
Germany		Phagecon - Servicos e Consultoria Farmaceutica, Lda.	Trazodon Phagecon 75 mg Tabletten mit veränderter Wirkstofffreisetzung	Trazodone	75 mg	Modified-release tablet	Oral use
Germany		PharmConsul s.r.o.	Olanzapine Oro PharmConsul 10 mg Schmelztabletten	Olanzapine	10 mg	Orodispersible tablet	Oral use
Germany		PharmConsul s.r.o.	Olanzapine Oro PharmConsul 15 mg Schmelztabletten	Olanzapine	15 mg	Orodispersible tablet	Oral use
Germany		PharmConsul s.r.o.	Olanzapine Oro PharmConsul 20 mg Schmelztabletten	Olanzapine	20 mg	Orodispersible tablet	Oral use
Germany		PharmConsul s.r.o.	Olanzapine Oro PharmConsul 5 mg Schmelztabletten	Olanzapine	5 mg	Orodispersible tablet	Oral use
Germany		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 150 mg Hartkapseln	Nilotinib	150 mg	Capsule, hard	Oral use
Germany		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 150 mg Hartkapseln	Nilotinib	150 mg	Capsule, hard	Oral use
Germany		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris 150 mg Hartkapseln	Nilotinib	150 mg	Capsule, hard	Oral use
Germany		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 200 mg Hartkapseln	Nilotinib	200 mg	Capsule, hard	Oral use
Germany		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 200 mg Hartkapseln	Nilotinib	200 mg	Capsule, hard	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris Hartkapseln	Nilotinib	200 mg	Capsule, hard	Oral use
Germany		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 50 mg Hartkapseln	Nilotinib	50 mg	Capsule, hard	Oral use
Germany		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 50 mg Hartkapseln	Nilotinib	50 mg	Capsule, hard	Oral use
Germany		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris 50 mg Hartkapseln	Nilotinib	50 mg	Capsule, hard	Oral use
Germany		Torrent Pharma (Malta) Ltd	Pazopanib 200 mg	Pazopanib	200 mg	Film-coated tablet	Oral use
Germany		Umedica Netherlands B.V.	Dimethyl Fumarat Umedica 120 mg magensaftresistente Hartkapseln	Dimethyl fumarate	120 mg	Gastro-resistant capsule, hard	Oral use
Germany		Umedica Netherlands B.V.	Dimethyl Fumarat Umedica 240 mg magensaftresistente Hartkapseln	Dimethyl fumarate	240 mg	Gastro-resistant capsule, hard	Oral use
Germany		Umedica Netherlands B.V.	Oxcarbazepin 150 mg Filmtabletten	Oxcarbazepine	150 mg	Film-coated tablet	Oral use
Germany		Umedica Netherlands B.V.	Oxcarbazepin 300 mg Filmtabletten	Oxcarbazepine	300 mg	Film-coated tablet	Oral use
Germany		Umedica Netherlands B.V.	Oxcarbazepin 600 mg Filmtabletten	Oxcarbazepine	600 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany		Zentiva k.s.	Zymela 375 mg Retardtabletten	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Germany		Zentiva k.s.	Zymela 500 mg Retardtabletten	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Germany		Zentiva k.s.	Zymela 750 mg Retardtabletten	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Greece	Baxter B.V.		Propofol Baxter	Propofol	10 mg/ml	Emulsion for injection/ infusion	Intravenous use
Greece	Elpen Pharmaceutical Co. Inc		Ebimia	Amlodipine/ irbesartan	10 mg/ 150 mg	Film-coated tablet	Oral use
Greece	Elpen Pharmaceutical Co. Inc		Ebimia	Amlodipine/ irbesartan	10 mg/ 300 mg	Film-coated tablet	Oral use
Greece	Elpen Pharmaceutical Co. Inc		Ebimia	Amlodipine/ irbesartan	5 mg/ 150 mg	Film-coated tablet	Oral use
Greece	Elpen Pharmaceutical Co. Inc		Ebimia	Amlodipine/ irbesartan	5 mg/ 300 mg	Film-coated tablet	Oral use
Greece	Elpen Pharmaceutical Co. Inc		Valsimia HCT	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Greece	Elpen Pharmaceutical Co. Inc		Valsimia HCT	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Greece	Elpen Pharmaceutical Co. Inc		Valsimia HCT	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 320 mg/ 25 mg	Film-coated tablet	Oral use
Greece	Elpen Pharmaceutical Co. Inc		Valsimia HCT	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use

ELI: http://data.europa.eu/eli/C/2024/3878/oj

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Greece	Elpen Pharmaceutical Co. Inc		Valsimia HCT	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Greece	Elpen Pharmaceutical Co. Inc		Antorcin	Atorvastatin	10 mg	Film-coated tablet	Oral use
Greece	Elpen Pharmaceutical Co. Inc		Dodefar	Darunavir	150 mg	Film-coated tablet	Oral use
Greece	Elpen Pharmaceutical Co. Inc		Dodefar	Darunavir	300 mg	Film-coated tablet	Oral use
Greece	Elpen Pharmaceutical Co. Inc		Dodefar	Darunavir	400 mg	Film-coated tablet	Oral use
Greece	Elpen Pharmaceutical Co. Inc		Dodefar	Darunavir	600 mg	Film-coated tablet	Oral use
Greece	Elpen Pharmaceutical Co. Inc		Dodefar	Darunavir	75 mg	Film-coated tablet	Oral use
Greece	Elpen Pharmaceutical Co. Inc		Dodefar	Darunavir	800 mg	Film-coated tablet	Oral use
Greece	Elpen Pharmaceutical Co. Inc		Issoferrol Max	Deferasirox	900 mg	Film-coated tablet	Oral use
Greece	Elpen Pharmaceutical Co. Inc		Hemocinol	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
Greece	Elpen Pharmaceutical Co. Inc		Padlas	Vildagliptin	50 mg	Tablet	Oral use
Greece	Enorasis		Amlodipine+Valsartan+Hydrochlorothiazide/ Aenorasis	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Greece	Enorasis		Amlodipine+Valsartan+Hydrochlorothiazide/ Aenorasis	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Greece	Enorasis		Amlodipine+Valsartan+Hydrochlorothiazide/ Aenorasis	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 320 mg/ 25 mg	Film-coated tablet	Oral use
Greece	Enorasis		Amlodipine+Valsartan+Hydrochlorothiazide/ Aenorasis	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Greece	Enorasis		Amlodipine+Valsartan+Hydrochlorothiazide/ Aenorasis	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Greece	Genepharm S.A.		Amlodipine+Valsartan+Hydrochlorothiazide/ Genepharm	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Greece	Genepharm S.A.		Amlodipine+Valsartan+Hydrochlorothiazide/ Genepharm	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Greece	Genepharm S.A.		Amlodipine+Valsartan+Hydrochlorothiazide/ Genepharm	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 320 mg/ 25 mg	Film-coated tablet	Oral use
Greece	Genepharm S.A.		Amlodipine+Valsartan+Hydrochlorothiazide/ Genepharm	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Greece	Genepharm S.A.		Amlodipine+Valsartan+Hydrochlorothiazide/ Genepharm	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Greece	Genepharm S.A.		Lacosamide Genepharm	Lacosamide	100 mg	Film-coated tablet	Oral use
Greece	Genepharm S.A.		Lacosamide Genepharm	Lacosamide	150 mg	Film-coated tablet	Oral use
Greece	Genepharm S.A.		Lacosamide Genepharm	Lacosamide	200 mg	Film-coated tablet	Oral use
Greece	Genepharm S.A.		Lacosamide Genepharm	Lacosamide	50 mg	Film-coated tablet	Oral use
Greece	Genepharm S.A.		Posaconazole Genepharm	Posaconazole	40 mg/ ml	Oral suspension	Oral use
Greece	Genepharm S.A.		Genement	Tadalafil	10 mg	Film-coated tablet	Oral use
Greece	Genepharm S.A.		Genement	Tadalafil	2,5 mg	Film-coated tablet	Oral use
Greece	Genepharm S.A.		Genement	Tadalafil	20 mg	Film-coated tablet	Oral use
Greece	Genepharm S.A.		Genement	Tadalafil	5 mg	Film-coated tablet	Oral use
Greece	Genepharm S.A.		Vildagliptin Genepharm	Vildagliptin	50 mg	Tablet	Oral use
Greece	Genepharm S.A.		Radicut	Vildagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Greece	Genepharm S.A.		Radicut	Vildagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Greece	Mylan Ireland Limited		Erlotinib Mylan	Erlotinib	100 mg	Film-coated tablet	Oral use
Greece	Mylan Ireland Limited		Erlotinib Mylan	Erlotinib	150 mg	Film-coated tablet	Oral use
Greece	Pharmaselect International Beteiligungs GmbH		Colchicin/Pharmaselect	Colchicine	0,5 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Greece	Pharmaselect International Beteiligungs GmbH		Colchicin/Pharmaselect	Colchicine	1 mg	Tablet	Oral use
Greece	Rafarm		Ranolazine Rafarm	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Greece	Rafarm		Ranolazine Rafarm	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Greece	Rafarm		Ranolazine Rafarm	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Greece	Sandoz d.d.		Sitagliptin+ Metformin Sandoz	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Greece	Sandoz d.d.		Sorafenib Sandoz	Sorafenib	400 mg	Film-coated tablet	Oral use
Greece	Viatris Limited		Tuttecvi	Vildagliptin	50 mg	Tablet	Oral use
Greece	Win Medica S.A.		Combipress	Amlodipine/ irbesartan	10 mg/ 150 mg	Film-coated tablet	Oral use
Greece	Win Medica S.A.		Combipress	Amlodipine/ irbesartan	10 mg/ 300 mg	Film-coated tablet	Oral use
Greece	Win Medica S.A.		Combipress	Amlodipine/ irbesartan	5 mg/ 150 mg	Film-coated tablet	Oral use
Greece	Win Medica S.A.		Combipress	Amlodipine/ irbesartan	5 mg/ 300 mg	Film-coated tablet	Oral use
Greece	Win Medica S.A.		Combipress Plus	Amlodipine/ irbesartan / hydrochlorothiazide	10 mg/ 300 mg/ 12,5 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Greece	Win Medica S.A.		Combipress Plus	Amlodipine/ irbesartan / hydrochlorothia-zide	5 mg/ 300 mg/ 12,5 mg	Film-coated tablet	Oral use
Greece	Win Medica S.A.		Vildus	Vildagliptin	50 mg	Tablet	Oral use
Greece		Elpen Pharma-ceutical Co. Inc.	Roxaza	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Greece		Elpen Pharma-ceutical Co. Inc.	Zirana/Jexera	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Greece		Elpen Pharma-ceutical Co. Inc.	Roxaza	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Greece		Elpen Pharma-ceutical Co. Inc.	Zirana/Jexera	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Greece		Elpen Pharma-ceutical Co. Inc.	Roxaza	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Greece		Elpen Pharma-ceutical Co. Inc.	Zirana/Jexera	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Greece		Genepharm S.A.	Bottiar	Linagliptin	5 mg	Film-coated tablet	Oral use
Greece		Genepharm S.A.	LAFAVAL	Tadalafil	20 mg	Film-coated tablet	Oral use
Greece		Innovis	Renofrin	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Greece		Innovis	Renofrin	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Greece		Innovis	Renofrin	Ranolazine	750 mg	Prolonged-release tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Greece		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	150 mg	Capsule, hard	Oral use
Greece		Pharos Pharmaceutical Oriented Services Ltd.	NILOTINIB PHAROS	Nilotinib	150 mg	Capsule	Oral use
Greece		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	200 mg	Capsule	Oral use
Greece		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	200 mg	Capsule, hard	Oral use
Greece		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	50 mg	Capsule, hard	Oral use
Greece		Sandoz Pharmaceuticals d.d.	RANOLAZINE/SANDOZ	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Greece		Sandoz Pharmaceuticals d.d.	RANOLAZINE/SANDOZ	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Greece		Sandoz Pharmaceuticals d.d.	RANOLAZINE/SANDOZ	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Greece		Viatris Limited	Nilotinib Viatris	Nilotinib	150 mg	Capsule, hard	Oral use
Greece		Viatris Limited	Nilotinib Viatris	Nilotinib	200 mg	Capsule, hard	Oral use
Greece		Win Medica S.A.	Ranange	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Greece		Win Medica S.A.	Ranange	Ranolazine	500 mg	Prolonged-release tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Greece		Win Medica S.A.	Ranange	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Hungary	1 A Pharma GmbH		SITAGLIPTIN/METFORMIN 1 A PHARMA 50 mg/850 mg filmtabletta	Sitagliptin/ metformin	50 mg / 850 mg	Film-coated tablet	Oral use
Hungary	Alkaloid - INT d.o.o.		Losmorid 100 mg filmtabletta	Lacosamide	100 mg	Film-coated tablet	Oral use
Hungary	Alkaloid - INT d.o.o.		Losmorid 150 mg filmtabletta	Lacosamide	150 mg	Film-coated tablet	Oral use
Hungary	Alkaloid - INT d.o.o.		Losmorid 200 mg filmtabletta	Lacosamide	200 mg	Film-coated tablet	Oral use
Hungary	Alkaloid - INT d.o.o.		Losmorid 50 mg filmtabletta	Lacosamide	50 mg	Film-coated tablet	Oral use
Hungary	AOP Orphan Pharmaceuticals GmbH		TADALAFIL AOP 20 mg filmtabletta	Tadalafil	20 mg	Film-coated tablet	Oral use
Hungary	Elpen Pharmaceutical Co. Inc		Padlas 50 mg Tabletta	Vildagliptin	50 mg	Tablet	Oral use
Hungary	Elpen Pharmaceutical Co. Inc		Vildagliptin Elpen 50 mg tabletta	Vildagliptin	50 mg	Tablet	Oral use
Hungary	Genepharm S.A.		Lacosamide/Genepharm 100 mg filmtabletta	Lacosamide	100 mg	Film-coated tablet	Oral use
Hungary	Genepharm S.A.		Lacosamide/Genepharm 150 mg filmtabletta	Lacosamide	150 mg	Film-coated tablet	Oral use
Hungary	Genepharm S.A.		Lacosamide/Genepharm 200 mg filmtabletta	Lacosamide	200 mg	Film-coated tablet	Oral use
Hungary	Genepharm S.A.		Lacosamide/Genepharm 50 mg filmtabletta	Lacosamide	50 mg	Film-coated tablet	Oral use
Hungary	Genepharm S.A.		Posaconazole Genepharm 40 mg/ml szuszpenzió	Posaconazole	40 mg/ ml	Oral suspension	Oral use
Hungary	Genepharm S.A.		Radicut 50 mg/850 mg filmtabletta	Vildagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Hungary	Genepharm S.A.		Radicut 50 mg/1 000 mg filmtabletta	Vildagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Hungary	Pharmascience International Limited		Erlotinib Pharmascience 100 mg filmtabletta	Erlotinib	100 mg	Film-coated tablet	Oral use
Hungary	Pharmascience International Limited		Erlotinib Pharmascience 150 mg filmtabletta	Erlotinib	150 mg	Film-coated tablet	Oral use
Hungary	Sandoz Hungária Kereskedelmi Kft.		Erlotinib Sandoz 100 mg, filmtabletta	Erlotinib	100 mg	Film-coated tablet	Oral use
Hungary	Sandoz Hungária Kereskedelmi Kft.		Erlotinib Sandoz 100 mg, filmtabletta	Erlotinib	100 mg	Film-coated tablet	Oral use
Hungary	Sandoz Hungária Kereskedelmi Kft.		Erlotinib Sandoz 150 mg, filmtabletta	Erlotinib	150 mg	Film-coated tablet	Oral use
Hungary	Sandoz Hungária Kereskedelmi Kft.		Erlotinib Sandoz 150 mg, filmtabletta	Erlotinib	150 mg	Film-coated tablet	Oral use
Hungary	Sandoz Hungária Kereskedelmi Kft.		Erlotinib Sandoz 25 mg, filmtabletta	Erlotinib	25 mg	Film-coated tablet	Oral use
Hungary	Sandoz Hungária Kereskedelmi Kft.		Erlotinib Sandoz 25 mg, filmtabletta	Erlotinib	25 mg	Film-coated tablet	Oral use
Hungary	Stada Arzneimittel AG		Erlotinib Stada 100 mg filmtabletta	Erlotinib	100 mg	Film-coated tablet	Oral use
Hungary	Stada Arzneimittel AG		Erlotinib Stada 150 mg filmtabletta	Erlotinib	150 mg	Film-coated tablet	Oral use
Hungary	Stada Arzneimittel AG		Erlotinib Stada 25 mg filmtabletta	Erlotinib	25 mg	Film-coated tablet	Oral use
Hungary	Stada Arzneimittel AG		Erlotinib Stada 50 mg filmtabletta	Erlotinib	50 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Hungary	Stada Arzneimittel AG		SORAFENIB STADA 400 mg filmtabletta	Sorafenib	400 mg	Film-coated tablet	Oral use
Hungary	Supremex Kft.		Vildagliptin/metformin Supremex 50/1 000 mg filmtabletta	Vildagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Hungary	Viatris Limited		Erlotinib Mylan 100 mg filmtabletta	Erlotinib	100 mg	Film-coated tablet	Oral use
Hungary	Viatris Limited		Erlotinib Mylan 150 mg filmtabletta	Erlotinib	150 mg	Film-coated tablet	Oral use
Hungary	Viatris Limited		Erlotinib Mylan 25 mg filmtabletta	Erlotinib	25 mg	Film-coated tablet	Oral use
Hungary	Viatris Limited		Erlotinib Mylan 50 mg filmtabletta	Erlotinib	50 mg	Film-coated tablet	Oral use
Hungary	Vipharm S.A.		Anvildis 50 mg tabletta	Vildagliptin	50 mg	Tablet	Oral use
Hungary	Vipharm S.A.		Anvildismet 50 mg/850 mg filmtabletta	Vildagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Hungary	Vipharm S.A.		Anvildismet 50 mg/1 000 mg filmtabletta	Vildagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Hungary	Win Medica S.A.		Vildus 50 mg Tabletta	Vildagliptin	50 mg	Tablet	Oral use
Hungary	Zentiva k.s.		Varlota 100 mg filmtabletta	Erlotinib	100 mg	Film-coated tablet	Oral use
Hungary	Zentiva k.s.		Varlota 150 mg filmtabletta	Erlotinib	150 mg	Film-coated tablet	Oral use
Hungary	Zentiva k.s.		Varlota 50 mg filmtabletta	Erlotinib	50 mg	Film-coated tablet	Oral use
Hungary		Aenorasis S.A.	NilotinibAenorasis 150 mg kemény kapszula	Nilotinib	150 mg	Capsule, hard	Oral use
Hungary		Aenorasis S.A.	NilotinibAenorasis 200 mg kemény kapszula	Nilotinib	200 mg	Capsule, hard	Oral use
Hungary		Aenorasis S.A.	NilotinibAenorasis 50 mg kemény kapszula	Nilotinib	50 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Hungary		Egis Pharmaceuticals PLC	Granoza 150 mg hard capsules	Nilotinib	150 mg	Capsule, hard	Oral use
Hungary		Egis Pharmaceuticals PLC	Granoza 200 mg hard capsules	Nilotinib	200 mg	Capsule, hard	Oral use
Hungary		Egis Pharmaceuticals PLC	Granoza 50 mg hard capsules	Nilotinib	50 mg	Capsule, hard	Oral use
Hungary		Kappler Pharma Consult GmbH	Betahistin Kappler 16 mg tabletta	Betahistine	16 mg	Tablet	Oral use
Hungary		Kappler Pharma Consult GmbH	Betahistin Kappler 24 mg tabletta	Betahistine	24 mg	Tablet	Oral use
Hungary		Kappler Pharma Consult GmbH	Betahistin Kappler 8 mg tabletta	Betahistine	8 mg	Tablet	Oral use
Hungary		Pharmascience International Limited	Nilotinib Pharmascience 150 mg kemény kapszula	Nilotinib	150 mg	Capsule, hard	Oral use
Hungary		Pharmascience International Limited	Nilotinib Pharmascience 200 mg kemény kapszula	Nilotinib	200 mg	Capsule, hard	Oral use
Hungary		Pharos Pharmaceutical Oriented Services Ltd.	Evaness 150 mg mg kemény kapszula	Nilotinib	150 mg	Capsule, hard	Oral use
Hungary		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 150mg hard capsules	Nilotinib	150 mg	Capsule, hard	Oral use
Hungary		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 150mg hard capsules	Nilotinib	150 mg	Capsule, hard	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Hungary		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 150mg hard capsules	Nilotinib	150 mg	Capsule, hard	Oral use
Hungary		Pharos Pharmaceutical Oriented Services Ltd.	Evaness 200 mg kemény kapszula	Nilotinib	200 mg	Capsule, hard	Oral use
Hungary		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 200mg hard capsules	Nilotinib	200 mg	Capsule, hard	Oral use
Hungary		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 200mg hard capsules	Nilotinib	200 mg	Capsule, hard	Oral use
Hungary		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 200mg hard capsules	Nilotinib	200 mg	Capsule, hard	Oral use
Hungary		Pharos Pharmaceutical Oriented Services Ltd.	Evaness 50 mg mg kemény kapszula	Nilotinib	50 mg	Capsule, hard	Oral use
Hungary		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 50mg hard capsules	Nilotinib	50 mg	Capsule, hard	Oral use
Hungary		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 50mg hard capsules	Nilotinib	50 mg	Capsule, hard	Oral use
Hungary		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 50mg hard capsules	Nilotinib	50 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Hungary		Viatris Limited	Nilotinib Viatris 150 mg kemény kapszula	Nilotinib	150 mg	Capsule, hard	Oral use
Hungary		Viatris Limited	Nilotinib Viatris 200 mg kemény kapszula	Nilotinib	200 mg	Capsule, hard	Oral use
Hungary		Viatris Limited	Nilotinib Viatris 50 mg kemény kapszula	Nilotinib	50 mg	Capsule, hard	Oral use
Hungary		Zentiva k.s.	Nilotinib Zentiva 150 mg kemény kapszula	Nilotinib	150 mg	Capsule, hard	Oral use
Hungary		Zentiva k.s.	Nilotinib Zentiva 200mg kemény kapszula	Nilotinib	200 mg	Capsule, hard	Oral use
Hungary		Zentiva k.s.	Nilotinib Zentiva 50 mg kemény kapszula	Nilotinib	50 mg	Capsule, hard	Oral use
Iceland	Newbury Pharmaceuticals AB		Lapatinib Newbury	Lapatinib	250 mg	Film-coated tablet	Oral use
Iceland	Sandoz A/S		Padviram	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
Iceland	Stada Arzneimittel AG		Atazanavir Stada	Atazanavir	150 mg	Capsule, hard	Oral use
Iceland	Stada Arzneimittel AG		Atazanavir Stada	Atazanavir	200 mg	Capsule, hard	Oral use
Iceland	Stada Arzneimittel AG		Atazanavir Stada	Atazanavir	300 mg	Capsule, hard	Oral use
