Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 June 2017 to 30 June 2017

(Decisions taken pursuant to Article 34 of Directive 2001/83/EC [1] or Article 38 of Directive 2001/82/EC [2])

(2017/C 245/02)

— Issuing, maintenance or modification of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorization	Member State concerned	Date of notification
23.6.2017	Micro therapeutic Research Labs	Not applicable	Not applicable	See Annex I	26.6.2017
26.6.2017	Etopophos and associated names	etoposide phosphate	Not applicable	See Annex II	27.6.2017
26.6.2017	Vepesid and associated names	etoposide	Not applicable	See Annex III	27.6.2017
12.6.2017	Haldol and associated names	haloperidol	Not applicable	See Annex V	13.6.2017
20.6.2017	Veterinary medicinal products containing methylprednisolone hydrogen succinat	Methylprednisolone hydrogen succinate	Not applicable	See Annex VI	21.6.2017

— Refusal of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorization	Member State concerned	Date of notification
6.6.2017	Veterinary medicinal products containing Zinc oxide	zinc oxide	Not applicable	See Annex IV	27.6.2017
20.6.2017	Veterinary medicinal products containing methylprednisolone hydrogen succinat	Methylprednisolone hydrogen succinate	Not applicable	See Annex VI	21.6.2017

— Suspension of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorization	Member State concerned	Date of notification
23.6.2017	Micro therapeutic Research Labs	Not applicable	Not applicable	See Annex I	26.6.2017

[1] OJ L 311, 28.11.2001, p. 67.
[2] OJ L 311, 28.11.2001, p. 1.

— **Revocation of a national marketing authorization**

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorization	Member State concerned	Date of notification
26.6.2017	Veterinary medicinal products containing Zinc oxide	zinc oxide	Not applicable	See Annex IV	27.6.2017

ANNEX I

List of medicinal products and presentations

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

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Czech Republic	SVUS Pharma a.s.		MORYSA 10 MG POTAHOVANÉ TABLETY	memantine	10 mg	Film-coated tablet	Oral use
Czech Republic	SVUS Pharma a.s.		MORYSA 20 MG POTAHOVANÉ TABLETY	memantine	20 mg	Film-coated tablet	Oral use
Denmark		Alternova A/S	Hydrokortison Alternova	hydrocortisone	10 mg	Tablet	Oral use
Denmark		Alternova A/S	Hydrokortison Alternova	hydrocortisone	20 mg	Tablet	Oral use
France	Pharmascope Ltd.		Memantin Pharmascope 10 mg Filmtabletten	memantine	10 mg	Film-coated tablet	Oral use
France	Pharmascope Ltd.		Memantin Pharmascope 20 mg Filmtabletten	memantine	20 mg	Film-coated tablet	Oral use
Germany	Pharmascope Ltd.		Memantin Pharmascope 10 mg Filmtabletten	memantine	10 mg	Film-coated tablet	Oral use
Germany	Pharmascope Ltd.		Memantin Pharmascope 20 mg Filmtabletten	memantine	20 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Hungary	SVUS Pharma a.s.		Morysa	memantine	10 mg	Film-coated tablet	Oral use
Hungary	SVUS Pharma a.s.		Morysa	memantine	20 mg	Film-coated tablet	Oral use
Poland	SVUS Pharma a.s.		Morysa	memantine	10 mg	Film-coated tablet	Oral use
Poland	SVUS Pharma a.s.		Morysa	memantine	20 mg	Film-coated tablet	Oral use
Portugal	SVUS Pharma a.s.		Morysa	memantine	10 mg	Film-coated tablet	Oral use
Portugal	SVUS Pharma a.s.		Morysa	memantine	20 mg	Film-coated tablet	Oral use
Romania	Pharmascope Ltd.		Memantin Pharmascope 10 mg Filmtabletten	memantine	10 mg	Film-coated tablet	Oral use
Romania	Pharmascope Ltd.		Memantin Pharmascope 20 mg Filmtabletten	memantine	20 mg	Film-coated tablet	Oral use
Slovak Republic	SVUS Pharma a.s.		Morysa	memantine	10 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Slovak Republic	SVUS Pharma a.s.		Morysa	memantine	20 mg	Film-coated tablet	Oral use
Sweden	Pharmascope Ltd.		Memantine Pharmascope	memantine	10 mg	Film-coated tablet	Oral use
Sweden	Pharmascope Ltd.		Memantine Pharmascope	memantine	20 mg	Film-coated tablet	Oral use
Sweden	Alternova A/S		Bendro-flumetiazid Alternova	bendro-flumethiazide	2,5 mg	Tablet	Oral use
Sweden		BBS Consult Aps	Hydrokortison BBS	hydrocortisone	10 mg	Tablet	Oral use
Sweden		BBS Consult Aps	Hydrokortison BBS	hydrocortisone	20 mg	Tablet	Oral use
The Netherlands	Pharmascope Ltd.		Memantine Pharmascope 10 mg filmomhulde tabletten	memantine	10 mg	Film-coated tablet	Oral use
The Netherlands	Pharmascope Ltd.		Memantine Pharmascope 20 mg filmomhulde tabletten	memantine	20 mg	Film-coated tablet	Oral use
United Kingdom	Dawa Limited		Memantine Dawa 10 mg film-coated tablets	memantine	10 mg	Film-coated tablet	Oral use
United Kingdom	Dawa Limited		Memantine Dawa 20 mg film-coated tablets	memantine	20 mg	Film-coated tablet	Oral use
United Kingdom	Dawa Limited		Paracetamol 1000 mg Film-Coated Tablets	paracetamol	1000 mg	Film-coated tablet	Oral use

Annex Ib: Products for which the marketing authorisations are recommended for suspension and marketing authorisation applications which do not satisfy the criteria for authorisation

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Austria	Sandoz GmbH		Bupropion Sandoz 300 mg — Tablette mit veränderter Wirkstofffreisetzung	bupropion	300 mg	Modified-release tablet	Oral use