Iceland	Stada Arzneimittel AG		Lacosamide Stada	Lacosamide	100 mg	Film-coated tablet	Oral use
Iceland	Stada Arzneimittel AG		Lacosamide Stada	Lacosamide	150 mg	Film-coated tablet	Oral use
Iceland	Stada Arzneimittel AG		Lacosamide Stada	Lacosamide	200 mg	Film-coated tablet	Oral use
Iceland	Stada Arzneimittel AG		Lacosamide Stada	Lacosamide	50 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Iceland		Kappler Pharma Consult GmbH	Betahistin Kappler	Betahistine	16 mg	Tablet	Oral use
Iceland		Kappler Pharma Consult GmbH	Betahistin Kappler	Betahistine	24 mg	Tablet	Oral use
Iceland		Kappler Pharma Consult GmbH	Betahistin Kappler	Betahistine	8 mg	Tablet	Oral use
Iceland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS	Nilotinib	150 mg	Capsule, hard	Oral use
Iceland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris	Nilotinib	150 mg	Capsule	Oral use
Iceland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS	Nilotinib	200 mg	Capsule, hard	Oral use
Iceland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris	Nilotinib	200 mg	Capsule	Oral use
Iceland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS	Nilotinib	50 mg	Capsule, hard	Oral use
Iceland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris	Nilotinib	50 mg	Capsule	Oral use
Ireland	Baxter B.V.		Propofol 10 mg/ml Emulsion for injection/infusion	Propofol	10 mg/ml	Emulsion for injection/ infusion	Intravenous use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Ireland	Baxter B.V.		Propofol 20 mg/ml Emulsion for injection/infusion	Propofol	20 mg/ml	Emulsion for injection/ infusion	Intravenous use
Ireland	Brillpharma (Ireland) Limited		Trazodone hydrochloride	Trazodone	100 mg	Capsule, hard	Oral use
Ireland	Brillpharma (Ireland) Limited		Trazodone hydrochloride	Trazodone	150 mg	Film-coated tablet	Oral use
Ireland	Brillpharma (Ireland) Limited		Trazodone hydrochloride	Trazodone	50 mg	Capsule, hard	Oral use
Ireland	Brown & Burk IR Limited		Rimicorim	Lymecycline	300 mg	Capsule, hard	Oral use
Ireland	Brown & Burk IR Limited		Nefopam hydrochloride	Nefopam	30 mg	Film-coated tablet	Oral use
Ireland	Clonmel Healthcare Ltd		Darunavir Clonmel 600 mg film-coated tablets	Darunavir	600 mg	Film-coated tablet	Oral use
Ireland	Clonmel Healthcare Ltd		Darunavir Clonmel 800 mg film-coated tablets	Darunavir	800 mg	Film-coated tablet	Oral use
Ireland	Clonmel Healthcare Ltd		Efavirenz/Emtricitabine/Tenofovir Disoproxil Clonmel 600 mg/200 mg/245 mg film-coated tablets	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
Ireland	Crescent Pharma International Limited		Dilacort	Prednisolone	2,5 mg	Gastro-resistant tablet	Oral use
Ireland	Crescent Pharma International Limited		Dilacort	Prednisolone	5 mg	Gastro-resistant tablet	Oral use
Ireland	Milstein C.V.		Midodrine hydrochloride tablets	Midodrine	2,5 mg	Tablet	Oral use
Ireland	Milstein C.V.		Midodrine hydrochloride tablets	Midodrine	5 mg	Tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Ireland	Rowex Ltd.		Atazanavir Rowex 300 mg Capsules hard	Atazanavir	300 mg	Capsule, hard	Oral use
Ireland	Rowex Ltd.		Darunavir Rowex 800 mg Film-coated tablets	Darunavir	800 mg	Film-coated tablet	Oral use
Ireland	Syri Pharma Limited t/a Thame Laboratories		Dipyridamole	Dipyridamole	40 mg/ ml	Oral suspension	Oral use
Ireland	Syri Pharma Limited t/a Thame Laboratories		Oxybutynin hydrochloride	Oxybutynin	2,5 mg/ 5 ml	Oral solution	Oral use
Ireland	Syri Pharma Limited t/a Thame Laboratories		Oxybutynin hydrochloride	Oxybutynin	5 mg/ 5 ml	Oral solution	Oral use
Ireland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 150 mg, harde capsules	Nilotinib	150 mg	Capsule, hard	Oral use
Ireland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 200 mg, harde capsules	Nilotinib	200 mg	Capsule, hard	Oral use
Ireland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 50 mg, harde capsules	Nilotinib	50 mg	Capsule, hard	Oral use
Italy	Almus S.R.L.		Metformina Almus	Metformin	500 mg	Film-coated tablet	Oral use
Italy	Aurobindo Pharma (Italia) S.r.L.		Amiloride E Idroclorotiazide Aurobindo	Amiloride/ hydrochlorothiazide	5 mg/ 50 mg	Tablet	Oral use
Italy	Aurobindo Pharma (Italia) S.r.L.		Bosentan Aurobindo	Bosentan	125 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Italy	Aurobindo Pharma (Italia) S.r.L.		Bosentan Aurobindo	Bosentan	62,5 mg	Film-coated tablet	Oral use
Italy	Aurobindo Pharma (Italia) S.r.L.		Olanzapina Aurobindo Pharma Italia	Olanzapine	10 mg	Orodispersible tablet	Oral use
Italy	Aurobindo Pharma (Italia) S.r.L.		Olanzapina Aurobindo	Olanzapine	5 mg	Tablet	Oral use
Italy	Aurobindo Pharma (Italia) S.r.L.		Olanzapina Aurobindo	Olanzapine	10 mg	Tablet	Oral use
Italy	Aurobindo Pharma (Italia) S.r.L.		Olanzapina Aurobindo Pharma Italia	Olanzapine	15 mg	Orodispersible tablet	Oral use
Italy	Aurobindo Pharma (Italia) S.r.L.		Olanzapina Aurobindo	Olanzapine	2,5 mg	Tablet	Oral use
Italy	Aurobindo Pharma (Italia) S.r.L.		Olanzapina Aurobindo Pharma Italia	Olanzapine	20 mg	Orodispersible tablet	Oral use
Italy	Aurobindo Pharma (Italia) S.r.L.		Olanzapina Aurobindo Pharma Italia	Olanzapine	5 mg	Orodispersible tablet	Oral use
Italy	Aurobindo Pharma (Italia) S.r.L.		Olanzapina Aurobindo	Olanzapine	7,5 mg	Tablet	Oral use
Italy	Baxter Holding B.V.		Rapiva	Propofol	10 mg/ml	Emulsion for injection/ infusion	Intravenous use
Italy	Baxter Holding B.V.		Rapiva	Propofol	20 mg/ml	Emulsion for injection/ infusion	Intravenous use
Italy	DOC Generici S.r.l.		Sitagliptin e metformina DOC Generici	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Italy	Dr. Reddy's S.r.l.		Abacavir e Lamivudina Dr. Reddy's	Abacavir/ lamivudine	600 mg/300 mg	Film-coated tablet	Oral use
Italy	EG SpA		Lacosamide EG	Lacosamide	100 mg	Film-coated tablet	Oral use
Italy	EG SpA		Lacosamide EG	Lacosamide	150 mg	Film-coated tablet	Oral use
Italy	EG SpA		Lacosamide EG	Lacosamide	200 mg	Film-coated tablet	Oral use
Italy	EG SpA		Lacosamide EG	Lacosamide	50 mg	Film-coated tablet	Oral use
Italy	EG SpA		Lapatinib EG	Lapatinib	250 mg	Film-coated tablet	Oral use
Italy	EG SpA		Posaconazolo EG	Posaconazole	40 mg/ml	Oral suspension	Oral use
Italy	EG SpA		Tadalafil EG	Tadalafil	10 mg	Film-coated tablet	Oral use
Italy	EG SpA		Tadalafil EG	Tadalafil	20 mg	Film-coated tablet	Oral use
Italy	EG SpA		Tadalafil EG	Tadalafil	5 mg	Film-coated tablet	Oral use
Italy	Eugia Pharma (Malta) Limited		Anastrozolo Aurobindo Italia	Anastrozole	1 mg	Film-coated tablet	Oral use
Italy	Mylan SpA		Amlodipinea/Valsartan/ Idroclorotiazide Mylan Pharma	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Italy	Mylan SpA		Amlodipinea/Valsartan/ Idroclorotiazide Mylan Pharma	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Italy	Mylan SpA		Amlodipinea/Valsartan/ Idroclorotiazide Mylan Pharma	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 320 mg/ 25 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Italy	Mylan SpA		Amlodipinea/Valsartan/ Idroclorotiazide Mylan Pharma	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Italy	Mylan SpA		Amlodipinea/Valsartan/ Idroclorotiazide Mylan Pharma	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Italy	Mylan SpA		Erlotinib Mylan	Erlotinib	100 mg	Film-coated tablet	Oral use
Italy	Mylan SpA		Erlotinib Mylan	Erlotinib	150 mg	Film-coated tablet	Oral use
Italy	Mylan SpA		Posaconazolol Mylan	Posaconazole	40 mg/ ml	Oral suspension	Oral use
Italy	Mylan SpA		Vildagliptin Mylan	Vildagliptin	50 mg	Tablet	Oral use
Italy	Pharmaselect International Beteiligungs GmbH		Colchicina Pharmaselect	Colchicine	0,5 mg	Tablet	Oral use
Italy	Pharmaselect International Beteiligungs GmbH		Colcamexx	Colchicine	1 mg	Tablet	Oral use
Italy	Sandoz GmbH		Sitagliptin e Metformina Sandoz GmbH	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Italy	Sandoz SpA		Atazanavi Sandoz	Atazanavir	200 mg	Capsule, hard	Oral use
Italy	Sandoz SpA		Atazanavir Sandoz	Atazanavir	300 mg	Capsule, hard	Oral use
Italy	Sandoz SpA		Darunavir Sandoz	Darunavir	600 mg	Film-coated tablet	Oral use
Italy	Sandoz SpA		Darunavir Sandoz	Darunavir	75 mg	Film-coated tablet	Oral use
Italy	Sandoz SpA		Darunavir Sandoz	Darunavir	800 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Italy	Sandoz SpA		Erlotinib Sandoz	Erlotinib	100 mg	Film-coated tablet	Oral use
Italy	Sandoz SpA		Erlotinib Sandoz	Erlotinib	150 mg	Film-coated tablet	Oral use
Italy		Aurobindo Pharma (Italia) S.r.l.	Dapagliflozina e Metformina Aurobindo	Dapagliflozin/ metformin	5 mg / 850 mg	Film-coated tablet	Oral use
Italy		Aurobindo Pharma (Italia) S.r.l.	Dapagliflozina e Metformina Aurobindo	Dapagliflozin/ metformin	5 mg/ 1 000 mg	Film-coated tablet	Oral use
Italy		Aurobindo Pharma (Italia) S.r.l.	Furosemide Aurobindo Italia	Furosemide	500 mg	Tablet	Oral use
Italy		Aurobindo Pharma (Italia) S.r.l.	Teriflunomide Aurobindo	Teriflunomide	14 mg	Film-coated tablet	Oral use
Italy		Aurobindo Pharma (Italia) S.r.l.	Trazodone Aurobindo	Trazodone	100 mg	Film-coated tablet	Oral use
Italy		Aurobindo Pharma (Italia) S.r.l.	Trazodone Aurobindo	Trazodone	150 mg	Film-coated tablet	Oral use
Italy		DOC Generici S.r.l.	Rovalo	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Italy		DOC Generici S.r.l.	Rovalo	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Italy		DOC Generici S.r.l.	Rovalo	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Italy		Elpen Pharmaceutical Co. Inc.	Ranolpen	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Italy		Elpen Pharmaceutical Co. Inc.	Ranolpen	Ranolazine	500 mg	Prolonged-release tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Italy		Elpen Pharmaceutical Co. Inc.	Ranolpen	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Italy		Kappler Pharma Consult GmbH	Betaistina Kapplerpharma	Betahistine	16 mg	Tablet	Oral use
Italy		Kappler Pharma Consult GmbH	Betaistina Kapplerpharma	Betahistine	24 mg	Tablet	Oral use
Italy		Kappler Pharma Consult GmbH	Betaistina Kapplerpharma	Betahistine	8 mg	Tablet	Oral use
Italy		LaNova farmaceutici S.r.l.	Dalafil	Tadalafil	10 mg	Film-coated tablet	Oral use
Italy		LaNova farmaceutici S.r.l.	Dalafil	Tadalafil	20 mg	Film-coated tablet	Oral use
Italy		LaNova farmaceutici S.r.l.	Dalafil	Tadalafil	5 mg	Film-coated tablet	Oral use
Italy		Sandoz SpA	Ranolazina Sandoz	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Italy		Sandoz SpA	Ranolazina Sandoz	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Italy		Sandoz SpA	Ranolazina Sandoz	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Latvia	Accord Healthcare B.V.		Abacavir/Lamivudine Accord 600 mg/300 mg film-coated tablets	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Latvia	AOP Orphan Pharmaceuticals GmbH		Tadalafil AOP 20 mg film-coated tablets	Tadalafil	20 mg	Film-coated tablet	Oral use
Latvia	Baxter B.V.		Anesia 10 mg/ml emulsion for injection/infusion	Propofol	10 mg/ml	Emulsion for injection/ infusion	Intravenous use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Latvia	Baxter B.V.		Anesia 20 mg/ml emulsion for injection/infusion	Propofol	20 mg/ ml	Emulsion for injection/ infusion	Intravenous use
Latvia	Elvim, SIA, Latvia		Vildagliptin/Metformin ELVIM 50 mg/850 mg film-coated tablets	Vildagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Latvia	Elvim, SIA, Latvia		Vildagliptin/Metformin ELVIM 50 mg/1 000 mg film-coated tablets	Vildagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Latvia	LV System Service, Latvia		Suphrex 12.5 mg hard capsules	Sunitinib	12,5 mg	Capsule, hard	Oral use
Latvia	LV System Service, Latvia		Suphrex 50 mg hard capsules	Sunitinib	50 mg	Capsule, hard	Oral use
Latvia	Mylan Pharmaceuticals Limited		Erlotinib Mylan 100 mg film-coated tablets	Erlotinib	100 mg	Film-coated tablet	Oral use
Latvia	Mylan Pharmaceuticals Limited		Erlotinib Mylan 150 mg film-coated tablets	Erlotinib	150 mg	Film-coated tablet	Oral use
Latvia	Sandoz d.d.		Atazanavir Sandoz 200 mg hard capsules	Atazanavir	200 mg	Capsule, hard	Oral use
Latvia	Sandoz d.d.		Atazanavir Sandoz 300 mg hard capsules	Atazanavir	300 mg	Capsule, hard	Oral use
Latvia	Sandoz d.d.		Erlotinib Sandoz 100 mg film-coated tablets	Erlotinib	100 mg	Film-coated tablet	Oral use
Latvia	Sandoz d.d.		Erlotinib Sandoz 150 mg film-coated tablets	Erlotinib	150 mg	Film-coated tablet	Oral use
Latvia	Sandoz d.d.		Sitagliptin/Metformin hydrochloride Sandoz 50 mg/850 mg film-coated tablets	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Latvia	Sandoz d.d.		Sorafenib Sandoz 400 mg film-coated tablets	Sorafenib	400 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Latvia	Umedica Netherlands B.V.		Deferasirox Umedica 180 mg film-coated tablets	Deferasirox	180 mg	Film-coated tablet	Oral use
Latvia	Umedica Netherlands B.V.		Deferasirox Umedica 360 mg film-coated tablets	Deferasirox	360 mg	Film-coated tablet	Oral use
Latvia	Umedica Netherlands B.V.		Deferasirox Umedica 90 mg film-coated tablets	Deferasirox	90 mg	Film-coated tablet	Oral use
Latvia	Umedica Netherlands B.V.		Pirfenidone Umedica 267 mg film-coated tablets	Pirfenidone	267 mg	Film-coated tablet	Oral use
Latvia	Umedica Netherlands B.V.		Pirfenidone Umedica 801 mg film-coated tablets	Pirfenidone	801 mg	Film-coated tablet	Oral use
Latvia	Umedica Netherlands B.V.		Ranolazine Umedica 375 mg prolonged-release tablets	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Latvia	Umedica Netherlands B.V.		Ranolazine Umedica 500 mg prolonged-release tablets	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Latvia	Umedica Netherlands B.V.		Ranolazine Umedica 750 mg prolonged-release tablets	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Latvia	Unifarma, SIA, Latvia		Atorvastatin Unifarma 10 mg film-coated tablets	Atorvastatin	10 mg	Film-coated tablet	Oral use
Latvia	Unifarma, SIA, Latvia		Atorvastatin Unifarma 20 mg film-coated tablets	Atorvastatin	20 mg	Film-coated tablet	Oral use
Latvia	Unifarma, SIA, Latvia		Atorvastatin Unifarma 40 mg film-coated tablets	Atorvastatin	40 mg	Film-coated tablet	Oral use
Latvia	Unifarma, SIA, Latvia		Atorvastatin Unifarma 80 mg film-coated tablets	Atorvastatin	80 mg	Film-coated tablet	Oral use
Latvia		Elpen Pharmaceutical Co. Inc.	Raupresil 375 mg prolonged-release tablets	Ranolazine	375 mg	Prolonged-release tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Latvia		Elpen Pharmaceutical Co. Inc.	Raupresil 500 mg prolonged-release tablets	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Latvia		Elpen Pharmaceutical Co. Inc.	Raupresil 750 mg prolonged-release tablets	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Latvia		Hexal Aktiengesellschaft	Ranzolva 375 mg prolonged-release tablets	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Latvia		Hexal Aktiengesellschaft	Ranzolva 500 mg prolonged-release tablets	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Latvia		Hexal Aktiengesellschaft	Ranzolva 750 mg prolonged-release tablets	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Latvia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 150 mg hard capsules	Nilotinib	150 mg	Capsule, hard	Oral use
Latvia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Zentiva 150 mg hard capsules	Nilotinib	150 mg	Capsule, hard	Oral use
Latvia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 200 mg hard capsules	Nilotinib	200 mg	Capsule, hard	Oral use
Latvia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris 200 mg hard capsules	Nilotinib	200 mg	Capsule, hard	Oral use
Latvia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Zentiva 200 mg hard capsules	Nilotinib	200 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Latvia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 50 mg hard capsules	Nilotinib	50 mg	Capsule, hard	Oral use
Lithuania	Accord Healthcare B.V.		Abacavir/Lamivudine Accord 600 mg/300 mg plėvele dengtos tabletės	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Lithuania	AOP Orphan Pharmaceuticals GmbH		Tadalafil AOP 20 mg plėvele dengtos tabletės	Tadalafil	20 mg	Film-coated tablet	Oral use
Lithuania	Baxter B.V.		Anesia 10 mg/ml injekcinė ar infuzinė emulsija	Propofol	10 mg/ml	Emulsion for injection/ infusion	Intravenous use
Lithuania	Baxter B.V.		Anesia 20 mg/ml injekcinė ar infuzinė emulsija	Propofol	20 mg/ml	Emulsion for injection/ infusion	Intravenous use
Lithuania	Elvim, SIA, Latvia		Vildagliptin/Metformin hydrochloride ELVIM 50 mg/850 mg plėvele dengtos tabletės	Vildagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Lithuania	Elvim, SIA, Latvia		Vildagliptin/Metformin hydrochloride ELVIM 50 mg/1 000 mg plėvele dengtos tabletės	Vildagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Lithuania	Mylan Pharmaceuticals Limited		Erlotinib Mylan 100 mg plėvele dengtos tabletės	Erlotinib	100 mg	Film-coated tablet	Oral use
Lithuania	Mylan Pharmaceuticals Limited		Erlotinib Mylan 100 mg plėvele dengtos tabletės	Erlotinib	100 mg	Film-coated tablet	Oral use
Lithuania	Mylan Pharmaceuticals Limited		Erlotinib Mylan 150 mg plėvele dengtos tabletės	Erlotinib	150 mg	Film-coated tablet	Oral use
Lithuania	Mylan Pharmaceuticals Limited		Erlotinib Mylan 150 mg plėvele dengtos tabletės	Erlotinib	150 mg	Film-coated tablet	Oral use
Lithuania	Sandoz d.d.		Sitagliptin/Metformin hydrochloride Sandoz 50 mg/850 mg plėvele dengtos tabletės	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Lithuania	Sandoz d.d.		Sorafenib Sandoz 400 mg plėvele dengtos tabletės	Sorafenib	400 mg	Film-coated tablet	Oral use
Lithuania		Elpen Pharmaceutical Co. Inc.	Raupresil 375 mg pailginto atpalaidavimo tabletės	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Lithuania		Elpen Pharmaceutical Co. Inc.	Raupresil 500 mg pailginto atpalaidavimo tabletės	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Lithuania		Elpen Pharmaceutical Co. Inc.	Raupresil 750 mg pailginto atpalaidavimo tabletės	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Lithuania		Genepharm S.A.	X-Etium 5mg film-coated tablet	Linagliptin	5 mg	Film-coated tablet	Oral use
Lithuania		Hexal AG	Ranzolva 375 mg pailginto atpalaidavimo tabletės	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Lithuania		Hexal AG	Ranzolva 500 mg pailginto atpalaidavimo tabletės	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Lithuania		Hexal AG	Ranzolva 750 mg pailginto atpalaidavimo tabletės	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Lithuania		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 150 mg kietosios kapsulės	Nilotinib	150 mg	Capsule, hard	Oral use
Lithuania		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Zentiva 150 mg kietosios kapsulės	Nilotinib	150 mg	Capsule, hard	Oral use
Lithuania		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 200 mg kietosios kapsulės	Nilotinib	200 mg	Capsule, hard	Oral use
Lithuania		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris 200 mg kietosios kapsulės	Nilotinib	200 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Lithuania		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Zentiva 200 mg kietosios kapsulės	Nilotinib	200 mg	Capsule, hard	Oral use
Lithuania		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 50 mg kietosios kapsulės	Nilotinib	50 mg	Capsule, hard	Oral use
Luxembourg	C4 health GmbH		Metformin C4 health 1 000 mg Filmtabletten	Metformin	1 000 mg	Film-coated tablet	Oral use
Luxembourg	C4 health GmbH		Metformin C4 health 500 mg Filmtabletten	Metformin	500 mg	Film-coated tablet	Oral use
Luxembourg	C4 health GmbH		Metformin C4 health 850 mg Filmtabletten	Metformin	850 mg	Film-coated tablet	Oral use
Luxembourg	Denk Pharma GmbH & Co. KG		Tadalafil Denk 10 mg Filmtabletten	Tadalafil	10 mg	Film-coated tablet	Oral use
Luxembourg	Denk Pharma GmbH & Co. KG		Tadalafil Denk 2,5 mg Filmtabletten	Tadalafil	2,5 mg	Film-coated tablet	Oral use
Luxembourg	Denk Pharma GmbH & Co. KG		Tadalafil Denk 20 mg Filmtabletten	Tadalafil	20 mg	Film-coated tablet	Oral use
Luxembourg	Denk Pharma GmbH & Co. KG		Tadalafil Denk 5 mg Filmtabletten	Tadalafil	5 mg	Film-coated tablet	Oral use