Austria	1A Pharma GmbH		Bupropion 1A Pharma 300 mg — Tablette mit veränderter Wirkstofffreisetzung	bupropion	300 mg	Modified-release tablet	Oral use
Belgium	Aurobindo Pharma BV		Amlodipine-Valsartan AB	amlodipine/valsartan	5 mg/80 mg	Film-coated tablet	Oral use
Belgium	Aurobindo Pharma BV		Amlodipine-Valsartan AB	amlodipine/valsartan	5 mg/160 mg	Film-coated tablet	Oral use
Belgium	Aurobindo Pharma BV		Amlodipine-Valsartan AB	amlodipine/valsartan	10 mg/160 mg	Film-coated tablet	Oral use
Belgium	Sandoz n.v./s.a.		Betados 8 mg	betahistine	8 mg	Tablet	Oral use
Belgium	Sandoz n.v./s.a.		Betados 16 mg	betahistine	16 mg	Tablet	Oral use
Belgium	Sandoz n.v./s.a.		Betahistine Sandoz 24 mg	betahistine	24 mg	Tablet	Oral use
Belgium	Aurobindo Pharma BV		Voriconazole AB	voriconazol	50 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Belgium	Aurobindo Pharma BV		Voriconazole AB	voriconazol	200 mg	Tablet	Oral use
Belgium	Aurobindo Pharma BV		Tadalafil AB	tadalafil	5 mg	Film-coated tablet	Oral use
Belgium	Aurobindo Pharma BV		Tadalafil AB	tadalafil	10 mg	Film-coated tablet	Oral use
Belgium	Aurobindo Pharma BV		Tadalafil AB	tadalafil	20 mg	Film-coated tablet	Oral use
Belgium	Aurobindo Pharma BV		Naproxen Aurobindo	naproxen	250 mg	Tablet	Oral use
Belgium	Sandoz n.v./s.a.		Bupropion HCl Sandoz	bupropion	300 mg	Modified-release tablet	Oral use
Belgium	Aurobindo Pharma BV		Naproxen Aurobindo	naproxen	500 mg	Tablet	Oral use
Bulgaria		Sandoz B.V.	Betahistin HEXAL 16 mg Tabletten	betahistine	16 mg	Tablet	Oral use
Bulgaria		Sandoz B.V.	Betahistin HEXAL 24 mg Tabletten	betahistine	24 mg	Tablet	Oral use
Bulgaria		Sandoz B.V.	Betahistin HEXAL 8 mg Tabletten	betahistine	8 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Bulgaria	Proenzi s.r.o.		Etrixenal	naproxen	250 mg	Tablet	Oral use
Czech Republic		Famy Care Europe Ltd.	LARCIA 125 MIKROGRAMŮ/30 MIKROGRAMŮ	ethinylestradiol/levonorgestrel	0,03 mg/ 0,125 mg	Tablet	Oral use
Czech Republic		Famy Care Europe Ltd.	Levonorgestrel/Ethinylestradiol Famy Care 125 mikrogramů/30 mikrogramů	ethinylestradiol/levonorgestrel	0.03 mg/ 0,125 mg	Tablet	Oral use
Czech Republic		Sandoz B.V.	BETAHISTIN SANDOZ 8 MG	betahistine dihydrochloride	8 mg	Tablet	Oral use
Czech Republic		Sandoz B.V.	BETAHISTIN SANDOZ 16 MG	betahistine dihydrochloride	16 mg	Tablet	Oral use
Czech Republic		Sandoz B.V.	BETAHISTIN SANDOZ 24 MG	betahistine dihydrochloride	24 mg	Tablet	Oral use
Czech Republic	Proenzi s.r.o.		ETRIXENAL 250 MG TABLETY	naproxen	250 mg	Tablet	Oral use
Denmark	EQL Pharma AB		Hydroxyzinhydrochlorid EQL Pharma	hydroxyzine	25 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Denmark	Alternova A/S		Dicloxacillin Alternova	dicloxacillin	250 mg	Capsule, hard	Oral use
Denmark	Alternova A/S		Dicloxacillin Alternova	dicloxacillin	500 mg	Capsule, hard	Oral use
Denmark	2care4 Aps		Betahistin 2care4	betahistine	8 mg	Tablet	Oral use
Denmark	2care4 Aps		Betahistin 2care4	betahistine	16 mg	Tablet	Oral use
Denmark	2care4 Aps		Betahistin 2care4	betahistine	24 mg	Tablet	Oral use
Denmark	Alternova A/S		Novertigo	betahistine	8 mg	Tablet	Oral use
Denmark	Alternova A/S		Novertigo	betahistine	16 mg	Tablet	Oral use
Denmark		Orifarm Generics A/S	Loperamid Orifarm	loperamide	2 mg	Tablet	Oral use
Denmark		Alternova A/S	Baklofen Alternova	baclofen	10 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Denmark	Orion Corporation, Finland		Tadalafil Orion	tadalafil	5 mg	Film-coated tablet	Oral use
Denmark	Orion Corporation, Finland		Tadalafil Orion	tadalafil	10 mg	Film-coated tablet	Oral use
Denmark	Orion Corporation, Finland		Tadalafil Orion	tadalafil	20 mg	Film-coated tablet	Oral use
Denmark		Alternova A/S	Etodolac Alternova	etodolac	300 mg	Film-coated tablet	Oral use
Denmark	Aurobindo Pharma (Malta) Limited		Naproxen Orion	naproxen	250 mg	Tablet	Oral use
Denmark	Aurobindo Pharma (Malta) Limited		Naproxen Orion	naproxen	500 mg	Tablet	Oral use
Estonia		Sandoz B.V.	Betahistidine Sandoz	betahistine	8 mg	Tablet	Oral use
Estonia		Sandoz B.V.	Betahistidine Sandoz	betahistine	16 mg	Tablet	Oral use
Estonia		Sandoz B.V.	Betahistidine Sandoz	betahistine	24 mg	Tablet	Oral use
Estonia	Proenzi s.r.o.		Etrixenal	naproxen	250 mg	Tablet	Oral use
Finland	Orion Corporation		Bupropion Orion	bupropion	300 mg	modified-release tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Finland	Sandoz A/S, Denmark		Hydroxyzine Sandoz	hydroxyzine	25 mg	Film-coated tablet	Oral use
Finland	Orion Corporation Orion Pharma, Finland		Tadalafil Orion	tadalafil	5 mg	Film-coated tablet	Oral use
Finland	Orion Corporation Orion Pharma, Finland		Tadalafil Orion	tadalafil	10 mg	Film-coated tablet	Oral use
Finland	Orion Corporation Orion Pharma, Finland		Tadalafil Orion	tadalafil	20 mg	Film-coated tablet	Oral use
Finland	Aurobindo Pharma Ltd, Malta		Naproxen Orion	naproxen	250 mg	Tablet	Oral use
Finland	Sandoz A/S, Denmark		Bupropion Sandoz	bupropion	300 mg	Modified-release tablet	Oral use
Finland	Aurobindo Pharma Ltd, Malta		Naproxen Orion	naproxen	500 mg	Tablet	Oral use
Finland	Alternova A/S		Prednisolon Alternova	prednisolone	20 mg		
France		Arrow Génériques	amlodipine/valsartan Arrow	amlodipine/valsartan	5 mg/80 mg	Film-coated tablet	Oral use
France		Arrow Génériques	amlodipine/valsartan Arrow	amlodipine/valsartan	5 mg/160 mg	Film-coated tablet	Oral use
France		Arrow Génériques	amlodipine/valsartan Arrow	amlodipine/valsartan	10 mg/160 mg	Film-coated tablet	Oral use
France		Sandoz B.V.	BETAHISTINE GNR	betahistine	8 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
France		Sandoz B.V.	BETAHISTINE GNR	betahistine	24 mg	Tablet	Oral use
France	Sanofi Aventis France		Hydroxyzine ZENTIVA	hydroxyzine	25 mg	Film-coated tablet	Oral use
France	Mylan SAS		Hydroxyzine MYLAN	hydroxyzine	25 mg	Film-coated tablet	Oral use
France	Sandoz		Hydroxyzine SANDOZ	hydroxyzine	25 mg	Film-coated tablet	Oral use
France	Biogaran		hydroxyzine BIOGARAN	hydroxyzine	25 mg	Film-coated tablet	Oral use
France	Arrow Génériques		Hydroxyzine ARROW	hydroxyzine	25 mg	Film-coated tablet	Oral use
France	Cristers		Hydroxyzine CRISTERS	hydroxyzine	25 mg	Film-coated tablet	Oral use
France	EG LABO — Laboratoires Eurogenerics		Hydroxyzine EG	hydroxyzine	25 mg	Film-coated tablet	Oral use
France	Teva Sante		Hydroxyzine TEVA	hydroxyzine	25 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
France		Special Concept Development (UK) Ltd	Metformine Almus	metformin hydrochloride	500 mg	Tablet	Oral use
France		Special Concept Development (UK) Ltd	Metformine Almus	metformin hydrochloride	850 mg	Tablet	Oral use
France		Special Concept Development (UK) Ltd	Metformine Almus	metformin hydrochloride	1000 mg	Tablet	Oral use
France		ELC Group s.r.o.	Esters ethyliques d'acides omega-3 Strides	omega-3-acid-ethyl esters 90	1 g	Capsule, soft	Oral use
France		ARROW GENERIQUES	tadalafil Arrow	tadalafil	2,5 mg	Film-coated tablet	Oral use
France		ARROW GENERIQUES	tadalafil Arrow	tadalafil	5 mg	Film-coated tablet	Oral use
France		ARROW GENERIQUES	tadalafil Arrow	tadalafil	10 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
France		ARROW GENERIQUES	tadalafil Arrow	tadalafil	20 mg	Film-coated tablet	Oral use
France		AUROVITAS UNIPESSOAL Lda	Tadalafil Quiver	tadalafil	20 mg	Film-coated tablet	Oral use
France	ZYDUS France		TIANEPTINE ZYDUS	tianeptine	12,5 mg	Tablet	Oral use
France		SUBSTIPHARM DEVELOPPEMENT	PERURCIL	ursodeoxycholic acid	500 mg	Film-coated tablet	Oral use
France		SUBSTIPHARM DEVELOPPEMENT	acide ursodesoxycholique Inopharm	ursodeoxycholic acid	500 mg	Film-coated tablet	Oral use
France		SUBSTIPHARM DEVELOPPEMENT	VALDINE	ursodeoxycholic acid	500 mg	Film-coated tablet	Oral use
France		ARROW GENERIQUES	voriconazole Arrow	voriconazol	50 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
France		ARROW GENERIQUES	voriconazole Arrow	voriconazol	200 mg	Film-coated tablet	Oral use
France		Special Concept Development (UK) Limited	Paracetamol Almus Pharma	paracetamol	500 mg	Tablet	Oral use
France		Special Concept Development (UK) Limited	Paracetamol Almus Pharma	paracetamol	1000 mg	Tablet	Oral use
France	ZYDUS France		perindopril/Indapamide Zydus France	perindopril/indapamide	2 mg/0,625 mg	Tablet	Oral use
France	ZYDUS France		perindopril/Indapamide Zydus France	perindopril/indapamide	4 mg/1,25 mg	Tablet	Oral use
France	ZYDUS France		perindopril/Indapamide Zydus France	perindopril/indapamide	8 mg/2,5 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Germany	Hormosan Pharma GmbH		Maexeni 30 0,03 mg/ 0,15 mg Filmtabletten	ethinylestradiol/levonorgestrel	0,03 mg/ 0,15 mg	Film-coated tablet	Oral use
Germany	neuraxpharm Arzneimittel GmbH		Bupropion-neuraxpharm 300 mg Tabletten mit veränderter Wirkstofffreisetzung	bupropion	300 mg	Modified-release tablet	Oral use
Germany	HEC Pharm GmbH		Irbesartan HEC Pharm 75 mg Filmtabletten	irbesartan	75 mg	Film-coated tablet	Oral use
Germany	HEC Pharm GmbH		Irbesartan HEC Pharm 150 mg Filmtabletten	irbesartan	150 mg	Film-coated tablet	Oral use
Germany	HEC Pharm GmbH		Irbesartan HEC Pharm 300 mg Filmtabletten	irbesartan	300 mg	Film-coated tablet	Oral use
Germany	Famy Care Europe Ltd.		Ethinylestradiol/Levonorgeshel Famy Care 30 mikrogramm 125 mikrogramm tablette	ethinylestradiol/levonorgestrel	0,03 mg/ 0,125 mg	Film-coated tablet	Oral use
Germany	Mylan Dura GmbH		Oralcon 30 Microgramm/ 125 Microgramm Tabletten	ethinylestradiol/levonorgestrel	0,03 mg/ 0,125 mg	Film-coated tablet	Oral use
Germany	HEC Pharm GmbH		Olanzapin HEC Pharm 5 mg Schmelztabletten	olanzapin	5 mg	Orodispersible tablet	Oral use
Germany	HEC Pharm GmbH		Olanzapin HEC Pharm 10 mg Schmelztabletten	olanzapin	10 mg	Orodispersible tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Germany	HEC Pharm GmbH		Olanzapin HEC Pharm 15 mg Schmelztabletten	olanzapin	15 mg	Orodispersible tablet	Oral use
Germany	HEC Pharm GmbH		Olanzapin HEC Pharm 20 mg Schmelztabletten	olanzapin	20 mg	Orodispersible tablet	Oral use
Germany		Sandoz B.V.	Betahistin HEXAL 8 mg Tabletten	betahistine	8 mg	Tablet	Oral use
Germany		Sandoz B.V.	Betahistin HEXAL 16 mg Tabletten	betahistine	16 mg	Tablet	Oral use