Luxembourg	EG (Eurogenerics) NV		Efatriten 600 mg/200 mg/245 mg EG comprimés pélliculés	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
Luxembourg	EG (Eurogenerics) NV		Erlotinib EG	Erlotinib	100 mg	Film-coated tablet	Oral use
Luxembourg	EG (Eurogenerics) NV		Erlotinib EG	Erlotinib	150 mg	Film-coated tablet	Oral use
Luxembourg	EG (Eurogenerics) NV		Erlotinib EG	Erlotinib	25 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Luxembourg	EG (Eurogenerics) NV		Erlotinib EG	Erlotinib	50 mg	Film-coated tablet	Oral use
Luxembourg	EG (Eurogenerics) NV		Lacosamid EG 100 mg comprimés pélliculés	Lacosamide	100 mg	Film-coated tablet	Oral use
Luxembourg	EG (Eurogenerics) NV		Lacosamid EG 150 mg Comprimé pelliculé	Lacosamide	150 mg	Film-coated tablet	Oral use
Luxembourg	EG (Eurogenerics) NV		Lacosamid EG 200 mg Comprimé pelliculé	Lacosamide	200 mg	Film-coated tablet	Oral use
Luxembourg	EG (Eurogenerics) NV		Lacosamid EG 50 mg comprimés pelliculés	Lacosamide	50 mg	Film-coated tablet	Oral use
Luxembourg	EG (Eurogenerics) NV		Sorafenib EG 400 mg, comprimés pelliculés	Sorafenib	400 mg	Film-coated tablet	Oral use
Luxembourg	EG (Eurogenerics) NV		Tadalafil EG	Tadalafil	10 mg	Film-coated tablet	Oral use
Luxembourg	EG (Eurogenerics) NV		Tadalafil EG	Tadalafil	20 mg	Film-coated tablet	Oral use
Luxembourg	EG (Eurogenerics) NV		Tadalafil EG	Tadalafil	5 mg	Film-coated tablet	Oral use
Luxembourg		Elpen Pharmaceutical Co. Inc.	Ranolazin beta 375 mg Retardtabletten	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Luxembourg		Elpen Pharmaceutical Co. Inc.	Ranolazin Heumann 375 mg Retardtabletten	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Luxembourg		Elpen Pharmaceutical Co. Inc.	Ranolazin beta 500 mg Retardtabletten	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Luxembourg		Elpen Pharmaceutical Co. Inc.	Ranolazin Heumann 500 mg Retardtabletten	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Luxembourg		Elpen Pharmaceutical Co. Inc.	Ranolazin beta 750 mg Retardtabletten	Ranolazine	750 mg	Prolonged-release tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Luxembourg		Elpen Pharmaceutical Co. Inc.	Ranolazin Heumann 750 mg Retardtabletten	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Luxembourg		Hexal Aktiengesellschaft	RanolaHexal 375 mg Retardtabletten	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Luxembourg		Hexal Aktiengesellschaft	Ranzolva 375 mg Retardtabletten	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Luxembourg		Hexal Aktiengesellschaft	RanolaHexal 500 mg Retardtabletten	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Luxembourg		Hexal Aktiengesellschaft	Ranzolva 500 mg Retardtabletten	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Luxembourg		Hexal Aktiengesellschaft	RanolaHexal 750 mg Retardtabletten	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Luxembourg		Hexal Aktiengesellschaft	Ranzolva 750 mg Retardtabletten	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Luxembourg		Hexal AG	Ranolazin - 1 A Pharma 375 mg Retardtabletten	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Luxembourg		Hexal AG	Ranolazin - 1 A Pharma 500 mg Retardtabletten	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Luxembourg		Hexal AG	Ranolazin - 1 A Pharma 750 mg Retardtabletten	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Luxembourg		Kappler Pharma Consult GmbH	Betahistin Kappler 16 mg Tabletten	Betahistine	16 mg	Tablet	Oral use
Luxembourg		Kappler Pharma Consult GmbH	Betahistin Kappler 24 mg Tabletten	Betahistine	24 mg	Tablet	Oral use
Luxembourg		Kappler Pharma Consult GmbH	Betahistin Kappler 8 mg Tabletten	Betahistine	8 mg	Tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Luxembourg		Phagecon - Servicos e Consultoria Farmaceutica, Lda.	Trazodon Phagecon 150 mg Tabletten mit veränderter Wirkstofffreisetzung	Trazodone	150 mg	Modified-release tablet	Oral use
Luxembourg		Phagecon - Servicos e Consultoria Farmaceutica, Lda.	Trazodon Phagecon 75 mg Tabletten mit veränderter Wirkstofffreisetzung	Trazodone	75 mg	Modified-release tablet	Oral use
Luxembourg		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 150 mg, gélules	Nilotinib	150 mg	Capsule, hard	Oral use
Luxembourg		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 200 mg, gélules	Nilotinib	200 mg	Capsule, hard	Oral use
Luxembourg		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 50 mg, gélules	Nilotinib	50 mg	Capsule, hard	Oral use
Luxembourg		Viatris Limited	Nilotinib Viatris 150 mg, gélule	Nilotinib	150 mg	Capsule, hard	Oral use
Luxembourg		Viatris Limited	Nilotinib PharOS 200 mg tvrde kapsule	Nilotinib	200 mg	Capsule, hard	Oral use
Luxembourg		Viatris Limited	Nilotinib Viatris 200 mg, gélule	Nilotinib	200 mg	Capsule, hard	Oral use
Luxembourg		Viatris Limited	Nilotinib Viatris 50 mg, gélule	Nilotinib	50 mg	Capsule, hard	Oral use
Malta	Aurobindo Pharma (Malta) Limited		Bosentan Aurobindo 125mg film-coated tablets	Bosentan	125 mg	Film-coated tablet	Oral use
Malta	Aurobindo Pharma (Malta) Limited		Bosentan Aurobindo 62.5mg film-coated tablets	Bosentan	62,5 mg	Film-coated tablet	Oral use
Malta	Aurobindo Pharma (Malta) Limited		Olanzapina Aurobindo 10 mg orodispersible tablets	Olanzapine	10 mg	Orodispersible tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Malta	Aurobindo Pharma (Malta) Limited		Olanzapine Aurobindo 5 mg tablets	Olanzapine	5 mg	Tablet	Oral use
Malta	Aurobindo Pharma (Malta) Limited		Olanzapine Aurobindo 10 mg tablets	Olanzapine	10 mg	Tablet	Oral use
Malta	Aurobindo Pharma (Malta) Limited		Olanzapina Aurobindo 15 mg orodispersible tablets	Olanzapine	15 mg	Orodispersible tablet	Oral use
Malta	Aurobindo Pharma (Malta) Limited		Olanzapine Aurobindo 15 mg tablets	Olanzapine	15 mg	Tablet	Oral use
Malta	Aurobindo Pharma (Malta) Limited		Olanzapine Aurobindo 2.5 mg tablets	Olanzapine	2,5 mg	Tablet	Oral use
Malta	Aurobindo Pharma (Malta) Limited		Olanzapina Aurobindo 20 mg orodispersible tablets	Olanzapine	20 mg	Orodispersible tablet	Oral use
Malta	Aurobindo Pharma (Malta) Limited		Olanzapine Aurobindo 20 mg tablets	Olanzapine	20 mg	Tablet	Oral use
Malta	Aurobindo Pharma (Malta) Limited		Olanzapina Aurobindo 5 mg orodispersible tablets	Olanzapine	5 mg	Orodispersible tablet	Oral use
Malta	Aurobindo Pharma (Malta) Limited		Olanzapine Aurobindo 7.5 mg tablets	Olanzapine	7,5 mg	Tablet	Oral use
Malta	Aurobindo Pharma Limited		Olanzapine Oro PharmConsul 10 mg Orodispersible tablets	Olanzapine	10 mg	Orodispersible tablet	Oral use
Malta	Aurobindo Pharma Limited		Olanzapine Oro PharmConsul 15 mg Orodispersible tablets	Olanzapine	15 mg	Orodispersible tablet	Oral use
Malta	Aurobindo Pharma Limited		Olanzapine Oro PharmConsul 20 mg Orodispersible tablets	Olanzapine	20 mg	Orodispersible tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Malta	Aurobindo Pharma Limited		Olanzapine Oro PharmConsul 5 mg Orodispersible tablets	Olanzapine	5 mg	Orodispersible tablet	Oral use
Malta	Brillpharma (Ireland) Limited		Amlodipine 2.5mg Tablets	Amlodipine	2,5 mg	Tablet	Oral use
Malta	Denk Pharma GmbH & Co. KG		Vildagliptin Denk 50 mg tablets	Vildagliptin	50 mg	Tablet	Oral use
Malta	Heaton k.s.		Sipactimet 50 mg/850 mg film-coated tablets	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Malta	Morningside Healthcare (Malta) Ltd		Mebeverine Hydrochloride 135mg Film-coated Tablets	Mebeverine	135 mg	Film-coated tablet	Oral use
Malta	Morningside Healthcare (Malta) Ltd		Mebeverine Hydrochloride IBS 135mg Film-coated Tablets	Mebeverine	135 mg	Film-coated tablet	Oral use
Malta	Pharmconsul s.r.o.		Olanzapine PharmConsul 10 mg tablets	Olanzapine	10mg	Orodispersible tablet	Oral use
Malta	Pharmconsul s.r.o.		Olanzapine PharmConsul 5 mg tablets	Olanzapine	5mg	Orodispersible tablet	Oral use
Malta	Pharos Pharmaceutical Oriented Services Ltd.		Lapatinib PharOS 250 mg film-coated tablets	Lapatinib	250 mg	Film-coated tablet	Oral use
Malta	Pharos Pharmaceutical Oriented Services Ltd.		Sitagliptin / Metformin PharOS 50 mg/850 mg film-coated tablet	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Malta	RIA Generics Limited		Colchicine 0.5mg Tablets	Colchicine	0,5 mg	Tablet	Oral use
Malta		Aurobindo Pharma (Malta) Limited	Dapaglifozin/Metformin Hydrochloride Aurobindo 5 mg/850 mg film-coated tablets	Dapagliflozin/ metformin	5 mg / 850 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Malta		Aurobindo Pharma (Malta) Limited	Dapaglifozin/Metformin Hydrochloride Aurobindo 5 mg/850 mg film-coated tablets	Dapagliflozin/ metformin	5 mg / 850 mg	Film-coated tablet	Oral use
Malta		Aurobindo Pharma (Malta) Limited	Dapaglifozin/Metformin Hydrochloride Aurobindo Pharma 5 mg/850 mg film-coated tablets	Dapagliflozin/ metformin	5 mg / 850 mg	Film-coated tablet	Oral use
Malta		Aurobindo Pharma (Malta) Limited	Dapaglifozin/Metformin Hydrochloride Aurobindo Pharma 5 mg/850 mg film-coated tablets	Dapagliflozin/ metformin	5 mg / 850 mg	Film-coated tablet	Oral use
Malta		Morningside Healthcare (Malta) Ltd.	Mercaptopurine 10 mg Tablets	Mercaptopurine	10 mg	Tablet	Oral use
Malta		Morningside Healthcare (Malta) Ltd.	Mercaptopurine 50 mg Tablets	Mercaptopurine	50 mg	Tablet	Oral use
Malta		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 150 mg hard capsules	Nilotinib	150 mg	Capsule, hard	Oral use
Malta		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib/Viatris Capsules hard, 150 mg/cap	Nilotinib	150 mg	Capsule, hard	Oral use
Malta		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 200 mg hard capsules	Nilotinib	200 mg	Capsule, hard	Oral use
Malta		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib/Viatris Capsules hard, 200 mg/cap	Nilotinib	200 mg	Capsule, hard	Oral use
Malta		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 50 mg hard capsules	Nilotinib	50 mg	Capsule, hard	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Malta		Remedica Ltd.	ViaremBlu	Sildenafil	100 mg	Film-coated tablet	Oral use
Malta		Remedica Ltd.	ViaremBlu	Sildenafil	25 mg	Film-coated tablet	Oral use
Malta		Remedica Ltd.	ViaremBlu	Sildenafil	50 mg	Film-coated tablet	Oral use
Malta		Torrent Pharma (Malta) Ltd	Pazopanib 200 mg	Pazopanib	200 mg	Film-coated tablet	Oral use
Norway	Accord Healthcare B.V.		Abacavir/Lamivudine Accord 600 mg/300 mg	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Norway	Baxter B.V.		Profast	Propofol	10 mg/ml	Emulsion for injection/ infusion	Intravenous use
Norway	Baxter B.V.		Profast	Propofol	20 mg/ ml	Emulsion for injection/ infusion	Intravenous use
Norway	Brown & Burk IR Limited		Lymecyclin Brown & Burk	Lymecycline	300 mg	Capsule, hard	Oral use
Norway	Morningside Healthcare (Malta) Ltd		Dinetrel	Amantadine	100 mg	Capsule, hard	Oral use
Norway	Mylan AB		Amlodipine/Valsartan/Hydrochlorothiazide Mylan	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Norway	Mylan AB		Amlodipine/Valsartan/Hydrochlorothiazide Mylan	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Norway	Mylan AB		Amlodipine/Valsartan/Hydrochlorothiazide Mylan	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 320 mg/ 25 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Norway	Mylan AB		Amlodipine/Valsartan/Hydrochlorothiazide Mylan	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Norway	Mylan AB		Amlodipine/Valsartan/Hydrochlorothiazide Mylan	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Norway	Mylan AB		Vildagliptin Mylan	Vildagliptin	50 mg	Tablet	Oral use
Norway	Mylan AB		Amlodipine/ Valsartan/ Hydrochlorothia zide Mylan Pharma	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 160 mg / 12,5 mg	Film-coated tablet	Oral use
Norway	Mylan AB		Amlodipine/ Valsartan/ Hydrochlorothia zide Mylan Pharma	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 160 mg / 25 mg	Film-coated tablet	Oral use
Norway	Mylan AB		Amlodipine/ Valsartan/ Hydrochlorothia zide Mylan Pharma	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg / 320 mg / 25 mg	Film-coated tablet	Oral use
Norway	Mylan AB		Amlodipine/ Valsartan/ Hydrochlorothia zide Mylan Pharma	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg / 160 mg / 12,5 mg	Film-coated tablet	Oral use
Norway	Mylan AB		Amlodipine/ Valsartan/ Hydrochlorothia zide Mylan Pharma	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg / 160 mg / 25 mg	Film-coated tablet	Oral use
Norway	Newbury Pharmaceuticals AB		Lapatinib Newbury	Lapatinib	250 mg	Film-coated tablet	Oral use
Norway	Sandoz A/S		Padviram	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Norway		2care4 Generics ApS	Bendatol	Albendazole	400 mg	Tablet	Oral use
Norway		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	150 mg	Capsule	Oral use
Norway		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris	Nilotinib	150 mg	Capsule	Oral use
Norway		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	200 mg	Capsule	Oral use
Norway		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris	Nilotinib	200 mg	Capsule, hard	Oral use
Norway		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	50 mg	Capsule	Oral use
Norway		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris	Nilotinib	50 mg	Capsule	Oral use
Poland	+pharma arzneimittel gmbh		Sitagliptin + Metformin hydrochloride +pharma	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Poland	Accord Healthcare Polska Sp. z o.o.		Abacavir + Lamivudine Accord	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Poland	Aflofarm Farmacja Polska Sp. z o.o.		Tadalafil Inventum	Tadalafil	10 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Poland	Aflofarm Farmacja Polska Sp. z o.o.		Profitadal	Tadalafil	2,5 mg	Film-coated tablet	Oral use
Poland	Aflofarm Farmacja Polska Sp. z o.o.		Profitadal	Tadalafil	20 mg	Film-coated tablet	Oral use
Poland	Aflofarm Farmacja Polska Sp. z o.o.		Profitadal	Tadalafil	5 mg	Film-coated tablet	Oral use
Poland	Aurovitas Pharma Polska Sp. z o.o.		Leflunomide Aurovitas	Leflunomide	10 mg	Film-coated tablet	Oral use
Poland	Aurovitas Pharma Polska Sp. z o.o.		Leflunomide Aurovitas	Leflunomide	15 mg	Film-coated tablet	Oral use
Poland	Aurovitas Pharma Polska Sp. z o.o.		Olanzapine PharmConsul	Olanzapine	10 mg	Tablet	Oral use
Poland	Aurovitas Pharma Polska Sp. z o.o.		Olanzapine PharmConsul	Olanzapine	5 mg	Tablet	Oral use
Poland	Baxter B.V.		Propofol Baxter	Propofol	10 mg/ml	Emulsion for injection/ infusion	Intravenous use
Poland	Baxter B.V.		Propofol Baxter	Propofol	20 mg/ml	Emulsion for injection/ infusion	Intravenous use
Poland	Belupo lijekovi i kozmetika, d.d.		Tadalafil Belupo	Tadalafil	20 mg	Film-coated tablet	Oral use
Poland	Belupo lijekovi i kozmetika, d.d.		Tadalafil Belupo	Tadalafil	5 mg	Film-coated tablet	Oral use
Poland	Dr. Max Pharma s.r.o.		Loperamid Dr. Max	Loperamide	2 mg	Capsule, hard	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Poland	Eugia Pharma (Malta) Limited		Anastrozole Eugia	Anastrozole	1 mg	Film-coated tablet	Oral use
Poland	G.L. Pharma GmbH		Gerocilan	Tadalafil	10 mg	Film-coated tablet	Oral use
Poland	G.L. Pharma GmbH		Gerocilan	Tadalafil	2,5 mg	Film-coated tablet	Oral use
Poland	G.L. Pharma GmbH		Gerocilan	Tadalafil	20 mg	Film-coated tablet	Oral use
Poland	G.L. Pharma GmbH		Gerocilan	Tadalafil	5 mg	Film-coated tablet	Oral use
Poland	Glenmark Pharmaceuticals s.r.o.		Posaconazole Glenmark	Posaconazole	40 mg/ ml	Oral suspension	Oral use
Poland	Mylan Ireland Limited		Posaconazole Mylan	Posaconazole	40 mg/ ml	Oral suspension	Oral use
Poland	Neuraxpharm Arzneimittel GmbH		Azoneurax	Trazodone	150 mg	Modified-release tablet	Oral use
Poland	Neuraxpharm Arzneimittel GmbH		Azoneurax	Trazodone	75 mg	Modified-release tablet	Oral use
Poland	Pharmaselect International Beteiligungs GmbH		Colchianova	Colchicine	0,5 mg	Tablet	Oral use
Poland	Przedsiębiorstwo Produkcji Farmaceutycznej HASCO-LEK S.A.		Epilantin	Lacosamide	100 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Poland	Przedsiębiorstwo Produkcji Farmaceutycznej HASCO-LEK S.A.		Epilantin	Lacosamide	150 mg	Film-coated tablet	Oral use
Poland	Przedsiębiorstwo Produkcji Farmaceutycznej HASCO-LEK S.A.		Epilantin	Lacosamide	200 mg	Film-coated tablet	Oral use
Poland	Przedsiębiorstwo Produkcji Farmaceutycznej HASCO-LEK S.A.		Epilantin	Lacosamide	50 mg	Film-coated tablet	Oral use
Poland	Sandoz GmbH		Darunavir Sandoz	Darunavir	600 mg	Film-coated tablet	Oral use
Poland	Sandoz GmbH		Darunavir Sandoz	Darunavir	800 mg	Film-coated tablet	Oral use
Poland	Sandoz GmbH		Sitagliptin + Metformin hydrochloride Sandoz	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Poland	Sandoz GmbH		Sorafenib Sandoz	Sorafenib	400 mg	Film-coated tablet	Oral use
Poland	Stada Arzneimittel AG		Brastib	Lapatinib	250 mg	Film-coated tablet	Oral use
Poland	Stada Arzneimittel AG		Posaconazol Stada	Posaconazole	40 mg/ml	Oral suspension	Oral use
Poland	Stada Arzneimittel AG		Sorafenib Stada	Sorafenib	400 mg	Film-coated tablet	Oral use
Poland	Teva B.V.		Posaconazole Teva	Posaconazole	40 mg/ ml	Oral suspension	Oral use
Poland	Vipharm S.A.		Anvildis	Vildagliptin	50 mg	Tablet	Oral use
Poland	Vipharm S.A.		Anvildis Duo	Vildagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Poland	Vipharm S.A.		Anvildis Duo	Vildagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Poland		Aurovitas Pharma Polska Sp. z o.o.	Xiglodia	Dapagliflozin/ metformin	5 mg / 850 mg	Film-coated tablet	Oral use
Poland		Aurovitas Pharma Polska Sp. z o.o.	Xiglodia	Dapagliflozin/ metformin	5 mg/ 1 000 mg	Film-coated tablet	Oral use
Poland		Generis Farmacêutica, S.A.	Teriflunomide Aurovitas	Teriflunomide	14 mg	Film-coated tablet	Oral use
Poland		Generis Farmacêutica, S.A.	Trazodone Aurovitas	Trazodone	100 mg	Film-coated tablet	Oral use
Poland		Generis Farmacêutica, S.A.	Trazodone Aurovitas	Trazodone	150 mg	Film-coated tablet	Oral use
Poland		Medreg s.r.o.	Betahistine Medreg	Betahistine	24 mg	Tablet	Oral use
Poland		Nutra Essential OTC, S.L.	Ibuprofen Winadol	Ibuprofen	400 mg	Capsule, soft	Oral use
Poland		PharmConsul s.r.o.	Olanzapine Oro PharmConsul	Olanzapine	10 mg	Orodispersible tablet	Oral use
Poland		PharmConsul s.r.o.	Olanzapine Oro PharmConsul	Olanzapine	15 mg	Orodispersible tablet	Oral use
Poland		PharmConsul s.r.o.	Olanzapine Oro PharmConsul	Olanzapine	20 mg	Orodispersible tablet	Oral use
Poland		PharmConsul s.r.o.	Olanzapine Oro PharmConsul	Olanzapine	5 mg	Orodispersible tablet	Oral use
Poland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS	Nilotinib	150 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Poland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris	Nilotinib	150 mg	Capsule, hard	Oral use
Poland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Zentiva	Nilotinib	150 mg	Capsule, hard	Oral use
Poland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS	Nilotinib	200 mg	Capsule, hard	Oral use
Poland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris	Nilotinib	200 mg	Capsule, hard	Oral use
Poland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Zentiva	Nilotinib	200 mg	Capsule, hard	Oral use
Poland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS	Nilotinib	50 mg	Capsule, hard	Oral use
Poland		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Viatris	Nilotinib	50 mg	Capsule, hard	Oral use
Poland		US Pharmacia Sp. z o.o.	Recenum	Racecadotril	100 mg	Capsule, hard	Oral use
Portugal	Alter Pharma NV		Oxinep	Phenoxymethylpenicillin	1 000 mg	Film-coated tablet	Oral use
Portugal	Alter Pharma NV		Oxinep	Phenoxymethylpenicillin	660 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Portugal	Alter Pharma NV		Oxinep	Phenoxymethyl-penicillin	800 mg	Film-coated tablet	Oral use
Portugal	Amdipharm Ltd		Ciprofibrato Amdipharm	Ciprofibrate	100 mg	Capsule	Oral use
Portugal	Baxter B.V.		Propofol Baxter	Propofol	10 mg/ml	Emulsion for injection/ infusion	Intravenous use