Germany		Sandoz B.V.	Betahistin HEXAL 24 mg Tabletten	betahistine	24 mg	Tablet	Oral use
Germany		Sandoz B.V.	Betahistin HEXAL bei Schwindel 8 mg Tabletten	betahistine	8 mg	Tablet	Oral use
Germany		Sandoz B.V.	Betahistin HEXAL bei Schwindel 16 mg Tabletten	betahistine	16 mg	Tablet	Oral use
Germany		Sandoz B.V.	Betahistin HEXAL bei Schwindel 24 mg Tabletten	betahistine	24 mg	Tablet	Oral use
Germany		Sandoz B.V.	Betahistin — 1 A Pharma 8 mg Tabletten	betahistine	8 mg	Tablet	Oral use
Germany		Sandoz B.V.	Betahistin — 1 A Pharma 16 mg Tabletten	betahistine	16 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Germany		Sandoz B.V.	Betahistin — 1 A Pharma 24 mg Tabletten	betahistine	24 mg	Tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG (in Germany)		Tadalafil Aurovitas	tadalafil	5 mg	Film-coated tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG (in Germany)		Tadalafil Aurovitas	tadalafil	10 mg	Film-coated tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG (in Germany)		Tadalafil Aurovitas	tadalafil	20 mg	Film-coated tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG (in Germany)		Amlodipina + Valsartan Aurovitas, Amlodipin/Valsartan PUREN (in Germany)	amlodipine/valsartan	5 mg/80 mg	Film-coated tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG (in Germany)		Amlodipina + Valsartan Aurovitas, Amlodipin/Valsartan PUREN (in Germany)	amlodipine/valsartan	5 mg/160 mg	Film-coated tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG (in Germany)		Amlodipina + Valsartan Aurovitas, Amlodipin/Valsartan PUREN (in Germany)	amlodipine/valsartan	10 mg/160 mg	Film-coated tablet	Oral use
Germany		Aurovitas Unipessoal, Lda.	Tadalafil Ritista	tadalafil	20 mg	Film-coated tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG		Voriconazol PUREN 50 mg Filmtabletten	voriconazol	50 mg	Film-coated tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG		Voriconazol PUREN 200 mg Filmtabletten	voriconazol	200 mg	Film-coated tablet	Oral use
Germany	Hexal AG, Germany		Buproprionhydrochlorid Hexal 300 mg	bupropion	300 mg	Modified-release tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Germany	1 A Pharma GmbH, Germany		Bupropion 1 A Pharma 300 mg	bupropion	300 mg	Modified-release tablet	Oral use
Greece	Pharmanel Commercial Pharmaceutical S.A.		PRABEX	ibuprofen	200 mg	Film-coated tablet	Oral use
Greece		Pharmanel Commercial Pharmaceutical S.A.	DUARIDE	dutasteride	0,5 mg	Capsule, soft	Oral use
Greece		ΦΑΡΜΑΖΑΚ ΑΝΩΝΥΜΗ ΦΑΡΜΑΚΕΥΤΙΚΗ ΕΜΠΟΡΙΚΗ ΒΙΟΜΗΧΑΝΙΚΗ ΕΤΑΙΡΕΙΑ Δ.Τ. PHARMAZAC AE	AMLODIPINE+ VALSARTAN/PHARMAZAC	amlodipine/valsartan	5 mg/80 mg	Film-coated tablet	Oral use
Greece		ΦΑΡΜΑΖΑΚ ΑΝΩΝΥΜΗ ΦΑΡΜΑΚΕΥΤΙΚΗ ΕΜΠΟΡΙΚΗ ΒΙΟΜΗΧΑΝΙΚΗ ΕΤΑΙΡΕΙΑ Δ.Τ. PHARMAZAC AE	AMLODIPINE+ VALSARTAN/PHARMAZAC	amlodipine/valsartan	5 mg/160 mg	Film-coated tablet	Oral use
Greece		ΦΑΡΜΑΖΑΚ ΑΝΩΝΥΜΗ ΦΑΡΜΑΚΕΥΤΙΚΗ ΕΜΠΟΡΙΚΗ ΒΙΟΜΗΧΑΝΙΚΗ ΕΤΑΙΡΕΙΑ Δ.Τ. PHARMAZAC AE	AMLODIPINE+ VALSARTAN/PHARMAZAC	amlodipine/valsartan	10 mg/160 mg	Film-coated tablet	Oral use
Greece		BRADEX AEBE	DUTASTERIDE/BRADEX	dutasteride	0,5 mg	Capsule, soft	Oral use
Greece	Pharmanel Commercial Pharmaceutical S.A.		PRABEX	ibuprofen	400 mg	Film-coated tablet	Oral use
Greece	Pharmanel Commercial Pharmaceutical S.A.		PRABEX	ibuprofen	600 mg	Film-coated tablet	Oral use
Hungary	Proenzi s.r.o.		ETRIXENAL	naproxen	250 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Ireland	Stasisport Pharma N.V.		Miofen	ibuprofen	200 mg	Film-coated tablet	Oral use
Ireland	Stasisport Pharma N.V.		Miofen	ibuprofen	400 mg	Film-coated tablet	Oral use
Ireland	Stasisport Pharma N.V.		Miofen	ibuprofen	600 mg	Film-coated tablet	Oral use
Ireland		Alissa Healthcare Research Limited	Carbocisteine 375 mg Capsules, Hard	carbocisteine	375 mg	Capsule, hard	Oral use
Italy	Aurobindo Pharma (Italia), srl		Tadalafil Aurobindo	tadalafil	5 mg	Film-coated tablet	Oral use
Italy	Aurobindo Pharma (Italia) srl		Voriconazolo Aurobindo	voriconazol	50 mg	Film-coated tablet	Oral use
Italy	Sandoz SpA		Bupropione Sandoz	bupropion	300 mg	Modified-release tablet	Oral use
Italy	Strides Arcolab International Limited		Omega 3 Strides Arcolab International	omega-3-acid-ethyl esters 90	1000 mg	Capsule, soft	Oral use
Italy		Special Concept Development (UK) Ltd	Metformina Almus	metformin hydrochloride	850 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Italy		Special Concept Development (UK) Ltd	Metformina Almus	metformin hydrochloride	1000 mg	Film-coated tablet	Oral use
Italy	Aurobindo Pharma (Italia), srl		Tadalafil Aurobindo	tadalafil	10 mg	Film-coated tablet	Oral use
Italy	Aurobindo Pharma (Italia), srl		Tadalafil Aurobindo	tadalafil	20 mg	Film-coated tablet	Oral use
Italy	Aurobindo Pharma (Italia) srl		Voriconazolo Aurobindo	voriconazol	200 mg	Film-coated tablet	Oral use
Italy	Strides Arcolab International Limited		Omega 3 Strides Arcolab International	omega-3-acid-ethyl esters 90	1000 mg	Capsule, soft	Oral use
Italy		Special Concept Development (UK) Ltd	Metformina Almus	metformin hydrochloride	500 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Latvia		Sandoz B.V.	Betahistin Sandoz 8 mg tabletes	betahistine	8 mg	Tablet	Oral use
Latvia		Sandoz B.V.	Betahistin Sandoz 16 mg tabletes	betahistine	16 mg	Tablet	Oral use
Latvia		Sandoz B.V.	Betahistin Sandoz 24 mg tabletes	betahistine	24 mg	Tablet	Oral use
Latvia	Proenzi s.r.o		Etrixenal 250 mg tabletes	naproxen	250 mg	Tablet	Oral use
Lithuania	Proenzi s.r.o		Etrixenal	naproxen	250 mg	Tablet	Oral use
Lithuania		Sandoz B. V.	Betahistine Sandoz	betahistine	8 mg	Tablet	Oral use
Lithuania		Sandoz B. V.	Betahistine Sandoz	betahistine	16 mg	Tablet	Oral use
Lithuania		Sandoz B. V.	Betahistine Sandoz	betahistine	24 mg	Tablet	Oral use
Luxembourg		Aurobindo Pharma B.V.	Naproxen Aurobindo	naproxen	250 mg	Tablet	Oral use
Luxembourg		Sandoz B.V.	Bupropion HCl Sandoz	bupropion	300 mg	Modified-release tablet	Oral use
Luxembourg		Aurobindo Pharma B.V.	Naproxen Aurobindo	naproxen	500 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Norway	EQL Pharma AB		Hydroxyzine EQL Pharma	hydroxyzine	25 mg	Film-coated tablet	Oral use
Norway	Alternova A/S		Dicloxacillin Alternova	dicloxacillin	250 mg	Capsule, hard	Oral use
Norway	Alternova A/S		Dicloxacillin Alternova	dicloxacillin	500 mg	Capsule, hard	Oral use
Norway	Orion Corporation		Tadalafil Orion	tadalafil	5 mg	Film-coated tablet	Oral use
Norway	Orion Corparation		Tadalafil Orion	tadalafil	10 mg	Film-coated tablet	Oral use
Norway	Orion Corporation		Tadalafil Orion	tadalafil	20 mg	Film-coated tablet	Oral use
Norway	Aurobindo Pharma Limited		Naproxen Orion	naproxen	250 mg	Tablet	Oral use
Norway	Aurobindo Pharma Limited		Naproxen Orion	naproxen	500 mg	Tablet	Oral use
Poland	Bluefish Pharmaceuticals AB		Betahistyna Bluefish	betahistine dihydrochloride	8 mg	Tablet	Oral use
Poland	VITAMA S.A.		Sarpin	amlodipine/valsartan	10 mg/160 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Poland	VITAMA S.A.		Napritum	naproxen	250 mg	Tablet	Oral use
Poland	VITAMA S.A.		Napritum	naproxen	500 mg	Tablet	Oral use
Poland	Bluefish Pharmaceuticals AB		Betahistyna Bluefish	betahistine dihydrochloride	16 mg	Tablet	Oral use
Poland	Bluefish Pharmaceuticals AB		Betahistyna Bluefish	betahistine dihydrochloride	24 mg	Tablet	Oral use
Poland	Orion Corporation		Bupropion Orion	bupropion	300 mg	Modified-release tablet	Oral use
Poland	Proenzi s.r.o.		Etrixenal	naproxen	250 mg	Tablet	Oral use
Portugal		Sandoz B.V.	Beta-histina Sandoz	betahistine	16 mg	Tablet	Oral use
Portugal		Sandoz B.V.	Beta-histina Sandoz	betahistine	24 mg	Tablet	Oral use
Portugal		Special Concept Development (UK) Ltd	Metformina Almus	metformin hydrochloride	850 mg	Film-coated tablet	Oral use
Portugal		Special Concept Development (UK) Ltd	Metformina Almus	metformin hydrochloride	1000 mg	Film-coated tablet	Oral use
Portugal	Aurobindo Pharma (Portugal), Unipessoal Lda.		Tadalafil Aurobindo	tadalafil	5 mg	Film-coated tablet	Oral use
Portugal	Aurovitas Unipessoal, Lda.		Tadalafil Aurovitas	tadalafil	2,5 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Portugal	Aurovitas Unipessoal, Lda.		Amlodipina + Valsartan Aurovitas	amlodipine/valsartan	5 mg/80 mg	Film-coated tablet	Oral use
Portugal	Bluefish Pharmaceuticals AB		Beta- histina Bluefish	betahistine	8 mg	Tablet	Oral use
Portugal	Farmoz — Sociedade Técnico Medicinal, S.A.		Beta- histina Farmoz	betahistine	16 mg	Tablet	Oral use
Portugal	Farmoz — Sociedade Técnico Medicinal, S.A.		Beta-histina Farmoz	betahistine	24 mg	Tablet	Oral use
Portugal		Pharma Bavaria International (PBI) Portugal, Unip. Lda.	Vasobex	betahistine	8 mg	Tablet	Oral use
Portugal		Pharma Bavaria International (PBI) Portugal, Unip. Lda.	Vasobex	betahistine	16 mg	Tablet	Oral use
Portugal		Pharma Bavaria International (PBI) Portugal, Unip. Lda.	Vasobex	betahistine	24 mg	Tablet	Oral use
Portugal		Generic Speciality Pharma Limited	Histabal	betahistine	8 mg	Tablet	Oral use
Portugal		Generic Speciality Pharma Limited	Histabal	betahistine	16 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Portugal		Generic Speciality Pharma Limited	Histabal	betahistine	24 mg	Tablet	Oral use
Portugal		Aurovitas Unipessoal, Lda.	Tadalafil Aurobindo	tadalafil	20 mg	Film-coated tablet	Oral use
Portugal	Laboratórios Basi — Indústria Farm		Beta-histina Basi	betahistine	8 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Baclofeno Generis	baclofen	10 mg	Tablet	Oral use
Portugal	Aurovitas Unipessoal, Lda.		Voriconazol Aurovitas	voriconazol	50 mg	Film-coated tablet	Oral use
Portugal	Glob Ltd.		Voriconazol Glob	voriconazol	50 mg	Film-coated tablet	Oral use
Portugal	Aurobindo Pharma (Portugal), Unipessoal Lda.		Naproxen Aurobindo	naproxen	250 mg	Tablet	Oral use
Portugal	Sandoz Farmacêutica, Lda.		Bupropion HCl Sandoz	bupropion	300 mg	Modified-release tablet	Oral use
Portugal	Aurobindo Pharma (Portugal), Unipessoal Lda.		Naproxeno Aurobindo	naproxen	500 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Portugal	Aurobindo Pharma (Portugal), Unipessoal Lda.		Tadalafil Aurobindo	tadalafil	10 mg	Film-coated tablet	Oral use
Portugal	Aurobindo Pharma (Portugal), Unipessoal Lda.		Tadalafil Aurobindo	tadalafil	20 mg	Film-coated tablet	Oral use