Portugal	Baxter B.V.		Propofol Baxter	Propofol	20 mg/ml	Emulsion for injection/ infusion	Intravenous use
Portugal	Ciclum Farma Unipessoal, Lda.		Tadalafil Ciclum	Tadalafil	10 mg	Film-coated tablet	Oral use
Portugal	Ciclum Farma Unipessoal, Lda.		Tadalafil Ciclum	Tadalafil	20 mg	Film-coated tablet	Oral use
Portugal	Ciclum Farma Unipessoal, Lda.		Tadalafil Ciclum	Tadalafil	5 mg	Film-coated tablet	Oral use
Portugal	Clydesdale Pharma Portugal, Unipessoal Lda.		Tadalafil Kosei	Tadalafil	10 mg	Film-coated tablet	Oral use
Portugal	Clydesdale Pharma Portugal, Unipessoal Lda.		Tadalafil Kosei	Tadalafil	2,5 mg	Film-coated tablet	Oral use
Portugal	Clydesdale Pharma Portugal, Unipessoal Lda.		Tadalafil Kosei	Tadalafil	20 mg	Film-coated tablet	Oral use
Portugal	Clydesdale Pharma Portugal, Unipessoal Lda.		Tadalafil Kosei	Tadalafil	5 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Portugal	Genepharm S.A.		Genement	Tadalafil	10 mg	Film-coated tablet	Oral use
Portugal	Genepharm S.A.		Genement	Tadalafil	2,5 mg	Film-coated tablet	Oral use
Portugal	Genepharm S.A.		Genement	Tadalafil	20 mg	Film-coated tablet	Oral use
Portugal	Genepharm S.A.		Genement	Tadalafil	5 mg	Film-coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Amilorida + Hidroclorotiazida Generis	Amiloride/ hydrochlorothiazide	2,5 mg/ 25 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Amilorida + Hidroclorotiazida Generis	Amiloride/ hydrochlorothiazide	5 mg/ 50 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Anastrozol Generis Phar	Anastrozole	1 mg	Film-coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Atazanavir Generis	Atazanavir	150 mg	Capsule, hard	Oral use
Portugal	Generis Farmacêutica, S.A.		Atazanavir Generis	Atazanavir	200 mg	Capsule, hard	Oral use
Portugal	Generis Farmacêutica, S.A.		Atazanavir Generis	Atazanavir	300 mg	Capsule, hard	Oral use
Portugal	Generis Farmacêutica, S.A.		Bosentano Aurobindo	Bosentan	125 mg	Film-coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Bosentano Aurobindo	Bosentan	62,5 mg	Film-coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Metformina + Dapagliflozina Generis	Dapagliflozin/ metformin	5 mg / 850 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Portugal	Generis Farmacêutica, S.A.		Metformina + Dapagliflozina Generis	Dapagliflozin/ metformin	5 mg/ 1 000 mg	Film-coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Leflunomida Generis	Leflunomide	10 mg	Film-coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Leflunomida Generis	Leflunomide	15 mg	Film-coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Nevirapina Generis	Nevirapine	400 mg	Prolonged-release tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurobindo xx mg	Olanzapine	10 mg	Orodispersible tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurobindo 5 mg comprimidos	Olanzapine	5 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurovitas xx mg comprimidos	Olanzapine	5 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Generis	Olanzapine	5 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurobindo 10 mg comprimidos	Olanzapine	10 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurovitas xx mg comprimidos	Olanzapine	10 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurovitas xx mg orodispersables	Olanzapine	10 mg	Orodispersible tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Generis	Olanzapine	10 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurobindo 15 mg comprimidos	Olanzapine	15 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurobindo xx mg	Olanzapine	15 mg	Orodispersible tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurovitas xx mg comprimidos	Olanzapine	15 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurovitas xx mg orodispersables	Olanzapine	15 mg	Orodispersible tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Generis	Olanzapine	15 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurobindo 2.5 mg comprimidos	Olanzapine	2,5 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurovitas xx mg comprimidos	Olanzapine	2,5 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Generis	Olanzapine	2,5 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurobindo 20 mg comprimidos	Olanzapine	20 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurobindo xx mg	Olanzapine	20 mg	Orodispersible tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurovitas xx mg comprimidos	Olanzapine	20 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurovitas xx mg orodispersables	Olanzapine	20 mg	Orodispersible tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Portugal	Generis Farmacêutica, S.A.		Olanzapina Generis	Olanzapine	20 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurobindo xx mg	Olanzapine	5 mg	Orodispersible tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurovitas xx mg orodispersables	Olanzapine	5 mg	Orodispersible tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurobindo 7.5 mg comprimidos	Olanzapine	7,5 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Aurovitas xx mg comprimidos	Olanzapine	7,5 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Olanzapina Generis	Olanzapine	7,5 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Racecadotril Generis	Racecadotril	100 mg	Capsule	Oral use
Portugal	Laboratórios Atral, S.A.		Limeciclina Atral	Lymecycline	408 mg	Capsule	Oral use
Portugal	Laboratorios Anova - Produtos Farmacêuticos Lda		Tutecvi	Vildagliptin	50 mg	Tablet	Oral use
Portugal	LifeWell Pharmaceutical & Healthcare, Lda.		Vipam	Vildagliptin	50 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Portugal	LifeWell Pharmaceutical & Healthcare, Lda.		Vipmin	Vildagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Portugal	LifeWell Pharmaceutical & Healthcare, Lda.		Vipmin	Vildagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Portugal	Mylan Lda		Amlodipina + Valsartan + Hidroclorotiazida Mylan	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Portugal	Mylan Lda		Amlodipina + Valsartan + Hidroclorotiazida Mylan	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Portugal	Mylan Lda		Amlodipina + Valsartan + Hidroclorotiazida Mylan	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 320 mg/ 25 mg	Film-coated tablet	Oral use
Portugal	Mylan Lda		Amlodipina + Valsartan + Hidroclorotiazida Mylan	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Portugal	Mylan Lda		Amlodipina + Valsartan + Hidroclorotiazida Mylan	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Portugal	Mylan Lda		Vildagliptin Mylan	Vildagliptin	50 mg	Tablet	Oral use
Portugal	Mylan Pharmaceuticals Limited		Erlotinib Mylan	Erlotinib	25 mg	Film-coated tablet	Oral use
Portugal	Mylan Pharmaceuticals Limited		Erlotinib Mylan	Erlotinib	50 mg	Film-coated tablet	Oral use
Portugal	Mylan, Lda.		Posaconazol Mylan	Posaconazole	40 mg/ ml	Oral suspension	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Portugal	Mylan, Lda.		Erlotinib Mylan	Erlotinib	100 mg	Film-coated tablet	Oral use
Portugal	Mylan, Lda.		Erlotinib Mylan	Erlotinib	150 mg	Film-coated tablet	Oral use
Portugal	Pharmaselect International Beteiligungs GmbH		Colcamexx	Colchicine	0,5 mg	Tablet	Oral use
Portugal	Pharmaselect International Beteiligungs GmbH		Colchicine Ria 1 mg tabletten	Colchicine	1 mg	Tablet	Oral use
Portugal	Sandoz Farmacêutica, Lda.		Darunavir Sandoz	Darunavir	600 mg	Film-coated tablet	Oral use
Portugal	Sandoz Farmacêutica, Lda.		Darunavir Sandoz 800 mg – Filmtabletten	Darunavir	800 mg	Film-coated tablet	Oral use
Portugal	Sandoz Farmacêutica, Lda.		Erlotinib Sandoz	Erlotinib	100 mg	Film-coated tablet	Oral use
Portugal	Sandoz Farmacêutica, Lda.		Erlotinib Sandoz	Erlotinib	150 mg	Film-coated tablet	Oral use
Portugal	Sandoz Farmacêutica, Lda.		Erlotinib Sandoz	Erlotinib	25 mg	Film-coated tablet	Oral use
Portugal	Sandoz Farmacêutica, Lda.		Metformina + Sitagliptina Sandoz	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Portugal	Sandoz Farmacêutica, Lda.		Sorafenib Sandoz	Sorafenib	400 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Portugal		Baroque Healthcare, Lda	Cefuroxima Baroque	Cefuroxime	250 mg	Tablet	Oral use
Portugal		Baroque Healthcare, Lda	Cefuroxima Baroque	Cefuroxime	500 mg	Tablet	Oral use
Portugal		Elpen Pharmaceutical Co. Inc.	Ranolpen	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Portugal		Elpen Pharmaceutical Co. Inc.	Ranolpen	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Portugal		Elpen Pharmaceutical Co. Inc.	Ranolpen	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Portugal		Generis Farmacêutica, S.A.	Furosemida Generis Phar	Furosemide	500 mg	Tablet	Oral use
Portugal		Generis Farmacêutica, S.A.	Teriflunomida Generis	Teriflunomide	14 mg	Film-coated tablet	Oral use
Portugal		Generis Farmacêutica, S.A.	Trazodona Aurobindo	Trazodone	100 mg	Film-coated tablet	Oral use
Portugal		Generis Farmacêutica, S.A.	Trazodona Generis Phar	Trazodone	100 mg	Film-coated tablet	Oral use
Portugal		Generis Farmacêutica, S.A.	Trazodona Aurobindo	Trazodone	150 mg	Film-coated tablet	Oral use
Portugal		Generis Farmacêutica, S.A.	Trazodona Generis Phar	Trazodone	150 mg	Film-coated tablet	Oral use
Portugal		Generis Phar, Unipessoal Lda	Teriflunomida Generis Phar	Teriflunomide	14 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Portugal		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Mylan	Nilotinib	150 mg	Capsule, hard	Oral use
Portugal		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	150 mg	Capsule, hard	Oral use
Portugal		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	150 mg	Capsule, hard	Oral use
Portugal		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Zentiva	Nilotinib	150 mg	Capsule, hard	Oral use
Portugal		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	200 mg	Capsule, hard	Oral use
Portugal		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	200 mg	Capsule, hard	Oral use
Portugal		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Zentiva	Nilotinib	200 mg	Capsule, hard	Oral use
Portugal		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Mylan	Nilotinib	50 mg	Capsule, hard	Oral use
Portugal		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	50 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Portugal		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Zentiva	Nilotinib	50 mg	Capsule, hard	Oral use
Portugal		Viatris Limited	Nilotinib Mylan	Nilotinib	200 mg	Capsule, hard	Oral use
Romania	Viatris Limited		Posaconazol Mylan 40 mg/ml suspensie orala	Posaconazole	40 mg/ ml	Oral suspension	Oral use
Romania	Baxter B.V.		Profast	Propofol	10 mg/ml	Emulsion for injection/ infusion	Intravenous use
Romania	Baxter B.V.		Profast	Propofol	20 mg/ ml	Emulsion for injection/ infusion	Intravenous use
Romania	Dr. Max Pharma s.r.o.		Loperamid Dr.Max	Loperamide	2 mg	Capsule, hard	Oral use
Romania	Lannacher Heilmittel Ges.m.b.H.		Gerocilan	Tadalafil	10 mg	Film-coated tablet	Oral use
Romania	Lannacher Heilmittel Ges.m.b.H.		Gerocilan	Tadalafil	2,5 mg	Film-coated tablet	Oral use
Romania	Lannacher Heilmittel Ges.m.b.H.		Gerocilan	Tadalafil	20 mg	Film-coated tablet	Oral use
Romania	Lannacher Heilmittel Ges.m.b.H.		Gerocilan	Tadalafil	5 mg	Film-coated tablet	Oral use
Romania	Mylan Pharmaceuticals Limited		Erlotinib Mylan	Erlotinib	100 mg	Film-coated tablet	Oral use
Romania	Mylan Pharmaceuticals Limited		Erlotinib Mylan 100 mg film-coated tablets	Erlotinib	100 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Romania	Mylan Pharmaceuticals Limited		Erlotinib Mylan	Erlotinib	150 mg	Film-coated tablet	Oral use
Romania	Mylan Pharmaceuticals Limited		Erlotinib Mylan 150 mg film-coated tablets	Erlotinib	150 mg	Film-coated tablet	Oral use
Romania	Mylan Pharmaceuticals Limited		Erlotinib Mylan 50 mg comprimat filmate	Erlotinib	50 mg	Film-coated tablet	Oral use
Romania	Pharmaselect International Beteiligungs GmbH		Colchicina Pharmacelect 0,5 mg comprimate	Colchicine	0,5 mg	Tablet	Oral use
Romania	Pharmaselect International Beteiligungs GmbH		Colchicina Pharmacelect 1mg comprimate	Colchicine	1 mg	Tablet	Oral use
Romania	Pharmaselect International Beteiligungs GmbH		Colchicina Pharmacelect 1mg comprimate	Colchicine	1 mg	Tablet	Oral use
Romania	Sandoz S.R.L.		Darunavir Sandoz 400 mg comprimate filmate	Darunavir	400 mg	Film-coated tablet	Oral use
Romania	Sandoz S.R.L.		Darunavir Sandoz 600 mg comprimate filmate	Darunavir	600 mg	Film-coated tablet	Oral use
Romania	Sandoz S.R.L.		Darunavir Sandoz 75 mg comprimate filmate	Darunavir	75 mg	Film-coated tablet	Oral use
Romania	Sandoz S.R.L.		Darunavir Sandoz 800 mg comprimate filmate	Darunavir	800 mg	Film-coated tablet	Oral use
Romania	Sandoz S.R.L.		Padviram 600 mg/ 200 mg /245 mg comprimate filmate	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
Romania	Sandoz S.R.L.		Erlotinib Sandoz 100 mg comprimate filmate	Erlotinib	100 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Romania	Sandoz S.R.L.		Erlotinib Sandoz 150 mg comprimate filmate	Erlotinib	150 mg	Film-coated tablet	Oral use
Romania	Sandoz S.R.L.		Erlotinib Sandoz 25 mg comprimate filmate	Erlotinib	25 mg	Film-coated tablet	Oral use
Romania	Sandoz S.R.L.		Sorafenib Sandoz 400 mg compimate filmate	Sorafenib	400 mg	Film-coated tablet	Oral use
Romania	Sanofi Romania SRL		Racecadotril Sanofi 100 mg capsule	Racecadotril	100 mg	Capsule, hard	Oral use
Romania	Stada M&D Srl		Abacavir/Lamivudina Stada 600 mg/300 mg comprimate filmate	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Romania	Stada M&D Srl		Atazanavir Stada 150 mg	Atazanavir	150 mg	Capsule, hard	Oral use
Romania	Stada M&D Srl		Atazanavir Stada 300 mg	Atazanavir	300 mg	Capsule, hard	Oral use
Romania	Stada M&D Srl		Lapatinib Stada 250 mg comprimate filmate	Lapatinib	250 mg	Film-coated tablet	Oral use
Romania	Stada M&D Srl		Lapatinib Stada 250 mg comprimate filmate	Lapatinib	250 mg	Film-coated tablet	Oral use
Romania	Stada M&D Srl		Sorafenib Stada 400 mg comprimate filmate	Sorafenib	400 mg	Film-coated tablet	Oral use
Romania	Stada M&D Srl		Revestad 20 mg comprimate filmate	Tadalafil	20 mg	Film-coated tablet	Oral use
Romania	Viatris Limited		Posaconazol Viatris 40 mg/ml suspensie oral	Posaconazole	40 mg/ ml	Oral suspension	Oral use
Romania	Zentiva k.s.		Asbima HCT	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Romania	Zentiva k.s.		Asbima HCT	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Romania		Medreg s.r.o.	Betahistine Medreg	Betahistine	24 mg	Tablet	Oral use
Romania		Nutra Essential OTC, S.L.	Ibuprofen Nutra Essential	Ibuprofen	400 mg	Capsule, soft	Oral use
Romania		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib 150 mg capsule	Nilotinib	150 mg	Capsule, hard	Oral use
Romania		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 150 mg capsulă	Nilotinib	150 mg	Capsule, hard	Oral use
Romania		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib 200 mg capsule	Nilotinib	200 mg	Capsule, hard	Oral use
Romania		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 200 mg Hartkapseln	Nilotinib	200 mg	Capsule, hard	Oral use
Romania		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 50 mg Hartkapseln	Nilotinib	50 mg	Capsule, hard	Oral use
Slovakia	AOP Orphan Pharmaceuticals GmbH		Tadalafil AOP 20 mg filmom obalené tablety	Tadalafil	20 mg	Film-coated tablet	Oral use
Slovakia	Ardez Pharma, spol. s r.o.		Tadard	Tadalafil	20 mg	Film-coated tablet	Oral use
Slovakia	Ardez Pharma, spol. s r.o.		Tadard	Tadalafil	5 mg	Film-coated tablet	Oral use
Slovakia	Belupo lijekovi i kozmetika, d.d.		MIDZA 100 mg filmom obalené tablety	Lacosamide	100 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Slovakia	Belupo lijekovi i kozmetika, d.d.		MIDZA 150 mg filmom obalené tablety	Lacosamide	150 mg	Film-coated tablet	Oral use
Slovakia	Belupo lijekovi i kozmetika, d.d.		MIDZA 200 mg filmom obalené tablety	Lacosamide	200 mg	Film-coated tablet	Oral use
Slovakia	Belupo lijekovi i kozmetika, d.d.		MIDZA 50 mg filmom obalené tablety	Lacosamide	50 mg	Film-coated tablet	Oral use
Slovakia	Belupo lijekovi i kozmetika, d.d.		Tadalafil Belupo	Tadalafil	20 mg	Film-coated tablet	Oral use
Slovakia	Dr. Max Pharma s.r.o.		Loperamid Dr.Max	Loperamide	2 mg	Capsule, hard	Oral use
Slovakia	G.L. Pharma GmbH		Gerocilan 10 mg filmom obalené tablety	Tadalafil	10 mg	Film-coated tablet	Oral use
Slovakia	G.L. Pharma GmbH		Gerocilan 2,5 mg filmom obalené tablety	Tadalafil	2,5 mg	Film-coated tablet	Oral use
Slovakia	G.L. Pharma GmbH		Gerocilan 20 mg filmom obalené tablety	Tadalafil	20 mg	Film-coated tablet	Oral use
Slovakia	G.L. Pharma GmbH		Gerocilan 5 mg filmom obalené tablety	Tadalafil	5 mg	Film-coated tablet	Oral use
Slovakia	Heaton k.s.		Sipactimet 50 mg/850 mg filmom obalené tablety	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Slovakia	Mylan Ireland Limited		Erlotinib Mylan	Erlotinib	100 mg	Film-coated tablet	Oral use
Slovakia	Mylan Ireland Limited		Erlotinib Mylan	Erlotinib	150 mg	Film-coated tablet	Oral use
Slovakia	Neuraxpharm Bohemia s.r.o.		Arkvimma	Lacosamide	100 mg	Film-coated tablet	Oral use
Slovakia	Neuraxpharm Bohemia s.r.o.		Arkvimma	Lacosamide	150 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Slovakia	Neuraxpharm Bohemia s.r.o.		Arkvimma	Lacosamide	200 mg	Film-coated tablet	Oral use
Slovakia	Neuraxpharm Bohemia s.r.o.		Arkvimma	Lacosamide	50 mg	Film-coated tablet	Oral use
Slovakia	Neuraxpharm Bohemia s.r.o.		Azoneurax	Trazodone	150 mg	Modified-release tablet	Oral use
Slovakia	Neuraxpharm Bohemia s.r.o.		Azoneurax	Trazodone	75 mg	Modified-release tablet	Oral use
Slovakia	Opella Healthcare Slovakia s.r.o.,		ENDITRIL 100 mg tvrdé kapsuly	Racecadotril	100 mg	Capsule, hard	Oral use
Slovakia	Pharmaselect International Beteiligungs GmbH		Colcamedin 0,5 mg tablety	Colchicine	0,5 mg	Tablet	Oral use
Slovakia	Pharmaselect International Beteiligungs GmbH		Colcamedin 1 mg tablety	Colchicine	1 mg	Tablet	Oral use
Slovakia	Sandoz GmbH		Sitagliptin/Metformin Sandoz 50 mg/850 mg filmom obalené tablety	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Slovakia	Sandoz Pharmaceuticals d.d.		Erlotinib Sandoz 100 mg	Erlotinib	100 mg	Film-coated tablet	Oral use
Slovakia	Sandoz Pharmaceuticals d.d.		Erlotinib Sandoz 150 mg	Erlotinib	150 mg	Film-coated tablet	Oral use
Slovakia	Sandoz Pharmaceuticals d.d.		Sorafenib Sandoz 400 mg	Sorafenib	400 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Slovakia	Stada Arzneimittel AG		Posakonazol Stada	Posaconazole	40 mg/ml	Oral suspension	Oral use
Slovakia	STADA Arznei-mittel AG,		Erlotinib STADA 100 mg	Erlotinib	100 mg	Film-coated tablet	Oral use
Slovakia	STADA Arznei-mittel AG,		Erlotinib STADA 150 mg	Erlotinib	150 mg	Film-coated tablet	Oral use
Slovakia	Viatris Limited		Tutecvi 50 mg	Vildagliptin	50 mg	Tablet	Oral use
Slovakia	Vipharm S.A.		Anvildis	Vildagliptin	50 mg	Tablet	Oral use
Slovakia	Vipharm S.A.		Anvildis Duo 50 mg/850 mg filmom obalené tablety	Vildagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Slovakia	Vipharm S.A.		Anvildis Duo 50 mg/1 000 mg filmom obalené tablety	Vildagliptin/ metformin	50 mg/ 1 000 mg	Film-coated tablet	Oral use
Slovakia	Xantis Pharma Limited		Tadalafil Xantis	Tadalafil	10 mg	Film-coated tablet	Oral use
Slovakia	Xantis Pharma Limited		Tadalafil Xantis	Tadalafil	2,5 mg	Film-coated tablet	Oral use
Slovakia	Xantis Pharma Limited		Tadalafil Xantis	Tadalafil	20 mg	Film-coated tablet	Oral use
Slovakia	Xantis Pharma Limited		Tadalafil Xantis	Tadalafil	5 mg	Film-coated tablet	Oral use
Slovakia		Medreg s.r.o.	Betahistine Medreg	Betahistine	16 mg	Tablet	Oral use
Slovakia		Medreg s.r.o.	Betahistine Medreg	Betahistine	24 mg	Tablet	Oral use
Slovakia		Pharos Phar-maceutical Oriented Ser-vices Ltd.	Nilotinib Egis	Nilotinib	150 mg	Capsule, hard	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Slovakia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib STADA 150 mg tvrdé kapsuly	Nilotinib	150 mg	Capsule, hard	Oral use