Portugal	Aurovitas Unipessoal, Lda.		Tadalafil Aurovitas	tadalafil	5 mg	Film-coated tablet	Oral use
Portugal	Aurovitas Unipessoal, Lda.		Tadalafil Aurovitas	tadalafil	10 mg	Film-coated tablet	Oral use
Portugal	Aurovitas Unipessoal, Lda.		Tadalafil Aurovitas	tadalafil	20 mg	Film-coated tablet	Oral use
Portugal	Aurovitas Unipessoal, Lda.		Amlodipina + Valsartan Aurovitas	amlodipine/valsartan	5 mg/160 mg	Film-coated tablet	Oral use
Portugal	Aurovitas Unipessoal, Lda.		Amlodipina + Valsartan Aurovitas	amlodipine/valsartan	10 mg/160 mg	Film-coated tablet	Oral use
Portugal	Aurovitas Unipessoal, Lda.		Voriconazol Aurovitas	voriconazol	200 mg	Film-coated tablet	Oral use
Portugal	Glob Ltd.		Voriconazol Glob	voriconazol	200 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Portugal	Bluefish Pharmaceuticals AB		Beta- histina Bluefish	betahistine dihydrochloride	16 mg	Tablet	Oral use
Portugal	Bluefish Pharmaceuticals AB		Beta- histina Bluefish	betahistine dihydrochloride	24 mg	Tablet	Oral use
Portugal		Special Concept Development (UK) Ltd	Metformina Almus	metformin hydrochloride	500 mg	Film-coated tablet	Oral use
Portugal		Almus, Lda.	Paracetamol 500 mg Tablets	paracetamol	500 mg	Tablet	Oral use
Portugal		Almus, Lda.	Paracetamol 1000 mg Tablets	paracetamol	1000 mg	Tablet	Oral use
Portugal	SVUS Pharma a.s.		Belfada	aripiprazole	10 mg	Tablet	Oral use
Portugal	SVUS Pharma a.s.		Belfada	aripiprazole	15 mg	Tablet	Oral use
Romania		Sandoz B.V.	Betahistin HEXAL 8 mg Tabletten	betahistine	8 mg	Tablet	Oral use
Romania		Sandoz B.V.	Betahistin HEXAL 16 mg Tabletten	betahistine	16 mg	Tablet	Oral use
Romania		Sandoz B.V.	Betahistin HEXAL 24 mg Tabletten	betahistine	24 mg	Tablet	Oral use
Romania	Aurobindo Pharma (Malta) Limited		Amlodipina/Valsartan Aurobindo 5 mg/80 mg comprimate filmate	amlodipine/valsartan	5 mg/80 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Romania	Aurobindo Pharma (Malta) Limited		Amlodipina/Valsartan Aurobindo 5 mg/160 mg comprimate filmate	amlodipine/valsartan	5 mg/160 mg	Film-coated tablet	Oral use
Romania	Aurobindo Pharma (Malta) Limited		Amlodipina/Valsartan Aurobindo 10 mg/160 mg comprimate filmate	amlodipine/valsartan	10 mg/160 mg	Film-coated tablet	Oral use
Romania	Aurobindo Pharma (Malta) Limited		Naproxen Aurobindo	naproxen	250 mg	Tablet	Oral use
Romania	Aurobindo Pharma (Malta) Limited		Naproxen Aurobindo	naproxen	500 mg	Tablet	Oral use
Romania	Proenzi s.r.o.		Etrixenal	naproxen	250 mg	Tablet	Oral use
Slovak Republic		Sandoz B.V.	Betahistin Sandoz 8 mg	betahistine	8 mg	Tablet	Oral use
Slovak Republic		Sandoz B.V.	Betahistin Sandoz 16 mg	betahistine	16 mg	Tablet	Oral use
Slovak Republic		Sandoz B.V.	Betahistin Sandoz 24 mg	betahistine	24 mg	Tablet	Oral use
Slovak Republic	Proenzi s.r.o.		Etrixenal	naproxen	250 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Slovenia		Sandoz B.V.	Betahistin Sandoz 8 mg tablete	betahistine	8 mg	Tablet	Oral use
Slovenia		Sandoz B.V.	Betahistin Sandoz 16 mg tablete	betahistine	16 mg	Tablet	Oral use
Slovenia		Sandoz B.V.	Betahistin Sandoz 24 mg tablete	betahistine	24 mg	Tablet	Oral use
Slovenia	Sandoz GmbH		Bupropion Sandoz 300 mg tablete s prirejenim sproščanjem	bupropion	300 mg	Modified-release tablet	Oral use
Spain	AUROVITAS SPAIN, SAU		Tadalafilo Aurovitas 5 mg comprimidos recubiertos con película EFG	tadalafil	5 mg	Film-coated tablet	Oral use
Spain	AUROVITAS SPAIN, SAU		Tadalafilo Aurovitas 10 mg comprimidos recubiertos con película EFG	tadalafil	10 mg	Film-coated tablet	Oral use
Spain	AUROVITAS SPAIN, SAU		Tadalafilo Aurovitas 20 mg comprimidos recubiertos con película	tadalafil	20 mg	Film-coated tablet	Oral use
Spain		AUROVITAS UNIPESSONAL, LDA	Tadalafilo Aurovit 20 mg comprimidos recubiertos con película EFG	tadalafil	20 mg	Film-coated tablet	Oral use
Spain	Strides Arcolab International Limited		Ácidos Omega 3 Strides 1000 mg cápsulas blandas EFG	omega-3-acid-ethyl esters 90	1000 mg	Capsule, soft	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Spain		ALMUS FARMACEUTICA, SA	Metformina Almus Pharma 850 mg comprimdos recubiertos con película EFG	metformin hydrochloride	850 mg	Film-coated tablet	Oral use
Spain		ALMUS FARMACEUTICA, SA	Metformina Almus Pharma 1000 mg comprimdos recubiertos con película EFG	metformin hydrochloride	1000 mg	Film-coated tablet	Oral use
Spain	Bluefish Pharmaceuticals AB		Betahistina Bluefish	betahistine dihydrochloride	8 mg	Tablet	Oral use
Spain	Bluefish Pharmaceuticals AB		Betahistina Bluefish	betahistine dihydrochloride	16 mg	Tablet	Oral use
Spain	LABORATORIOS AUROBINDO, SLU		Amlodipino/Valsartán Aurobindo 5 mg/160 mg comprimidos recubiertos con película EFG	amlodipine/valsartan	5 mg/160 mg	Film-coated tablet	Oral use
Spain	LABORATORIOS AUROBINDO, SLU		Amlodipino/Valsartán Aurobindo 10 mg/160 mg comprimidos recubiertos con película EFG	amlodipine/valsartan	10 mg/160 mg	Film-coated tablet	Oral use
Spain	LABORATORIOS AUROBINDO, SLU		Naproxeno Aurobindo 250 mg comprimidos EFG	naproxen	250 mg	Tablet	Oral use
Spain	LABORATORIOS AUROBINDO, SLU		Naproxeno Aurobindo 500 mg comprimidos EFG	naproxen	500 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Spain		Aurovitas Spain	Voriconazol Aurovitas 50 mg comprimidos recubiertos con película EFG	voriconazol	50 mg	Tablet	Oral use
Spain		Aurovitas Spain SAU	Voriconazol Aurovitas 200 mg comprimidos recubiertos con película EFG	voriconazol	200 mg	Tablet	Oral use
Spain	AUROVITAS SPAIN, SAU		Amlodipino/Valsartan Aurovitas 5 mg/160 mg comprimidos recubiertos con película EFG	amlodipine/valsartan	5 mg/160 mg	Film-coated tablet	Oral use
Spain	AUROVITAS SPAIN, SAU		Amlodipino/Valsartan Aurovitas 10 mg/160 mg comprimidos recubiertos con película EFG	amlodipine/valsartan	10 mg/160 mg	Film-coated tablet	Oral use
Spain	QUALIGEN, SL		Hidroxizina Qualigen 25 mg comprimidos recubiertos con película EFG	hydroxyzine	25 mg	Film-coated tablet	Oral use
Spain	LABORATORIOS COMBIX, SLU		Perindopril/Indapamida Combix 2 mg/0,625 mg comprimidos EFG	perindopril/indapamide	2 mg/0,625 mg	Tablet	Oral use
Spain	LABORATORIOS COMBIX, SLU		Perindopril/Indapamida Combix 4 mg/1,25 mg comprimidos EFG	perindopril/indapamide	4 mg/1,25 mg	Tablet	Oral use
Spain	LABORATORIOS COMBIX, SLU		Perindopril/Indapamida Combix 8 mg/2,5 mg comprimidos EFG	perindopril/indapamide	8 mg/2,5 mg	Tablet	Oral use
Spain		LABORATORIOS CINFA, SA	Bupropion Cinfa 300 mg comprimidos de liberación modificada EFG	bupropion	300 mg	Modified-release tablet	Oral use
Spain	SANDOZ FARMACEUTICA, SA		Bupropion Sandoz 300 mg comprimidos de liberación modificada EFG	bupropion	300 mg	Modified-release tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Spain		ALMUS FARMACEUTICA, SA	Paracetamol Almus 500 mg comprimidos EFG	paracetamol	500 mg	Tablet	Oral use
Spain		ALMUS FARMACEUTICA, SA	Paracetamol Almus 1000 mg comprimidos EFG	paracetamol	1000 mg	Tablet	Oral use
Sweden	Orion Corporation		Bupropion Orion	bupropion	300 mg	modified-release tablet	Oral use
Sweden	EQL Pharma AB		Hydroxyzine EQL Pharma	hydroxyzine	25 mg	Film-coated tablet	Oral use
Sweden	2care4 Aps		Betahistin 2care4	betahistine	8 mg	Tablet	Oral use
Sweden	2care4 Aps		Betahistin 2care4	betahistine	16 mg	Tablet	Oral use
Sweden	2care4 Aps		Betahistin 2care4	betahistine	24 mg	Tablet	Oral use
Sweden	Orion Corporation		Tadalafil Orion	tadalafil	5 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Sweden	Orion Corporation		Tadalafil Orion	tadalafil	10 mg	Film-coated tablet	Oral use
Sweden	Orion Corporation		Tadalafil Orion	tadalafil	20 mg	Film-coated tablet	Oral use
Sweden	2care4 Generics ApS		Ibuprofen 2care4	ibuprofen	200 mg	Film-coated tablet	Oral use
Sweden	2care4 Generics ApS		Ibuprofen 2care4	ibuprofen	400 mg	Film-coated tablet	Oral use
Sweden	2care4 Generics ApS		Ibuprofen 2care4	ibuprofen	600 mg	Film-coated tablet	Oral use
Sweden	Alternova A/S		Metoklopramid Alternova	metoclopramide	10 mg	Film-coated tablet	Oral use
Sweden	EQL Pharma AB		Atyxine	hydroxyzine	25 mg	Film-coated tablet	Oral use
Sweden	Alternova A/S		Clindamycin Alternova	clindamycin	150 mg	Capsule, hard	Oral use
Sweden		Apofri AB	Loperamid Apofri	loperamide	2 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Sweden		Evolan Pharma AB	Loperamid ABECE	loperamide	2 mg	Tablet	Oral use
Sweden		Evolan Pharma AB	Loperamid Evolan	loperamide	2 mg	Tablet	Oral use
Sweden		BBS Consult ApS	Loperamid BBS	loperamide	2 mg	Tablet	Oral use
Sweden	Aurobindo Pharma (Malta) Limited		Naproxen Orion	naproxen	250 mg	Tablet	Oral use
Sweden	Aurobindo Pharma (Malta) Limited		Naproxen Orion	naproxen	500 mg	Tablet	Oral use
Sweden	Sandoz A/S		Bupropion Sandoz	bupropion	300 mg	Modified-release tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Tadalafil Aurobindo 5 mg, filmomhulde tabletten	tadalafil	5 mg	Film-coated tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Tadalafil Aurobindo 10 mg, filmomhulde tabletten	tadalafil	10 mg	Film-coated tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Tadalafil Aurobindo 20 mg, filmomhulde tabletten	tadalafil	20 mg	Film-coated tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Amlodipine/Valsartan Aurobindo 5/80 mg, filmomhulde tabletten	amlodipine/valsartan	5 mg/80 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
The Netherlands	Aurobindo Pharma B.V.		Amlodipine/Valsartan Aurobindo 5/160 mg, filmomhulde tabletten	amlodipine/valsartan	5 mg/160 mg	Film-coated tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Amlodipine/Valsartan Aurobindo 10/160 mg, filmomhulde tabletten	amlodipine/valsartan	10 mg/160 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Bupropion HCl Sandoz retard 300 mg, tabletten met gereguleerde afgifte	bupropion	300 mg	Modified-release tablet	Oral use
The Netherlands	Sandoz B.V.		Bupropion HCl Sandoz retard 300 mg, tabletten met gereguleerde afgifte	bupropion	300 mg	Modified-release tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Naproxen Aurobindo 250 mg, tabletten	naproxen	250 mg	Tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Naproxen Aurobindo 500 mg, tabletten	naproxen	500 mg	Tablet	Oral use
The Netherlands		Sandoz B.V.	Betahistine Sandoz 8 mg, tabletten	betahistine	8 mg	Tablet	Oral use