Slovakia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Egis	Nilotinib	200 mg	Capsule, hard	Oral use
Slovakia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib STADA 200 mg tvrdé kapsuly	Nilotinib	200 mg	Capsule, hard	Oral use
Slovakia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Egis	Nilotinib	50 mg	Capsule, hard	Oral use
Slovakia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib STADA 50 mg tvrdé kapsuly	Nilotinib	50 mg	Capsule, hard	Oral use
Slovakia		Viatris Limited	Nilotinib Viatris 150 mg	Nilotinib	150 mg	Capsule, hard	Oral use
Slovakia		Viatris Limited	Nilotinib Viatris 200 mg	Nilotinib	200 mg	Capsule, hard	Oral use
Slovakia		Zentiva k.s.	Nilotinib Zentiva	Nilotinib	150 mg	Capsule, hard	Oral use
Slovakia		Zentiva k.s.	Nilotinib Zentiva	Nilotinib	200 mg	Capsule, hard	Oral use
Slovenia	Alkaloid - INT d.o.o.		Awerkano	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Slovenia	Alkaloid - INT d.o.o.		Awerkano	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Slovenia	Alkaloid - INT d.o.o.		Awerkano	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 320 mg/ 25 mg	Film-coated tablet	Oral use
Slovenia	Alkaloid - INT d.o.o.		Awerkano	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Slovenia	Alkaloid - INT d.o.o.		Awerkano	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Slovenia	Alkaloid - INT d.o.o.		Losmorid	Lacosamide	100 mg	Film-coated tablet	Oral use
Slovenia	Alkaloid - INT d.o.o.		Losmorid	Lacosamide	150 mg	Film-coated tablet	Oral use
Slovenia	Alkaloid - INT d.o.o.		Losmorid	Lacosamide	200 mg	Film-coated tablet	Oral use
Slovenia	Alkaloid - INT d.o.o.		Losmorid	Lacosamide	50 mg	Film-coated tablet	Oral use
Slovenia	AOP Orphan Pharmaceuticals GmbH		Tadalafil AOP Orphan	Tadalafil	20 mg	Film-coated tablet	Oral use
Slovenia	Baxter B.V.		Anesia	Propofol	10 mg/ml	Emulsion for injection/ infusion	Intravenous use
Slovenia	Baxter B.V.		Anesia	Propofol	20 mg/ ml	Emulsion for injection/ infusion	Intravenous use
Slovenia	Belupo lijekovi i kozmetika, d.d.		Midza	Lacosamide	100 mg	Film-coated tablet	Oral use
Slovenia	Belupo lijekovi i kozmetika, d.d.		Midza	Lacosamide	150 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Slovenia	Belupo lijekovi i kozmetika, d.d.		Midza	Lacosamide	200 mg	Film-coated tablet	Oral use
Slovenia	Belupo lijekovi i kozmetika, d.d.		Midza	Lacosamide	50 mg	Film-coated tablet	Oral use
Slovenia	Belupo lijekovi i kozmetika, d.d.		Tadalafil Belupo	Tadalafil	20 mg	Film-coated tablet	Oral use
Slovenia	Belupo lijekovi i kozmetika, d.d.		Tadalafil Belupo	Tadalafil	5 mg	Film-coated tablet	Oral use
Slovenia		Hexal AG	Ranzolva	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Slovenia		Hexal AG	Ranzolva	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Slovenia		Hexal AG	Ranzolva	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Slovenia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharmascience	Nilotinib	150 mg	Capsule, hard	Oral use
Slovenia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	150 mg	Capsule, hard	Oral use
Slovenia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharmascience	Nilotinib	200 mg	Capsule, hard	Oral use
Slovenia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	200 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Slovenia		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	50 mg	Capsule, hard	Oral use
Spain	Almus Farmaceutica S.A.U.		Tramadol Almus 50 mg capsulas duras EFG	Tramadol	50 mg	Capsule, hard	Oral use
Spain	Aurobindo Pharma B.V.		Bosentan Aurovitas 125 mg Comprimidos Recubiertos con Pelicula EFG	Bosentan	125 mg	Film-coated tablet	Oral use
Spain	Aurovitas Spain S.A.U.		Amilorida/Hidroclorotiazida Aurovitas 5 mg/50 mg ComprimidosEFG	Amiloride/ hydrochlorothiazide	5 mg/ 50 mg	Tablet	Oral use
Spain	Aurovitas Spain S.A.U.		Bosentan Aurovitas 62,5 mg Comprimidos Recubiertos con Pelicula EFG	Bosentan	62,5 mg	Film-coated tablet	Oral use
Spain	Aurovitas Spain S.A.U.		Leflunomida Aurovitas 10 mg Comprimidos Recubiertos con Pelicula EFG	Leflunomide	10 mg	Film-coated tablet	Oral use
Spain	Aurovitas Spain S.A.U.		Nevirapina Aurovitas 400 mg Comprimidos de Liberacion Prolongada EFG	Nevirapine	400 mg	Prolonged-release tablet	Oral use
Spain	Aurovitas Spain S.A.U.		Olanzapina Aurovitas xx mg comprimidos	Olanzapine	10 mg	Tablet	Oral use
Spain	Aurovitas Spain S.A.U.		Olanzapina Aurovitas xx mg orodispersables	Olanzapine	10 mg	Orodispersible tablet	Oral use
Spain	Aurovitas Spain S.A.U.		Olanzapina Aurovitas xx mg comprimidos	Olanzapine	5 mg	Tablet	Oral use
Spain	Aurovitas Spain S.A.U.		Olanzapina Aurovitas xx mg comprimidos	Olanzapine	7,5 mg	Tablet	Oral use
Spain	Aurovitas Spain S.A.U.		Olanzapina Aurovitas xx mg orodispersables	Olanzapine	15 mg	Orodispersible tablet	Oral use
Spain	Aurovitas Spain S.A.U.		Olanzapina Aurovitas xx mg comprimidos	Olanzapine	2,5 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Spain	Aurovitas Spain S.A.U.		Olanzapina Aurovitas xx mg orodispersables	Olanzapine	5 mg	Orodispersible tablet	Oral use
Spain	Baxter B.V.		Propofol Baxter 10 mg/ml Emulsion Inyectable y para Perfusion EFG	Propofol	10 mg/ml	Emulsion for injection/ infusion	Intravenous use
Spain	Baxter B.V.		Propofol Baxter 20 mg/ml Emulsion Inyectable y para Perfusion EFG	Propofol	20 mg/ ml	Emulsion for injection/ infusion	Intravenous use
Spain	Eugia Pharma (Malta) Limited		Anastrozol Aurovitas 1 mg Comprimidos Recubiertos con Pelicula EFG	Anastrozole	1 mg	Film-coated tablet	Oral use
Spain	Glenmark Arzneimittel GmbH		Posaconazol Glenmark 40 mg/ml Suspension Oral EFG	Posaconazole	40 mg	Oral suspension	Oral use
Spain	GP-Pharm, S.A.		Acore 10 mg comprimidos recubiertos con pelicula EFG	Tadalafil	10 mg	Film-coated tablet	Oral use
Spain	GP-Pharm, S.A.		Acore 20 mg comprimidos recubiertos con pelicula EFG	Tadalafil	20 mg	Film-coated tablet	Oral use
Spain	GP-Pharm, S.A.		Acore 5 mg comprimidos recubiertos con pelicula EFG	Tadalafil	5 mg	Film-coated tablet	Oral use
Spain	LABORATORIO STADA, S.L.		Atazanavir Stada 200 mg Capsulas Duras EFG	Atazanavir	200 mg	Capsule, hard	Oral use
Spain	LABORATORIO STADA, S.L.		Atazanavir Stada 300 mg Capsulas Duras EFG	Atazanavir	300 mg	Capsule, hard	Oral use
Spain	LABORATORIO STADA, S.L.		Darunavir Stada 600 mg Comprimidos Recubiertos con Pelicula EFG	Darunavir	600 mg	Film-coated tablet	Oral use
Spain	LABORATORIO STADA, S.L.		Darunavir Stada 800 mg Comprimidos Recubiertos con Pelicula EFG	Darunavir	800 mg	Film-coated tablet	Oral use
Spain	Laboratorio Stada, S.L.		Lacosamida Stada 100 mg Comprimidos Recubiertos con Pelicula EFG	Lacosamide	100 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Spain	Laboratorio Stada, S.L.		Lacosamida Stada 150 mg Comprimidos Recubiertos con Pelicula EFG	Lacosamide	150 mg	Film-coated tablet	Oral use
Spain	Laboratorio Stada, S.L.		Lacosamida Stada 200 mg Comprimidos Recubiertos con Pelicula EFG	Lacosamide	200 mg	Film-coated tablet	Oral use
Spain	Laboratorio Stada, S.L.		Lacosamida Stada 50 mg Comprimidos Recubiertos con Pelicula EFG	Lacosamide	50 mg	Film-coated tablet	Oral use
Spain	LABORATORIO STADA, S.L.		Lapatinib Stada 250 mg Comprimidos Recubiertos con Pelicula EFG	Lapatinib	250 mg	Film-coated tablet	Oral use
Spain	LABORATORIO STADA, S.L.		Tadalafilo Stada 400 mg Comprimidos Recubiertos con Pelicula EFG	Sorafenib	400 mg	Film-coated tablet	Oral use
Spain	LABORATORIO STADA, S.L.		Tadalafilo Stada 10 mg Comprimidos Recubiertos con Pelicula EFG	Tadalafil	10 mg	Film-coated tablet	Oral use
Spain	LABORATORIO STADA, S.L.		Tadalafilo Stada 20 mg Comprimidos Recubiertos con Pelicula EFG	Tadalafil	20 mg	Film-coated tablet	Oral use
Spain	Laboratorios Cinfa, S.A.		Amlodipino/Valsartan/Hidroclorotiazida Cinfamed 10 mg/160 mg/25 mg Comprimidos Recubiertos con Pelicula EFG	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Spain	Laboratorios Cinfa, S.A.		Amlodipino/Valsartan/Hidroclorotiazida Cinfamed 10 mg/320 mg/25 mg Comprimidos Recubiertos con Pelicula EFG	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 320 mg/ 25 mg	Film-coated tablet	Oral use
Spain	Laboratorios Cinfa, S.A.		Amlodipino/Valsartan/Hidroclorotiazida Cinfamed 5 mg/160 mg/12,5 mg Comprimidos Recubiertos con Pelicula EFG	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Spain	Sandoz Farmaceutica S.A.		Sorafenib Sandoz 400 mg comprimidos recubiertos de pelicula	Sorafenib	400 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Spain	Laboratorios Q Pharma S.L.		Safilo 10 mg comprimidos recubiertos de pelicula EFG	Tadalafil	10 mg	Film-coated tablet	Oral use
Spain	Laboratorios Q Pharma S.L.		Safilo 20 mg comprimidos recubiertos de pelicula EFG	Tadalafil	20 mg	Film-coated tablet	Oral use
Spain	Laboratorios Q Pharma S.L.		Safilo 5 mg comprimidos recubiertos de pelicula EFG	Tadalafil	5 mg	Film-coated tablet	Oral use
Spain	Mabo Farma, S.A.		Fexion 100 mg comprimidos recubiertos con pelicula EFG	Sildenafil	100 mg	Film-coated tablet	Oral use
Spain	Mabo Farma, S.A.		Fexion 50 mg comprimidos recubiertos con pelicula EFG	Sildenafil	50 mg	Film-coated tablet	Oral use
Spain	Mabo Farma, S.A.		Tadalafilo Mabo 10 mg comprimidos recubiertos con pelicula EFG	Tadalafil	10 mg	Film-coated tablet	Oral use
Spain	Mabo Farma, S.A.		Tadalafilo Mabo 20 mg comprimidos recubiertos con pelicula EFG	Tadalafil	20 mg	Film-coated tablet	Oral use
Spain	Mabo Farma, S.A.		Tadalafilo Mabo 5 mg comprimidos recubiertos con pelicula EFG	Tadalafil	5 mg	Film-coated tablet	Oral use
Spain	Milstein C.V.		Pilocarpina Milstein 5 mg comprimidos recubiertos con pelicula EFG	Pilocarpine	5 mg	Film-coated tablet	Oral use
Spain	Mylan Pharmaceuticals, S.L.		Amlodipino/Valsartan/Hidroclorotiazida Mylan 10 mg/160 mg/12,5 mg Comprimidos Recubiertos con Pelicula EFG	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Spain	Mylan Pharmaceuticals, S.L.		Amlodipino/Valsartan/Hidroclorotiazida Mylan 10 mg/160 mg/25 mg Comprimidos Recubiertos con Pelicula EFG	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Spain	Mylan Pharmaceuticals, S.L.		Amlodipino/Valsartan/Hidroclorotiazida Mylan 10 mg/320 mg/25 mg Comprimidos Recubiertos con Pelicula EFG	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 320 mg/ 25 mg	Film-coated tablet	Oral use
Spain	Mylan Pharmaceuticals, S.L.		Amlodipino/Valsartan/Hidroclorotiazida Mylan 5 mg/160 mg/12,5 mg Comprimidos Recubiertos con Pelicula EFG	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
Spain	Mylan Pharmaceuticals, S.L.		Amlodipino/Valsartan/Hidroclorotiazida Mylan 5 mg/160 mg/25 mg Comprimidos Recubiertos con Pelicula EFG	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
Spain	Pharmaselect International Beteiligungs GmbH		Colcamexx 0,5 mg Comprimidos EFG	Colchicine	0,5 mg	Tablet	Oral use
Spain	Reddy Pharma Iberia S.A.		Abacavir/Lamivudina Dr. Reddys 600 mg/300 mg Comprimidos Recubiertos con Pelicula EFG	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Spain	Reddy Pharma Iberia S.A.		Efavirenz/Emtricitabina/Tenofovir Disoproxilo Dr Reddys 600 mg/200 mg/245 mg Comprimidos Recubiertos con Pelicula EFG	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
Spain	Sandoz Farmaceutica, S.A.		Darunavir Sandoz 600 mg Comprimidos Recubiertos con Pelicula EFG	Darunavir	600 mg	Film-coated tablet	Oral use
Spain	Sandoz Farmaceutica, S.A.		Darunavir Sandoz 800 mg Comprimidos Recubiertos con Pelicula EFG	Darunavir	800 mg	Film-coated tablet	Oral use
Spain	Sandoz Farmaceutica, S.A.		Efavirenz/Emtricitabina/Tenofovir Disoproxilo Sandoz 600 mg/200 mg/245 mg Comprimidos Recubiertos con Pelicula EFG	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Spain	Sandoz Farmaceutica, S.A.		Erlotinib Sandoz 100 mg Comprimidos Recubiertos con Pelicula EFG	Erlotinib	100 mg	Film-coated tablet	Oral use
Spain	Sandoz Farmaceutica, S.A.		Erlotinib Sandoz 150 mg Comprimidos Recubiertos con Pelicula EFG	Erlotinib	150 mg	Film-coated tablet	Oral use
Spain	Sandoz Farmaceutica, S.A.		Erlotinib Sandoz 25 mg Comprimidos Recubiertos con Pelicula EFG	Erlotinib	25 mg	Film-coated tablet	Oral use
Spain	Umedica Netherlands B.V.		Deferasirox Umedica 3180 mg Comprimidos Recubiertos con Pelicula EFG	Deferasirox	180 mg	Film-coated tablet	Oral use
Spain	Umedica Netherlands B.V.		Deferasirox Umedica 360 mg Comprimidos Recubiertos con Pelicula EFG	Deferasirox	360 mg	Film-coated tablet	Oral use
Spain	Umedica Netherlands B.V.		Deferasirox Umedica 90 mg Comprimidos Recubiertos con Pelicula EFG	Deferasirox	90 mg	Film-coated tablet	Oral use
Spain	Umedica Netherlands B.V.		Ranolazina Umedica 375 mg comprimidos de liberacion prolongada EFG	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Spain	Umedica Netherlands B.V.		Ranolazina Umedica 500 mg comprimidos de liberacion prolongada EFG	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Spain	Umedica Netherlands B.V.		Ranolazina Umedica 750 mg comprimidos de liberacion prolongada EFG	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Spain	Vegal Farmaceutica S.L.		Carbamazepina Vegal 100 mg Comprimidos EFG	Carbamazepine	100 mg	Tablet	Oral use
Spain	Vegal Farmaceutica S.L.		Carbamazepina Vegal 200 mg Comprimidos EFG	Carbamazepine	200 mg	Tablet	Oral use
Spain	Vegal Farmaceutica S.L.		Carbamazepina Vegal 400 mg Comprimidos EFG	Carbamazepine	400 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Spain	Sandoz Farmaceutica, S.A.		Sitagliptina/Metformina Sandoz Farmaceutica 50 mg/850 mg comprimidos recubiertos de pelicula EFG	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
Spain	Viatris Limited		Vildagliptina Viatris 50 mg comprimidos EFG	Vildagliptin	50 mg	Film-coated tablet	Oral use
Spain		Aurovitas Spain S.A.U.	Dapagliflozina/Metformina Aurovitas 5 mg/850 mg Comprimidos Recubiertos con Pelicula EFG	Dapagliflozin/ metformin	5 mg / 850 mg	Film-coated tablet	Oral use
Spain		Aurovitas Spain S.A.U.	Dapagliflozina/Metformina Aurovitas 5 mg/1 000 mg Comprimidos Recubiertos con Pelicula EFG	Dapagliflozin/ metformin	5 mg/ 1 000 mg	Film-coated tablet	Oral use
Spain		Aurovitas Spain S.A.U.	Trazadona Aurovitas 100 mg comprimidos recubiertos de pelicula EFG	Trazodone	100 mg	Film-coated tablet	Oral use
Spain		Generis Farmacêutica, S.A.	Teriflunomida Aurovitas 14 mg comprimidos recubiertos de pelicula EFG	Teriflunomide	14 mg	Film-coated tablet	Oral use
Spain		KAPPLER PHARMA CONSULT GMBH	Betahistine Kappler 16 mg tablets	Betahistine	16 mg	Tablet	Oral use
Spain		KAPPLER PHARMA CONSULT GMBH	Betahistine Kappler 24 mg tablets	Betahistine	24 mg	Tablet	Oral use
Spain		KAPPLER PHARMA CONSULT GMBH	Betahistine Kappler 8 mg tablets	Betahistine	8 mg	Tablet	Oral use
Spain		Nutra Essential OTC, S.L.	Ibuprofeno Winadol 400 mg Capsulas Blandas	Ibuprofen	400 mg	Capsule, soft	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Spain		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 150 mg capsula dura EFG	Nilotinib	150 mg	Capsule, hard	Oral use
Spain		Pharos Pharmaceutical Oriented Services Ltd.	Prostib 150 mg capsula dura EFG	Nilotinib	150 mg	Capsule, hard	Oral use
Spain		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 200 mg capsula dura EFG	Nilotinib	200 mg	Capsule, hard	Oral use
Spain		Pharos Pharmaceutical Oriented Services Ltd.	Prostib 200 mg capsula dura EFG	Nilotinib	200 mg	Capsule, hard	Oral use
Spain		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos 50 mg capsula dura EFG	Nilotinib	50 mg	Capsule, hard	Oral use
Spain		UMEDICA NETHERLANDS B.V.	Pirfenidona Umedica 267 mg comprimidos recubiertos de pelicula	Pirfenidone	267 mg	Film-coated tablet	Oral use
Spain		UMEDICA NETHERLANDS B.V.	Pirfenidona Umedica 801 mg comprimidos recubiertos de pelicula	Pirfenidone	801 mg	Film-coated tablet	Oral use
Spain		Zentiva k.s.	Zymela	Ranolazine	375 mg	Prolonged-release tablet	Oral use
Spain		Zentiva k.s.	Zymela	Ranolazine	500 mg	Prolonged-release tablet	Oral use
Spain		Zentiva k.s.	Zymela	Ranolazine	750 mg	Prolonged-release tablet	Oral use
Sweden	2care4 Generics ApS		Lymelysal	Lymecycline	300 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Sweden	Accord Healthcare B.V.		Abacavir/Lamivudine Accord	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Sweden	AOP Orphan Pharmaceuticals GmbH		Tadalafil AOP	Tadalafil	20 mg	Film-coated tablet	Oral use
Sweden	Baxter B.V.		Profast	Propofol	10 mg/ml	Emulsion for injection/ infusion	Parenteral use
Sweden	Baxter B.V.		Profast	Propofol	20 mg/ml	Emulsion for injection/ infusion	Parenteral use
Sweden	Brown & Burk IR Limited		Lymecyklin Brown & Burk	Lymecycline	300 mg	Capsule, hard	Oral use
Sweden	Glenmark Arzneimittel GmbH		Erlotinib Glenmark	Erlotinib	100 mg	Film-coated tablet	Oral use
Sweden	Glenmark Arzneimittel GmbH		Erlotinib Glenmark	Erlotinib	150 mg	Film-coated tablet	Oral use
Sweden	Glenmark Arzneimittel GmbH		Erlotinib Glenmark	Erlotinib	25 mg	Film-coated tablet	Oral use
Sweden	Morningside Healthcare (Malta) Ltd		Dinetrel	Amantadine	100 mg	Capsule, hard	Oral use
Sweden	Newbury Pharmaceuticals AB		Lapatinib Newbury	Lapatinib	250 mg	Film-coated tablet	Oral use
Sweden	Orifarm Generics A/S		Fenoximetylpenicillin Orifarm	Phenoxymethylpenicillin	1 g	Film-coated tablet	Oral use
Sweden	Orifarm Generics A/S		Fenoximetylpenicillin Orifarm	Phenoxymethylpenicillin	800 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Sweden	Sandoz A/S		Darunavir Sandoz	Darunavir	600 mg	Film-coated tablet	Oral use
Sweden	Sandoz A/S		Darunavir Sandoz	Darunavir	800 mg	Film-coated tablet	Oral use
Sweden	Sandoz A/S		Padviram	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
Sweden	Sandoz A/S		Erlotinib Sandoz	Erlotinib	100 mg	Film-coated tablet	Oral use
Sweden	Sandoz A/S		Erlotinib Sandoz	Erlotinib	150 mg	Film-coated tablet	Oral use
Sweden	Sandoz A/S		Erlotinib Sandoz	Erlotinib	25 mg	Film-coated tablet	Oral use
Sweden	Stada Arzneimittel AG		Abacavir/Lamivudine Stada	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
Sweden	Stada Arzneimittel AG		Atazanavir Stada	Atazanavir	200 mg	Capsule, hard	Oral use
Sweden	Stada Arzneimittel AG		Atazanavir Stada	Atazanavir	300 mg	Capsule, hard	Oral use
Sweden	Stada Arzneimittel AG		Darunavir Stada	Darunavir	600 mg	Film-coated tablet	Oral use
Sweden	Stada Arzneimittel AG		Darunavir Stada	Darunavir	800 mg	Film-coated tablet	Oral use
Sweden	Stada Arzneimittel AG		Emtenef	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
Sweden	Stada Arzneimittel AG		Erlotinib Stada	Erlotinib	100 mg	Film-coated tablet	Oral use
Sweden	Stada Arzneimittel AG		Erlotinib Stada	Erlotinib	150 mg	Film-coated tablet	Oral use
Sweden	Stada Arzneimittel AG		Erlotinib Stada	Erlotinib	25 mg	Film-coated tablet	Oral use
Sweden	Stada Arzneimittel AG		Lacosamide Stada	Lacosamide	100 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Sweden	Stada Arzneimittel AG		Lacosamide Stada	Lacosamide	150 mg	Film-coated tablet	Oral use
Sweden	Stada Arzneimittel AG		Lacosamide Stada	Lacosamide	200 mg	Film-coated tablet	Oral use
Sweden	Stada Arzneimittel AG		Lacosamide Stada	Lacosamide	50 mg	Film-coated tablet	Oral use
Sweden	Stada Arzneimittel AG		Posaconazole Stada	Posaconazole	40 mg/ml	Oral suspension	Oral use
Sweden	Stada Arzneimittel AG		Tadalafil Stada	Tadalafil	10 mg	Film-coated tablet	Oral use
Sweden	Stada Arzneimittel AG		Ciastad	Tadalafil	20 mg	Film-coated tablet	Oral use
Sweden	Stada Arzneimittel AG		Tadalafil Stada	Tadalafil	20 mg	Film-coated tablet	Oral use
Sweden	Stada Arzneimittel AG		Tadalafil Stada	Tadalafil	5 mg	Film-coated tablet	Oral use
Sweden		2care4 Generics ApS	Bentadol (suggested name)	Albendazole	400 mg	Tablet	Oral use
Sweden		Kappler Pharma Consult GmbH	Betahistin Kappler (suggested name)	Betahistine	16 mg	Tablet	Oral use
Sweden		Kappler Pharma Consult GmbH	Betahistin Kappler (suggested name)	Betahistine	24 mg	Tablet	Oral use
Sweden		Kappler Pharma Consult GmbH	Betahistin Kappler (suggested name)	Betahistine	8 mg	Tablet	Oral use
Sweden		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	150 mg	Capsule, hard	Oral use
Sweden		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS (suggested name)	Nilotinib	150 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
Sweden		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib Pharos	Nilotinib	200 mg	Capsule, hard	Oral use
Sweden		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS (suggested name)	Nilotinib	200 mg	Capsule, hard	Oral use
Sweden		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS (suggested name)	Nilotinib	50 mg	Capsule, hard	Oral use
The Netherlands	Accord Healthcare B.V.		Abacavir/Lamivudine Accord 600 mg/300 mg, filmomhulde tabletten	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
The Netherlands	Amdipharm Limited		Ciprofibraat Amdipharm 100 mg tabletten	Ciprofibrate	100 mg	Tablet	Oral use
The Netherlands	AOP Orphan Pharmaceuticals GmbH		Tadalafil AOP 20 mg filmomhulde tabletten	Tadalafil	20 mg	Film-coated tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Amiloride HCl/Hydrochloorthiazide Auro 2,5 mg/25 mg, tabletten	Amiloride/ hydrochlorothiazide	2,5 mg/ 25 mg	Tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Amiloride HCl/Hydrochloorthiazide Auro 5 mg/50 mg, tabletten	Amiloride/ hydrochlorothiazide	5 mg/ 50 mg	Tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Atazanavir Aurobindo 150 mg, harde capsules	Atazanavir	150 mg	Capsule, hard	Oral use
The Netherlands	Aurobindo Pharma B.V.		Atazanavir Aurobindo 200 mg, harde capsules	Atazanavir	200 mg	Capsule, hard	Oral use
The Netherlands	Aurobindo Pharma B.V.		Atazanavir Aurobindo 300 mg, harde capsules	Atazanavir	300 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	Aurobindo Pharma B.V.		Bosentan Aurobindo 125 mg filmomhulde tabletten	Bosentan	125 mg	Film-coated tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Bosentan Aurobindo 62,5 mg filmomhulde tabletten	Bosentan	62,5 mg	Film-coated tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Leflunomide Aurobindo 10 mg, filmomhulde tabletten	Leflunomide	10 mg	Film-coated tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Nevirapine Aurobindo 400 mg, tabletten met verlengde afgifte	Nevirapine	400 mg	Prolonged-release tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Olanzapine Aurobindo 5 mg Tabletten	Olanzapine	5 mg	Tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Olanzapine Aurobindo 10 mg Tabletten	Olanzapine	10 mg	Tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Olanzapine Aurobindo 15 mg Tabletten	Olanzapine	15 mg	Tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Olanzapine Aurobindo 2.5 mg Tabletten	Olanzapine	2,5 mg	Tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Olanzapine Aurobindo 20 mg Tabletten	Olanzapine	20 mg	Tablet	Oral use
The Netherlands	Baxter B.V.		Propofol Spiva 10 mg/ml, emulsie voor injectie of infusie	Propofol	10 mg/ml	Emulsion for injection/ infusion	Intravenous use
The Netherlands	Baxter B.V.		Propofol Spiva 20 mg/ml, emulsie voor injectie of infusie	Propofol	20 mg/ml	Emulsion for injection/ infusion	Intravenous use
The Netherlands	Brillpharma (Ireland) Limited		Gabapentine Brillpharma 50 mg/ml drank, suikervrij	Gabapentin	50 mg/ml	Oral solution	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	Brillpharma (Ireland) Limited		Solifenacinesuccinaat Brillpharma 1 mg/ml drank	Solifenacin	1 mg/ml	Oral solution	Oral use
The Netherlands	Centrafarm B.V.		Deferasirox CF 900 mg, filmomhulde tabletten	Deferasirox	900 mg	Film-coated tablet	Oral use
The Netherlands	Centrafarm B.V.		Efavirenz/Emtricitabine/Tenofovirdisoproxil CF 600/200/245 mg, filmomhulde tabletten	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
The Netherlands	Centrafarm B.V.		Erlotinib CF 100 mg, filmomhulde tabletten	Erlotinib	100 mg	Film-coated tablet	Oral use
The Netherlands	Centrafarm B.V.		Erlotinib CF 150 mg, filmomhulde tabletten	Erlotinib	150 mg	Film-coated tablet	Oral use
The Netherlands	Centrafarm B.V.		Erlotinib CF 25 mg, filmomhulde tabletten	Erlotinib	25 mg	Film-coated tablet	Oral use
The Netherlands	Centrafarm B.V.		Erlotinib CF 50 mg, filmomhulde tabletten	Erlotinib	50 mg	Film-coated tablet	Oral use
The Netherlands	Denk Pharma GmbH & Co. KG		Tadalafil Denk 10 mg filmomhulde tabletten	Tadalafil	10 mg	Film-coated tablet	Oral use
The Netherlands	Denk Pharma GmbH & Co. KG		Tadalafil Denk 2,5 mg filmomhulde tabletten	Tadalafil	2,5 mg	Film-coated tablet	Oral use
The Netherlands	Denk Pharma GmbH & Co. KG		Tadalafil Denk 20 mg filmomhulde tabletten	Tadalafil	20 mg	Film-coated tablet	Oral use
The Netherlands	Denk Pharma GmbH & Co. KG		Tadalafil Denk 5 mg filmomhulde tabletten	Tadalafil	5 mg	Film-coated tablet	Oral use
The Netherlands	Denk Pharma GmbH & Co. KG		Vildagliptine Denk 50 mg tabletten	Vildagliptin	50 mg	Tablet	Oral use
The Netherlands	DOC Generici S.r.l.		Sitagliptine/Metformine hydrochloride DOC Generici 50mg/850 mg, filmomhulde tabletten	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	G.L. Pharma GmbH		Sorafenib G.L. 400 mg, filmomhulde tabletten	Sorafenib	400 mg	Film-coated tablet	Oral use
The Netherlands	G.L. Pharma GmbH		Gerocilan 10 mg filmomhulde tabletten	Tadalafil	10 mg	Film-coated tablet	Oral use
The Netherlands	G.L. Pharma GmbH		Gerocilan 2,5 mg filmomhulde tabletten	Tadalafil	2,5 mg	Film-coated tablet	Oral use
The Netherlands	G.L. Pharma GmbH		Gerocilan 20 mg filmomhulde tabletten	Tadalafil	20 mg	Film-coated tablet	Oral use
The Netherlands	G.L. Pharma GmbH		Gerocilan 5 mg filmomhulde tabletten	Tadalafil	5 mg	Film-coated tablet	Oral use
The Netherlands	Genericon Pharma GmbH		Sitagliptine/Metformine hydrochloride Genericon 50 mg/850 mg filmomhulde tabletten	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
The Netherlands	Glenmark Arzneimittel GmbH		Posaconazol Glenmark 40 mg/ml suspensie voor oraal gebruik	Posaconazole	40 mg	Oral suspension	Oral use
The Netherlands	Heaton k.s.		Sipactimet 50mg/850 mg, filmomhulde tabletten	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
The Netherlands	Maddox Pharma Swiss B.V.		Sitaglamet 50 mg/850 mg filmomhulde tabletten	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
The Netherlands	Milstein C.V.		Clemastine Milstein 1 mg, tabletten	Clemastine	1 mg	Tablet	Oral use
The Netherlands	Mylan Pharmaceuticals Limited		Amlodipine/Valsartan/Hydrochloorthiazide Mylan 10 mg/160 mg/12,5 mg filmomhulde tabletten	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
The Netherlands	Mylan Pharmaceuticals Limited		Amlodipine/Valsartan/Hydrochloorthiazide Mylan 10 mg/160 mg/25 mg filmomhulde tabletten	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
The Netherlands	Mylan Pharmaceuticals Limited		Amlodipine/Valsartan/Hydrochloorthiazide Mylan 10 mg/320 mg/25 mg filmomhulde tabletten	Amlodipine/ valsartan/ hydrochlorothiazide	10 mg/ 320 mg/ 25 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	Mylan Pharmaceuticals Limited		Amlodipine/Valsartan/Hydrochloorthiazide Mylan 5 mg/160 mg/12,5 mg filmomhulde tabletten	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 12,5 mg	Film-coated tablet	Oral use
The Netherlands	Mylan Pharmaceuticals Limited		Amlodipine/Valsartan/Hydrochloorthiazide Mylan 5 mg/160 mg/25 mg filmomhulde tabletten	Amlodipine/ valsartan/ hydrochlorothiazide	5 mg/ 160 mg/ 25 mg	Film-coated tablet	Oral use
The Netherlands	Mylan Pharmaceuticals Limited		Erlotinib Mylan 100 mg, filmomhulde tabletten	Erlotinib	100 mg	Film-coated tablet	Oral use
The Netherlands	Mylan Pharmaceuticals Limited		Erlotinib Mylan 150 mg, filmomhulde tabletten	Erlotinib	150 mg	Film-coated tablet	Oral use
The Netherlands	Mylan Pharmaceuticals Limited		Erlotinib Mylan 25 mg, filmomhulde tabletten	Erlotinib	25 mg	Film-coated tablet	Oral use
The Netherlands	Mylan Pharmaceuticals Limited		Erlotinib Mylan 50 mg, filmomhulde tabletten	Erlotinib	50 mg	Film-coated tablet	Oral use
The Netherlands	Mylan Pharmaceuticals Limited		Nortriptyline Mylan 10 mg, filmomhulde tabletten	Nortriptyline	10 mg	Film-coated tablet	Oral use
The Netherlands	Mylan Pharmaceuticals Limited		Nortriptyline Mylan 25 mg, filmomhulde tabletten	Nortriptyline	25 mg	Film-coated tablet	Oral use
The Netherlands	Mylan Pharmaceuticals Ltd		Nortriptyline Mylan 50 mg, filmomhulde tabletten	Nortriptyline	50 mg	Film-coated tablet	Oral use
The Netherlands	Pharos Pharmaceutical Oriented Services Ltd.		Lapatinib PharOS 250 mg, filmomhulde tabletten	Lapatinib	250 mg	Film-coated tablet	Oral use
The Netherlands	RIA Generics Limited		Colchicine Ria 0.5 mg tabletten	Colchicine	0,5 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	RIA Generics Limited		Colchicine Ria 1 mg tabletten	Colchicine	1 mg	Tablet	Oral use
The Netherlands	Sandoz B.V.		Atazanavir Sandoz 100 mg, harde capsules	Atazanavir	100 mg	Capsule, hard	Oral use
The Netherlands	Sandoz B.V.		Atazanavir Sandoz 150 mg, harde capsules	Atazanavir	150 mg	Capsule, hard	Oral use
The Netherlands	Sandoz B.V.		Atazanavir Sandoz 150 mg, harde capsules	Atazanavir	150 mg	Capsule, hard	Oral use
The Netherlands	Sandoz B.V.		Atazanavir Sandoz 200 mg, harde capsules	Atazanavir	200 mg	Capsule, hard	Oral use
The Netherlands	Sandoz B.V.		Atazanavir Sandoz 200 mg, harde capsules	Atazanavir	200 mg	Capsule, hard	Oral use
The Netherlands	Sandoz B.V.		Atazanavir Sandoz 300 mg, harde capsules	Atazanavir	300 mg	Capsule, hard	Oral use
The Netherlands	Sandoz B.V.		Atazanavir Sandoz 300 mg, harde capsules	Atazanavir	300 mg	Capsule, hard	Oral use
The Netherlands	Sandoz B.V.		Darunavir Sandoz 150 mg, filmomhulde tabletten	Darunavir	150 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Darunavir Sandoz 300 mg, filmomhulde tabletten	Darunavir	300 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Darunavir Sandoz 400 mg, filmomhulde tabletten	Darunavir	400 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Darunavir Sandoz 600 mg, filmomhulde tabletten	Darunavir	600 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Darunavir Sandoz 600 mg, filmomhulde tabletten	Darunavir	600 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Darunavir Sandoz 600 mg, filmomhulde tabletten	Darunavir	600 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Darunavir Sandoz 75 mg, filmomhulde tabletten	Darunavir	75 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Darunavir Sandoz 75 mg, filmomhulde tabletten	Darunavir	75 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	Sandoz B.V.		Darunavir Sandoz 75 mg, filmomhulde tabletten	Darunavir	75 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Darunavir Sandoz 800 mg, filmomhulde tabletten	Darunavir	800 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Darunavir Sandoz 800 mg, filmomhulde tabletten	Darunavir	800 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Darunavir Sandoz 800 mg, filmomhulde tabletten	Darunavir	800 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Efavirenz/Emtricitabine/Tenofovirdisoproxil Sandoz 600 mg/200 mg/245 mg, filmomhulde tabletten	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Efavirenz/Emtricitabine/Tenofovirdisoproxil Sandoz 600 mg/200 mg/245 mg, filmomhulde tabletten	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Padviram 600 mg/200 mg/245 mg, filmomhulde tabletten	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Padviram 600 mg/200 mg/245 mg, filmomhulde tabletten	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Erlotinib Sandoz 100 mg, filmomhulde tabletten	Erlotinib	100 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Erlotinib Sandoz 150 mg, filmomhulde tabletten	Erlotinib	150 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Erlotinib Sandoz 25 mg, filmomhulde tabletten	Erlotinib	25 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine/Metformine HCl Sandoz 50mg/850 mg, filmomhulde tabletten	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine/Metformine HCl Sandoz 50mg/850 mg, filmomhulde tabletten	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	Sandoz B.V.		Sitagliptine/Metformine HCl Sandoz 50mg/850 mg, filmomhulde tabletten	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine/Metformine HCl Sandoz 50mg/850 mg, filmomhulde tabletten	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sitagliptine/Metformine HCl Sandoz 50mg/850 mg, filmomhulde tabletten	Sitagliptin/ metformin	50 mg/ 850 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Sorafenib Sandoz 400 mg, filmomhulde tabletten	Sorafenib	400 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Darunavir Stada 150 mg, filmomhulde tabletten	Darunavir	150 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Darunavir Stada 300 mg, filmomhulde tabletten	Darunavir	300 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Darunavir Stada 400 mg, filmomhulde tabletten	Darunavir	400 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Darunavir Stada 600 mg, filmomhulde tabletten	Darunavir	600 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Darunavir Stada 75 mg, filmomhulde tabletten	Darunavir	75 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Darunavir Stada 800 mg, filmomhulde tabletten	Darunavir	800 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Deferasirox Stada 900 mg, filmomhulde tabletten	Deferasirox	900 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Efatriten 600 mg/200 mg/245 mg, filmomhulde tabletten	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Lacosamide Stada 100 mg, filmomhulde tabletten	Lacosamide	100 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Lacosamide Stada 150 mg, filmomhulde tabletten	Lacosamide	150 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Lacosamide Stada 200 mg, filmomhulde tabletten	Lacosamide	200 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	Stada Arzneimittel AG		Lacosamide Stada 50 mg, filmomhulde tabletten	Lacosamide	50 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Brastib 250 mg, filmomhulde tabletten	Lapatinib	250 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Lapatinib Stada 250 mg, filmomhulde tabletten	Lapatinib	250 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Lapatinib Stada Arzneimittel AG 250 mg, filmomhulde tabletten	Lapatinib	250 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Sorafenib Stada Arzneimittel 400 mg, filmomhulde tabletten	Sorafenib	400 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Tadalafil Stada 10 mg, filmomhulde tabletten	Tadalafil	10 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Tadalafil Stada 2,5 mg, filmomhulde tabletten	Tadalafil	2,5 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Ciastad 20 mg filmomhulde tabletten	Tadalafil	20 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Tadalafil Stada 20 mg, filmomhulde tabletten	Tadalafil	20 mg	Film-coated tablet	Oral use
The Netherlands	Stada Arzneimittel AG		Tadalafil Stada 5 mg, filmomhulde tabletten	Tadalafil	5 mg	Film-coated tablet	Oral use
The Netherlands	Teva GmbH		Deferasirox Teva 900 mg, filmomhulde tabletten	Deferasirox	900 mg	Film-coated tablet	Oral use
The Netherlands	Umedica Netherlands B.V.		Carbamazepine Umedica 100 mg, tabletten	Carbamazepine	100 mg	Tablet	Oral use
The Netherlands	Umedica Netherlands B.V.		Carbamazepine Umedica 200 mg, tabletten	Carbamazepine	200 mg	Tablet	Oral use
The Netherlands	Umedica Netherlands B.V.		Carbamazepine Umedica 400 mg, tabletten	Carbamazepine	400 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	Umedica Netherlands B.V.		Deferasirox Umedica 180 mg filmomhulde tabletten	Deferasirox	180 mg	Film-coated tablet	Oral use
The Netherlands	Umedica Netherlands B.V.		Deferasirox Umedica 360 mg filmomhulde tabletten	Deferasirox	360 mg	Film-coated tablet	Oral use
The Netherlands	Umedica Netherlands B.V.		Deferasirox Umedica 90 mg filmomhulde tabletten	Deferasirox	90 mg	Film-coated tablet	Oral use
The Netherlands	Umedica Netherlands B.V.		Sildenafil Umedica 100 mg filmomhulde tabletten	Sildenafil	100 mg	Film-coated tablet	Oral use
The Netherlands	Umedica Netherlands B.V.		Sildenafil Umedica 20 mg filmomhulde tabletten	Sildenafil	20 mg	Film-coated tablet	Oral use
The Netherlands	Umedica Netherlands B.V.		Sildenafil Umedica 25 mg filmomhulde tabletten	Sildenafil	25 mg	Film-coated tablet	Oral use
The Netherlands	Umedica Netherlands B.V.		Sildenafil Umedica 50 mg filmomhulde tabletten	Sildenafil	50 mg	Film-coated tablet	Oral use
The Netherlands	Umedica Netherlands B.V.		Tadalafil Umedica 10 mg filmomhulde tabletten	Tadalafil	10 mg	Film-coated tablet	Oral use
The Netherlands	Umedica Netherlands B.V.		Tadalafil Umedica 20 mg filmomhulde tabletten	Tadalafil	20 mg	Film-coated tablet	Oral use
The Netherlands	Umedica Netherlands B.V.		Tadalafil Umedica 5 mg filmomhulde tabletten	Tadalafil	5 mg	Film-coated tablet	Oral use
The Netherlands	Zentiva k.s.		Darunavir Zentiva 400 mg, filmomhulde tabletten	Darunavir	400 mg	Film-coated tablet	Oral use
The Netherlands	Zentiva k.s.		Darunavir Zentiva 600 mg, filmomhulde tabletten	Darunavir	600 mg	Film-coated tablet	Oral use
The Netherlands	Zentiva k.s.		Darunavir Zentiva 800 mg, filmomhulde tabletten	Darunavir	800 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands		Aurobindo Pharma B.V.	Furosemide Aurobindo 500 mg, tabletten	Furosemide	500 mg	Tablet	Oral use
The Netherlands		Aurobindo Pharma B.V.	Trazodon HCl Aurobindo 100 mg, filmomhulde tabletten	Trazodone	100 mg	Film-coated tablet	Oral use
The Netherlands		Devatis GmbH	Eltrombopag Devatis 12,5 mg filmomhulde tabletten	Eltrombopag	12,5 mg	Film-coated tablet	Oral use
The Netherlands		Devatis GmbH	Eltrombopag Devatis 25 mg filmomhulde tabletten	Eltrombopag	25 mg	Film-coated tablet	Oral use
The Netherlands		Devatis GmbH	Eltrombopag Devatis 50 mg filmomhulde tabletten	Eltrombopag	50 mg	Film-coated tablet	Oral use
The Netherlands		Devatis GmbH	Eltrombopag Devatis 75 mg filmomhulde tabletten	Eltrombopag	75 mg	Film-coated tablet	Oral use
The Netherlands		Focus Care Pharmaceuticals B.V.	Amantadine HCl 100 mg Focus Care, harde capsules	Amantadine	100 mg	Capsule, hard	Oral use
The Netherlands		Focus Care Pharmaceuticals B.V.	Methotrexaat 2,5 mg Focus Care, filmomhulde tabletten	Methotrexate	2,5 mg	Film-coated tablet	Oral use
The Netherlands		Genepharm S.A.	Tadalafil/Genepharm 20 mg filmomhulde tablet	Tadalafil	20 mg	Film-coated tablet	Oral use
The Netherlands		Generis Farmacêutica, S.A.	Teriflunomide Aurobindo 14 mg, filmomhulde tabletten	Teriflunomide	14 mg	Film-coated tablet	Oral use
The Netherlands		Innovis Pharma S.A.	Renofrin 375 mg, tablet met verlengde afgifte	Ranolazine	375 mg	Prolonged-release tablet	Oral use
The Netherlands		Innovis Pharma S.A.	Renofrin 500 mg, tablet met verlengde afgifte	Ranolazine	500 mg	Prolonged-release tablet	Oral use
The Netherlands		Innovis Pharma S.A.	Renofrin 750 mg, tablet met verlengde afgifte	Ranolazine	750 mg	Prolonged-release tablet	Oral use
The Netherlands		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 150 mg, harde capsules	Nilotinib	150 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 150 mg, harde capsules	Nilotinib	150 mg	Capsule, hard	Oral use
The Netherlands		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 200 mg, harde capsules	Nilotinib	200 mg	Capsule, hard	Oral use
The Netherlands		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 200 mg, harde capsules	Nilotinib	200 mg	Capsule, hard	Oral use
The Netherlands		Pharos Pharmaceutical Oriented Services Ltd.	Nilotinib PharOS 50 mg, harde capsules	Nilotinib	50 mg	Capsule, hard	Oral use
The Netherlands		Umedica Netherlands B.V.	Oxcarbazepine Umedica 150 mg filmomhulde tabletten	Oxcarbazepine	150 mg	Film-coated tablet	Oral use
The Netherlands		Umedica Netherlands B.V.	Oxcarbazepine Umedica 300 mg filmomhulde tabletten	Oxcarbazepine	300 mg	Film-coated tablet	Oral use
The Netherlands		Umedica Netherlands B.V.	Oxcarbazepine Umedica 600 mg filmomhulde tabletten	Oxcarbazepine	600 mg	Film-coated tablet	Oral use
The Netherlands		Viatris Limited	Nilotinib Viatris 150 mg, harde capsules	Nilotinib	150 mg	Capsule, hard	Oral use
The Netherlands		Viatris Limited	Nilotinib Viatris 200 mg, harde capsules	Nilotinib	200 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Accord Healthcare Limited		Trospium 20 mg film-coated tablets	Trospium	20 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Accord UK Limited		Phenytoin Sodium NRIM 100 mg capsules	Phenytoin sodium	100 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Activase Pharmaceuticals Limited		Carbimazole 20 mg tablets	Carbimazole	20 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Activase Pharmaceuticals Limited		Carbimazole 5 mg tablets	Carbimazole	5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Avianta Pharma Limited		Tadalafil 10 mg film-coated tablets	Tadalafil	10 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Avianta Pharma Limited		Tadalafil 2.5 mg film-coated tablets	Tadalafil	2,5 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Avianta Pharma Limited		Tadalafil 20 mg film-coated tablets	Tadalafil	20 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Avianta Pharma Limited		Tadalafil 5 mg film-coated tablets	Tadalafil	5 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Baxter Healthcare Limited		Propofol 10 mg/ml emulsion for injection/infusion	Propofol	10 mg/ml	Emulsion for injection/ infusion	Intravenous use
United Kingdom (Northern Ireland)	Baxter Healthcare Limited		Propofol 20 mg/ml emulsion for injection/infusion	Propofol	20 mg/ml	Emulsion for injection/ infusion	Intravenous use
United Kingdom (Northern Ireland)	BRILLPHARMA LIMITED		Amlodipine 1mg/ml, oral solution	Amlodipine	1 mg/ ml	Oral solution	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Brillpharma Limited		Gabapentin 50 mg/ml oral solution	Gabapentin	50 mg/ ml	Oral solution	Oral use
United Kingdom (Northern Ireland)	Brillpharma Limited		Oxybutynin Hydrochloride Brillpharma 2,5 mg/ 5 ml oral solution	Oxybutynin	2,5 mg/ 5 ml	Oral solution	Oral use
United Kingdom (Northern Ireland)	Brillpharma Limited		Oxybutynin Hydrochloride Brillpharma 5 mg/ 5 ml oral solution	Oxybutynin	5 mg/ 5 ml	Oral solution	Oral use
United Kingdom (Northern Ireland)	Brillpharma Limited		Prednisolone 2,5 mg gastro-resitant tablets	Prednisolone	2,5 mg	Gastro-resistant tablet	Oral use
United Kingdom (Northern Ireland)	Brillpharma Limited		Prednisolone 5 mg gastro-resitant tablets	Prednisolone	5 mg	Gastro-resistant tablet	Oral use
United Kingdom (Northern Ireland)	Brillpharma Limited		Solifenacin succinate 1 mg/ml oral solution	Solifenacin	1 mg/ ml	Oral solution	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Amlodipine Bristol Lab 2,5 mg tablets	Amlodipine	2,5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Carbocisteine 375 mg capsules, hard	Carbocisteine	375 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Hydrocortisone 10 mg tablets	Hydrocortisone	10 mg	Tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Hydrocortisone 20 mg tablets	Hydrocortisone	20 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Ibuprofen 200 mg soft capsules	Ibuprofen	200 mg	Capsule, soft	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Angitate 10 mg tablets	Isosorbide mononitrate	10 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Isosorbide Mononitrate 10 mg tablets	Isosorbide mononitrate	10 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Angitate 20 mg tablets	Isosorbide mononitrate	20 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Isosorbide Mononitrate 20 mg tablets	Isosorbide mononitrate	20 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Angitate 40 mg tablets	Isosorbide mononitrate	40 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Isosorbide Mononitrate 40 mg tablets	Isosorbide mononitrate	40 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Nitrofurantoin Bristol Laboratories 100 mg capsules, hard	Nitrofurantoin	100 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Nitrofurantoin Bristol Laboratories 50 mg capsules, hard	Nitrofurantoin	50 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Olanzapine 10 mg film-coated tablets	Olanzapine	10 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Olanzapine 15 mg film-coated tablets	Olanzapine	15 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Olanzapine 2,5 mg film-coated tablets	Olanzapine	2,5 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Olanzapine 20 mg film-coated tablets	Olanzapine	20 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Olanzapine 5 mg film-coated tablets	Olanzapine	5 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Olanzapine 7,5 mg film-coated tablets	Olanzapine	7,5 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Prednisolone 2,5 mg gastro-resitant tablets	Prednisolone	2,5 mg	Gastro-resistant tablet	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Prednisolone 5 mg gastro-resitant tablets	Prednisolone	5 mg	Gastro-resistant tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Trazodone Hydrochloride 100 mg capsules, hard	Trazodone	100 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Trazodone Hydrochloride 150 mg capsules, hard	Trazodone	150 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Bristol Laboratories Limited		Trazodone Hydrochloride 50 mg capsules, hard	Trazodone	50 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Brown & Burk UK Limited		Lymecycline 408 mg capsules	Lymecycline	408 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Brown & Burk UK Limited		Nefopam Hydrochloride 30 mg film-coated tablets	Nefopam	30 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Brown & Burk UK Limited		Phenoxymethylpenicillin 250 mg film-coated tablets	Phenoxymethylpenicillin	250 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Clydesdale Pharma Ltd		Tadalafil 10 mg film-coated tablets	Tadalafil	10 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Clydesdale Pharma Ltd		Tadalafil 2.5 mg film-coated tablets	Tadalafil	2,5 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Clydesdale Pharma Ltd		Tadalafil 20 mg film-coated tablets	Tadalafil	20 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Clydesdale Pharma Ltd		Tadalafil 5 mg film-coated tablets	Tadalafil	5 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Clydesdale Pharma LTD		Vildagliptin 50 mg tablets	Vildagliptin	50 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Crescent Pharma Limited		Atorvastatin 10 mg film-coated tablets	Atorvastatin	10 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Crescent Pharma Limited		Atorvastatin 20 mg film-coated tablets	Atorvastatin	20 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Crescent Pharma Limited		Atorvastatin 40 mg film-coated tablets	Atorvastatin	40 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Crescent Pharma Limited		Atorvastatin 80 mg film-coated tablets	Atorvastatin	80 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Crescent Pharma Limited		Carbamazepine Crescent 100 mg tablets	Carbamazepine	100 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Crescent Pharma Limited		Carbamazepine Crescent 200 mg tablets	Carbamazepine	200 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Crescent Pharma Limited		Carbamazepine Crescent 400 mg tablets	Carbamazepine	400 mg	Tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Crescent Pharma Limited		Lacosamide Crescent 100 mg film-coated tablets	Lacosamide	100 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Crescent Pharma Limited		Lacosamide Crescent 150 mg film-coated tablets	Lacosamide	150 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Crescent Pharma Limited		Lacosamide Crescent 200 mg film-coated tablets	Lacosamide	200 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Crescent Pharma Limited		Lacosamide Crescent 50 mg film-coated tablets	Lacosamide	50 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Crescent Pharma Limited		Posaconazole Crescent 40 mg/ml oral suspension	Posaconazole	40 mg/ ml	Oral suspension	Oral use
United Kingdom (Northern Ireland)	Crescent Pharma Limited		Dilacort 2,5 mg gastro-resistant tablets Prednisolone 2,5 mg gastro-resitant tablets	Prednisolone	2,5 mg	Gastro-resistant tablet	Oral use
United Kingdom (Northern Ireland)	Crescent Pharma Limited		Dilacort 5 mg gastro-resistant tablets Prednisolone 5 mg gastro-resitant tablets	Prednisolone	5 mg	Gastro-resistant tablet	Oral use
United Kingdom (Northern Ireland)	Crescent Pharma Limited		Tadalafil Crescent 10 mg film-coated tablets	Tadalafil	10 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Crescent Pharma Limited		Tadalafil Crescent 2.5 mg film-coated tablets	Tadalafil	2,5 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Crescent Pharma Limited		Tadalafil Crescent 20 mg film-coated tablets	Tadalafil	20 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Crescent Pharma Limited		Tadalafil Crescent 5 mg film-coated tablets	Tadalafil	5 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Crescent Pharma Limited		Vildagliptin Crescent 50 mg tablets	Vildagliptin	50 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Cygnus Pharma Limited		Carbimazole 20 mg tablets	Carbimazole	20 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Cygnus Pharma Limited		Carbimazole 5 mg tablets	Carbimazole	5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Dawa Limited		Loperamide 2 mg capsules	Loperamide	2 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Dawa Limited		Metronidazole 200 mg/ 5 ml oral suspencion	Metronidazole	200 mg/ 5 ml	Oral suspension	Oral use
United Kingdom (Northern Ireland)	Dawa Limited		Trazodone Hydrochloride 100 mg capsules, hard	Trazodone	100 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Dawa Limited		Trazodone Hydrochloride 50 mg capsules, hard	Trazodone	50 mg	Capsule, hard	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Dr Reddy's Laboratories (EU) Limited		Abacavir/ LamivudineE Dr. Reddy's 600 mg/300 mg film-coated tablets	Abacavir/ lamivudine	600 mg/ 300 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Dr Reddy's Laboratories (UK) Limited		Atazanavir Dr. Reddy's 200 mg capsules, hard	Atazanavir	200 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Dr Reddy's Laboratories (UK) Limited		Atazanavir Dr. Reddy's 300 mg capsules, hard	Atazanavir	300 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Dr Reddy's Laboratories (UK) Limited		Dapsone 50 mg tablets	Dapsone	50 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Dr Reddy's Laboratories (UK) Limited		Efavirenz/ Emtricitabine/ Tenofovir Disoproxil Dr. Reddy's 600 mg/200 mg/245 mg film-coated tablets	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Dr Reddy's Laboratories (UK) Limited		Posaconazole Dr. Reddy's 40 mg/ml oral suspension	Posaconazole	40 mg/ ml	Oral suspension	Oral use
United Kingdom (Northern Ireland)	Focus Pharmaceuticals Limited		Ciprofibrate 100 mg tablet	Ciprofibrate	100 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Focus Pharmaceuticals Limited		Fluoxetine 60 mg capsules	Fluoxetine	60 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Generics (UK) Limited		Erlotinib 100 mg film-coated tablets	Erlotinib	100 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Generics (UK) Limited		Erlotinib 150 mg film-coated tablets	Erlotinib	150 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	GENERICS (UK) LIMITED		Erlotinib Mylan 150 mg film-coated tablets	Erlotinib	150 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Generics (UK) Limited		Erlotinib 25 mg film-coated tablets	Erlotinib	25 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Generics (UK) Limited		Nortriptyline 10 mg film-coated tablets	Nortriptyline	10 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Generics (UK) Limited		Nortriptyline 25 mg film-coated tablets	Nortriptyline	25 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Generics (UK) Limited		Nortriptyline 50 mg film-coated tablets	Nortriptyline	50 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Glenmark Pharmaceuticals Europe Limited		Erlotinib Glenmark 100 mg film-coated tablets	Erlotinib	100 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Glenmark Pharmaceuticals Europe Limited		Erlotinib Glenmark 150 mg film-coated tablets	Erlotinib	150 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Glenmark Pharmaceuticals Europe Limited		Erlotinib Glenmark 25 mg film-coated tablets	Erlotinib	25 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Kent Pharmaceuticals Limited		OTC Concepts Diarrhoea Relief 2 mg capsules, hard	Loperamide	2 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Key Pharmaceuticals Limited		Alimemazine Tartrate 10mg film-coated tablets	Alimemazine	10 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Key Pharmaceuticals Limited		Ezetimibe 10mg tablets	Ezetimibe	10 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Lyrus Life Sciences Limted		Nitrofurantoin 25 mg/5 ml Oral suspension	Nitrofurantoin	25 mg/ 5 ml	Oral suspension	Oral use
United Kingdom (Northern Ireland)	Lyrus Life Sciences Limted		Nitrofurantoin 50 mg/5 ml Oral suspension	Nitrofurantoin	50 mg/ 5 ml	Oral suspension	Oral use
United Kingdom (Northern Ireland)	Lyrus Life Sciences Limted		Lymecycline 408 mg capsule	Lymecycline	408 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)		Lyrus Life Sciences Limted	Mebeverine Hydrochloride 135mg tablets	Mebeverine	135 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Manx Healthcare Limited		Amantadine Hydrochloride 100mg capsules, hard	Amantadine	100 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Milpharm Limited		Anastrozole 1 mg film-coated tablets	Anastrozole	1 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Milpharm Limited		Bosentan Milpharm 125 mg film-coated tablet	Bosentan	125 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Milpharm Limited		Bosentan Milpharm 62,5 mg film-coated tablet	Bosentan	62,5 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Milpharm Limited		Leflunomide 10 mg film-coated tablets	Leflunomide	10 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Milpharm Limited		Nevirapine Milpharm 400 mg prolonged-release tablets	Nevirapine	400 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)	Milpharm Limited		Olanzapine 10 mg orodispersible tablets	Olanzapine	10 mg	Orodispersible tablet	Oral use
United Kingdom (Northern Ireland)	Milpharm Limited		Olanzapine Milpharm 5 mg tablets	Olanzapine	5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Milpharm Limited		Olanzapine Milpharm 10 mg tablets	Olanzapine	10 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Milpharm Limited		Olanzapine 15 mg orodispersible tablets	Olanzapine	15 mg	Orodispersible tablet	Oral use
United Kingdom (Northern Ireland)	Milpharm Limited		Olanzapine Milpharm 15 mg tablets	Olanzapine	15 mg	Tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Milpharm Limited		Olanzapine Milpharm 2,5 mg tablets	Olanzapine	2,5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Milpharm Limited		Olanzapine 20 mg orodispersible tablets	Olanzapine	20 mg	Orodispersible tablet	Oral use
United Kingdom (Northern Ireland)	Milpharm Limited		Olanzapine Milpharm 20 mg tablets	Olanzapine	20 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Milpharm Limited		Olanzapine 5 mg orodispersible tablets	Olanzapine	5 mg	Orodispersible tablet	Oral use
United Kingdom (Northern Ireland)	Milpharm Limited		Olanzapine Milpharm 7,5 mg tablets	Olanzapine	7,5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Amantadine Hydrochloride 100mg capsules, hard	Amantadine	100 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Carbimazole 10 mg tablets / Reduzol 10 mg tablets	Carbimazole	10 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Carbimazole 20 mg tablets / Reduzol 20 mg tablets	Carbimazole	20 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Carbimazole 5 mg tablets / Reduzol 5 mg tablets	Carbimazole	5 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Clindamycin 150 mg capsules, hard	Clindamycin	150 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Clindamycin 300 mg capsules, hard	Clindamycin	300 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Clindamycin 600 mg capsules, hard	Clindamycin	600 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Dapsone 100 mg tablets	Dapsone	100 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Dapsone 50 mg tablets	Dapsone	50 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Dexamethasone 0,5 mg tablets	Dexamethasone	0,5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Dexamethasone 2 mg tablets	Dexamethasone	2 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Doxepin 10 mg capsules	Doxepin	10 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Doxepin 25 mg capsules	Doxepin	25 mg	Capsule, hard	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Doxepin 50 mg capsules	Doxepin	50 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Hisone 10 mg dispersable tablets / Hydrocortisone 10 mg Dispersible Tablets	Hydrocortisone	10 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Hydrocortisone 10 mg tablets	Hydrocortisone	10 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Hisone 20 mg dispersable tablets / Hydrocortisone 20 mg Dispersible Tablets	Hydrocortisone	20 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Hydrocortisone 20 mg tablets	Hydrocortisone	20 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Hisone 5 mg dispersable tablets / Hydrocortisone 5 mg Dispersible Tablets	Hydrocortisone	5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Levomepromazine Maleate 100 mg tablets	Levomepromazine	100 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Levomepromazine Maleate 25 mg tablets	Levomepromazine	25 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Levomepromazine Maleate 50 mg tablets	Levomepromazine	50 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Levomepromazine Maleate 6 mg tablets	Levomepromazine	6 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Lymecycline 408 mg capsules, hard	Lymecycline	408 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Mebeverine Hydrochloride 135 mg film-coated tablets	Mebeverine	135 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Mebeverine Hydrochloride IBS 135 mg film-coated tablets	Mebeverine	135 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Bolamyn SR 750 mg prolonged-release tablet	Metformin	750 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Metabet SR 750 mg prolonged-release tablet	Metformin	750 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Metformin 750 mg prolonged-release tablet	Metformin	750 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Sukkarto SR 750 mg prolonged-release tablet	Metformin	750 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Metronidazole 200 mg/ 5 ml oral suspencion	Metronidazole	200 mg/ 5 ml	Oral suspension	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Posaconazole 40 mg/ml oral suspension	Posaconazole	40 mg/ ml	Oral suspension	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Marol 100 mg prolonged-release capsules	Tramadol	100 mg	Prolonged-release capsule, hard	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Tramadol Hydrochloride Morningside 100 mg prolonged-release capsules	Tramadol	100 mg	Prolonged-release capsule, hard	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Marol 150 mg prolonged-release capsules	Tramadol	150 mg	Prolonged-release capsule, hard	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Tramadol Hydrochloride Morningside 150 mg prolonged-release capsules	Tramadol	150 mg	Prolonged-release capsule, hard	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Marol 200 mg prolonged-release capsules	Tramadol	200 mg	Prolonged-release capsule, hard	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Tramadol Hydrochloride Morningside 200 mg prolonged-release capsules	Tramadol	200 mg	Prolonged-release capsule, hard	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Marol 50 mg prolonged-release capsules	Tramadol	50 mg	Prolonged-release capsule, hard	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Tramadol Hydrochloride Morningside 50 mg prolonged-release capsules	Tramadol	50 mg	Prolonged-release capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Trifluoperazine 1 mg tablets	Trifluoperazine	1 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Trifluoperazine 2 mg tablets	Trifluoperazine	2 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Trifluoperazine 5 mg tablets	Trifluoperazine	5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Vildagliptin 50 mg tablets	Vildagliptin	50 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Neon Healthcare Limited		Posaconazole 40 mg/ml oral suspension	Posaconazole	40 mg/ ml	Oral suspension	Oral use
United Kingdom (Northern Ireland)	Northumbria Pharma Limited		Tadalafil 10 mg film-coated tablets	Tadalafil	10 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Northumbria Pharma Limited		Tadalafil 20 mg film-coated tablets	Tadalafil	20 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Northumbria Pharma Limited		Tadalafil 5 mg film-coated tablets	Tadalafil	5 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Noumed Life Sciences Limited		Alimemazine Tartrate 10mg film-coated tablets	Alimemazine	10 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Noumed Life Sciences Limited		Colchicine 500 micrograms tablets	Colchicine	0,5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Noumed Life Sciences Limited		Methocarbamol 750 mg film-coated tablet	Methocarbamol	750 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Relonchem Limited		Sildenafil 100 mg film-coated tablets	Sildenafil	100 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Relonchem Limited		Sildenafil 50 mg film-coated tablets	Sildenafil	50 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Ria Generics Limited		Carbimazole 20 mg tablets	Carbimazole	20 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Ria Generics Limited		Carbimazole 5 mg tablets	Carbimazole	5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Ria Generics Limited		Colchicine 500 micrograms tablets	Colchicine	0,5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Sandoz Limited		Atazanavir Sandoz 100 mg capsule, hard	Atazanavir	100 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Sandoz Limited		Atazanavir Sandoz 150 mg capsule, hard	Atazanavir	150 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Sandoz Limited		Atazanavir Sandoz 200 mg capsule, hard	Atazanavir	200 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Sandoz Limited		Atazanavir Sandoz 300 mg capsule, hard	Atazanavir	300 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Sandoz Limited		Darunavir Sandoz 600 mg film-coated tablets	Darunavir	600 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Sandoz Limited		Darunavir Sandoz 75 mg film-coated tablets	Darunavir	75 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Sandoz Limited		Darunavir Sandoz 800 mg film-coated tablets	Darunavir	800 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Sandoz Limited		Efavirenz/ Emtricitabine/ Tenofovir Disoproxil 600 mg/200 mg/245 mg film-coated tablets	Efavirenz/ emtricitabine/ tenofovir	600 mg/ 200 mg/ 245 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Sandoz Limited		Erlotinib Sandoz 100 mg film-coated tablets	Erlotinib	100 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Sandoz Limited		Erlotinib Sandoz 150 mg film-coated tablets	Erlotinib	150 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Sandoz Limited		Erlotinib Sandoz 25 mg film-coated tablets	Erlotinib	25 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Special Concept Development (UK) Limited		Loperamide 2 mg capsule, hard	Loperamide	2 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Special Concept Development (UK) Limited		Loperamide 2 mg capsule, hard	Loperamide	2 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Special Concept Development (UK) Limited		Metformin 1 000 mg film-coated tablet	Metformin	1 000 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Special Concept Development (UK) Limited		Metformin 500 mg film-coated tablet	Metformin	500 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Special Concept Development (UK) Limited		Metformin 850 mg film-coated tablet	Metformin	850 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Special Concept Development (UK) Limited		Tramadol 50 mg capsules	Tramadol	50 mg	Prolonged-release capsule, hard	Oral use
United Kingdom (Northern Ireland)	Strandhaven Limited		Dapsone 100 mg tablets	Dapsone	100 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Strandhaven Limited		Dapsone 50 mg tablets	Dapsone	50 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Strandhaven Limited		Lodiarex 2 mg capsules, hard	Loperamide	2 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Strandhaven Limited		Midorine Hydrochloride 2,5 mg tablets	Midodrine	2,5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Strandhaven Limited		Midorine Hydrochloride 5 mg tablets	Midodrine	5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Strandhaven Limited		Pilocarpine Hydrochloride 5 mg film-coated tablets	Pilocarpine	5 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Strandhaven Limited		Trazodone Hydrochloride 100 mg capsules, hard	Trazodone	100 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Strandhaven Limited		Trazodone Hydrochloride 50 mg capsules, hard	Trazodone	50 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Strides Pharma UK Limited		Carbimazole 20 mg tablets	Carbimazole	20 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Strides Pharma UK Limited		Carbimazole 5 mg tablets	Carbimazole	5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Syri Limited		Dipyridamole 200 mg/ 5ml oral solution	Dipyridamole	200 mg/ 5 ml	Oral suspension	Oral use
United Kingdom (Northern Ireland)	Syri Limited		Oxybutynin Hydrochloride 2,5 mg/5 ml oral solution	Oxybutynin	2,5 mg / 5 ml	Oral solution	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Syri Limited		Oxybutynin Hydrochloride 5 mg/5 ml oral solution	Oxybutynin	5 mg / 5 ml	Oral solution	Oral use
United Kingdom (Northern Ireland)	Teva UK Limited		Primbital 250 mg tablets	Primidone	250 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Teva UK Limited		Primbital 50 mg tablets	Primidone	50 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Thornton & Ross Limited		Deferasirox 900 mg film-coated tablets	Deferasirox	900 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Thornton & Ross Limited		Lacosamide Stada 100 mg film-coated tablets	Lacosamide	100 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Thornton & Ross Limited		Lacosamide Stada 150 mg film-coated tablets	Lacosamide	150 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Thornton & Ross Limited		Lacosamide Stada 200 mg film-coated tablets	Lacosamide	200 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Thornton & Ross Limited		Lacosamide Stada 50 mg film-coated tablets	Lacosamide	50 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Thornton & Ross Limited		Posaconazole Thornton & Ross 40 mg/ml oral suspension	Posaconazole	40 mg/ml	Oral suspension	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Tillomed Laboratories Limited		Carbimazole 20 mg tablets	Carbimazole	20 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Tillomed Laboratories Limited		Carbimazole 5 mg tablets	Carbimazole	5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Umedica Limited		Sildenafil 100 mg film-coated tablets	Sildenafil	100 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Umedica Limited		Sildenafil 20 mg film-coated tablets	Sildenafil	20 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Umedica Limited		Sildenafil 50 mg film-coated tablets	Sildenafil	50 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Umedica Limited		Tadalafil 10 mg film-coated tablets	Tadalafil	10 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Umedica Limited		Tadalafil Crescent 2.5 mg film-coated tablets	Tadalafil	2,5 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Umedica Limited		Tadalafil 20 mg film-coated tablets	Tadalafil	20 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Umedica Limited		Tadalafil 5 mg film-coated tablets	Tadalafil	5 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Waymade PLC		Trazodone Hydrochloride 100 mg capsules, hard	Trazodone	100 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Waymade PLC		Trazodone Hydrochloride 50 mg capsules, hard	Trazodone	50 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Zista Pharma Limited		Acetazolamide 250 mg tablet	Acetazolamide	250 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Zista Pharma Limited		Amantadine Hydrochloride 100mg capsules, hard	Amantadine	100 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Zista Pharma Limited		Baclofen 10 mg tablets	Baclofen	10 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Zista Pharma Limited		Carbocisteine 375 mg capsules, hard	Carbocisteine	375 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Zista Pharma Limited		Trazodone Hydrochloride 100 mg capsules, hard	Trazodone	100 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Zista Pharma Limited		Trazodone Hydrochloride 50 mg capsules, hard	Trazodone	50 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)		Activase Pharmaceuticals Limited	Gabapentin 50 mg/ml oral solution	Gabapentin	50 mg/ ml	Oral solution	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)		Biovantic Pharma Limited	Betahistine Dihydrochloride 16 mg tablets	Betahistine	16 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Biovantic Pharma Limited	Betahistine Dihydrochloride 24 mg tablets	Betahistine	24 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Biovantic Pharma Limited	Betahistine Dihydrochloride 8 mg tablets	Betahistine	8 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		BRILLPHARMA LIMITED	Amlodipine Bristol Lab 2.5mg tablets	Amlodipine	2,5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Brillpharma Limited	Ramipril 0.5 mg/ml oral solution	Ramipril	0,5 mg/ ml	Oral solution	Oral use
United Kingdom (Northern Ireland)		Brillpharma Limited	Ramipril 1 mg/ml oral solution	Ramipril	1 mg/ ml	Oral solution	Oral use
United Kingdom (Northern Ireland)		Bristol Laboratories Limited	Amantadine Hydrochloride 100mg capsules, hard	Amantadine	100 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)		Bristol Laboratories Limited	Carbocisteine 375 mg capsules, hard	Carbocisteine	375 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)		Bristol Laboratories Limited	Hydrocortisone 2,5 mg tablets	Hydrocortisone	2,5 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)		Bristol Laboratories Limited	Hydrocortisone 5 mg tablets	Hydrocortisone	5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Bristol Laboratories Limited	Brilloper 2 mg capsules, hard	Loperamide	2 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)		Bristol Laboratories Limited	Loperamide Hydrochloride 2 mg capsules, hard	Loperamide	2 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)		Bristol Laboratories Limited	Nortriptyline 10 mg tablets	Nortriptyline	10 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Bristol Laboratories Limited	Nortriptyline 25 mg tablets	Nortriptyline	25 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Cygnus Pharma Limited	Loperamide 2 mg capsule, hard	Loperamide	2 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)		Cygnus Pharma Limited	Tramadol Hydrochloride 50 mg capsules, hard	Tramadol	50 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)		Cygnus Pharma Limited	Trazodone Hydrochloride 100 mg capsules, hard	Trazodone	100 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)		Cygnus Pharma Limited	Trazodone Hydrochloride 50 mg capsules, hard	Trazodone	50 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)		Dr Reddy's Laboratories (UK) Limited	Ranolazine 375 mg prolonged-release tablets	Ranolazine	375 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)		Dr Reddy's Laboratories (UK) Limited	Ranolazine 500 mg prolonged-release tablets	Ranolazine	500 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)		Dr Reddy's Laboratories (UK) Limited	Ranolazine 750 mg prolonged-release tablets	Ranolazine	750 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)		Genus Pharmaceuticals Limited	Nilotinib 150 mg hard capsules	Nilotinib	150 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)		Genus Pharmaceuticals Limited	Nilotinib 200 mg hard capsules	Nilotinib	200 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)		Manx Healthcare Limited	Betahistine Dihydrochloride 16 mg tablets	Betahistine	16 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Manx Healthcare Limited	Betahistine Dihydrochloride 24 mg tablets	Betahistine	24 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Manx Healthcare Limited	Betahistine Dihydrochloride 8 mg tablets	Betahistine	8 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Milpharm Limited	Dapagliflozin and Metformin hydrochloride 5mg/1 000mg film-coated tablets	Dapagliflozin/ metformin	5 mg/ 1 000 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)		Milpharm Limited	Dapagliflozin and Metformin hydrochloride 5mg/850mg film-coated tablets	Dapagliflozin/ metformin	5 mg/ 850 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)		Milpharm Limited	Dicycloverine Hydrochloride 10 mg tablets	Dicycloverine	10 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Milpharm Limited	Dicycloverine Hydrochloride 20 mg tablets	Dicycloverine	20 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Milpharm Limited	Teriflunomide 14 mg film-coated tablets	Teriflunomide	14 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)		Milpharm Limited	Topiramate 15 mg capsules	Topiramate	15 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)		Milpharm Limited	Topiramate 25 mg capsules	Topiramate	25 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)		Milpharm Limited	Topiramate 50 mg capsules	Topiramate	50 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)		Morningside Healthcare Limited	Fludrocortisone Acetate 0,1 mg tablets	Fludrocortisone	0,1 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Morningside Healthcare Limited	Mercaptopurine 10 mg tablets	Mercaptopurine	10 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)		Morningside Healthcare Limited	Mercaptopurine 50 mg tablets	Mercaptopurine	50 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Morningside Healthcare Limited	Pilocarpine Hydrochloride 5 mg film-coated tablets	Pilocarpine	5 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)		Morningside Healthcare Limited	Ranolazine 375 mg prolonged-release tablets	Ranolazine	375 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)		Morningside Healthcare Limited	Ranolazine 500 mg prolonged-release tablets	Ranolazine	500 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)		Morningside Healthcare Limited	Ranolazine 750 mg prolonged-release tablets	Ranolazine	750 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)		Morningside Healthcare Limited	Sertraline 100 mg Film-coates Tablets	Sertraline	100 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)		Morningside Healthcare Limited	Sertraline 150 mg Film-coates Tablets	Sertraline	150 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)		Morningside Healthcare Limited	Sertraline 200 mg Film-coates Tablets	Sertraline	200 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)		Morningside Healthcare Limited	Sertraline 25 mg Film-coates Tablets	Sertraline	25 mg	Film-coated tablet	Oral use

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Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)		Morningside Healthcare Limited	Sertraline 50 mg Film-coates Tablets	Sertraline	50 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)		Morningside Healthcare Limited	Tranylcypromine 10 mg film-coated tablets	Tranylcypromine	10 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)		Noumed Life Sciences Limited	Carbimazole 20 mg tablets	Carbimazole	20 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Noumed Life Sciences Limited	Carbimazole 5 mg tablets	Carbimazole	5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Noumed Life Sciences Limited	Dutasteride 0.5 mg soft capsules	Dutasteride	0,5 mg	Capsule, soft	Oral use
United Kingdom (Northern Ireland)		Noumed Life Sciences Limited	Ibuprofen 200 mg liquid capsules / Ibuprofen 200 mg soft capsules	Ibuprofen	200 mg	Capsule, soft	Oral use
United Kingdom (Northern Ireland)		Noumed Life Sciences Limited	Ibuprofen 400 mg soft capsules	Ibuprofen	400 mg	Capsule, soft	Oral use
United Kingdom (Northern Ireland)		Perennial Pharma Ltd	Montelukast 10 mg film-coated tablets	Montelukast	10 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)		Relonchem Limited	Loperamide 2 mg capsule, hard	Loperamide	2 mg	Capsule, hard	Oral use

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)		Relonchem Limited	Loperamide 2 mg capsule, hard	Loperamide	2 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)		Renata (UK) Limited	Dicycloverine Hydrochloride 10 mg tablets	Dicycloverine	10 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Renata (UK) Limited	Dicycloverine Hydrochloride 20 mg tablets	Dicycloverine	20 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Rosemont Pharmaceuti-cals Limited	Zonisamide Rosemont 20 mg/ml oral suspension	Zonisamide	20 mg/ ml	Oral suspension	Oral use
United Kingdom (Northern Ireland)		Strandhaven Limited	Carbimazole 20 mg tablets	Carbimazole	20 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Strandhaven Limited	Carbimazole 5 mg tablets	Carbimazole	5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Strandhaven Limited	Fludrocortisone Acetate 0,1 mg tablets	Fludrocortisone	0,1 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Strandhaven Limited	Nitrofurantoin 100 mg capsules, hard	Nitrofurantoin	100 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)		Strandhaven Limited	Nitrofurantoin 50 mg capsules, hard	Nitrofurantoin	50 mg	Capsule, hard	Oral use

ELI: http://data.europa.eu/eli/C/2024/3878/oj

Member State in EEA	Marketing authorisation holder	Applicant	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)		Strandhaven Limited	Timolol 10mg tablets	Timolol	10 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Torrent Pharma (UK) Limited	Pazopanib Torrent 200 mg film-coated tablet	Pazopanib	200 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)		Umedical Limited	Ranolizine 375 mg prolonged-release tablets	Ranolazine	375 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)		Umedical Limited	Ranolizine 500 mg prolonged-release tablets	Ranolazine	500 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)		Umedical Limited	Ranolizine 750 mg prolonged-release tablets	Ranolazine	750 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)		Zentiva Pharma UK Limited	Zirana 375 mg prolonged-release tablets	Ranolazine	375 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)		Zentiva Pharma UK Limited	Zirana 500 mg prolonged-release tablets	Ranolazine	500 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)		Zentiva Pharma UK Limited	Zirana 750 mg prolonged-release tablets	Ranolazine	750 mg	Prolonged-release tablet	Oral use