The Netherlands		Sandoz B.V.	Betahistine Sandoz 16 mg, tabletten	betahistine	16 mg	Tablet	Oral use
The Netherlands		Sandoz B.V.	Betahistine Sandoz 24 mg, tabletten	betahistine	24 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
The Netherlands		Sandoz B.V.	Betahistine Sandoz 8 mg, tabletten	betahistine	8 mg	Tablet	Oral use
The Netherlands		Sandoz B.V.	Betahistine Sandoz 16 mg, tabletten	betahistine	16 mg	Tablet	Oral use
The Netherlands		Sandoz B.V.	Betahistine Sandoz 24 mg, tabletten	betahistine	24 mg	Tablet	Oral use
The Netherlands		Sandoz B.V.	Betahistine Sandoz 8 mg, tabletten	betahistine	8 mg	Tablet	Oral use
The Netherlands		Sandoz B.V.	Betahistine Sandoz 16 mg, tabletten	betahistine	16 mg	Tablet	Oral use
The Netherlands		Sandoz B.V.	Betahistine Sandoz 24 mg, tabletten	betahistine	24 mg	Tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Voriconazol Aurobindo 50 mg, filmomhulde tabletten	voriconazol	50 mg	Film-coated tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Voriconazol Aurobindo 200 mg, filmomhulde tabletten	voriconazol	200 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
United Kingdom		Aurovitas Unipessoal, Lda.	Tadalafil Aurobindo	tadalafil	20 mg	Film-coated tablet	Oral use
United Kingdom	Milpharm Limited		Tadalafil Milpharm 2,5 mg film-coated tablets	tadalafil	2,5 mg	Film-coated tablet	Oral use
United Kingdom	Milpharm Limited		Tadalafil Milpharm 5 mg film-coated tablets	tadalafil	5 mg	Film-coated tablet	Oral use
United Kingdom	Milpharm Limited		Tadalafil Milpharm 10 mg film-coated tablets	tadalafil	10 mg	Film-coated tablet	Oral use
United Kingdom	Milpharm Limited		Tadalafil Milpharm 20 mg film-coated tablets	tadalafil	20 mg	Film-coated tablet	Oral use
United Kingdom	Milpharm Limited		Voriconazole Milpharm 50 mg film-coated tablets	voriconazol	50 mg	Film-coated tablet	Oral use
United Kingdom	Milpharm Limited		Voriconazole Milpharm 200 mg film-coated tablets	voriconazol	200 mg	Film-coated tablet	Oral use
United Kingdom	Milpharm Limited		Naproxen 250 mg tablets	naproxen	250 mg	Tablet	Oral use
United Kingdom	Milpharm Limited		Naproxen 500 mg tablets	naproxen	500 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
United Kingdom	HEC Pharm GmbH		Irbesartan 75 mg Film-coated Tablets	irbesartan	75 mg	Film-coated tablet	Oral use
United Kingdom	HEC Pharm GmbH		Irbesartan 150 mg Film-coated tablets	irbesartan	150 mg	Film-coated tablet	Oral use
United Kingdom	HEC Pharm GmbH		Irbesartan 300 mg Film-coated tablets	irbesartan	300 mg	Film-coated tablet	Oral use
United Kingdom	Strides Arcolab International Limited		Omega 3-acid-ethyl esters 1000 mg soft capsules	omega-3-acid-ethyl esters 90	1000 mg	Capsule, soft	Oral use
United Kingdom	Dawa Limited		Paracetamol 500 mg Film-Coated Tablets	paracetamol	500 mg	Film-coated tablet	Oral use
United Kingdom	Lupin (Europe) Limited		Maexeni 150/30 microgram Film-Coated Tablets	ethinylestradiol/levonorgestrel	0,03 mg/ 0,125 mg	Film-coated tablet	Oral use
United Kingdom	Kinedexe UK Limited (previously NRIM Limited)		Sodium Cromoglicate 100 mg hard Capsules	sodium cromoglicate	100 mg	Capsule, hard	Oral use
United Kingdom	Milpharm Limited		Tadalafil Milpharm 20 mg film-coated tablets	tadalafil	20 mg	Film-coated tablet	Oral use
United Kingdom		Crescent Pharma Limited	Aripiprazole 5 mg tablets	aripiprazole	5 mg	Tablet	Oral use
United Kingdom		Crescent Pharma Limited	Aripiprazole 10 mg tablets	aripiprazole	10 mg	Tablet	Oral use
United Kingdom		Crescent Pharma Limited	Aripiprazole 15 mg tablets	aripiprazole	15 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
United Kingdom		Crescent Pharma Limited	Aripiprazole 30 mg tablets	aripiprazole	30 mg	Tablet	Oral use
United Kingdom		Medreich PLC	Gliclazide 40 mg tablets	gliclazide	40 mg	Tablet	Oral use
United Kingdom	Medreich PLC		Hydroxyzine hydrochloride 25 mg film-coated tablets	hydroxyzine hydrochloride	25 mg	Film-coated tablet	Oral use
United Kingdom		Alissa Healthcare Research Limited	Carbocisteine 375 mg Capsules, Hard	carbocisteine	375 mg	Capsule, hard	Oral use
United Kingdom		Special Concept Development (UK) Limited	Metformin 500 mg Film-coated tablet	metformin hydrochloride	500 mg	Film-coated tablet	Oral use
United Kingdom		Special Concept Development (UK) Limited	Metformin 850 mg Film-coated tablet	metformin hydrochloride	850 mg	Film-coated tablet	Oral use
United Kingdom		Special Concept Development (UK) Limited	Metformin 1000 mg Film-coated tablet	metformin hydrochloride	1000 mg	Film-coated tablet	Oral use
United Kingdom		Special Concept Development (UK) Limited	Paracetamol 500 mg Tablets	paracetamol	500 mg	Tablet	Oral use
United Kingdom		Special Concept Development (UK) Limited	Paracetamol 1000 mg Tablets	paracetamol	1000 mg	Tablet	Oral use
United Kingdom		Special Concept Development (UK) Limited	Paracetamol 500 mg Tablets	paracetamol	500 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
United Kingdom		Special Concept Development (UK) Limited	Paracetamol 1000 mg Tablets	paracetamol	1000 mg	Tablet	Oral use
United Kingdom		Flamingo Pharma (UK) Limited	Gliclazide 80 mg Tablets	gliclazide	80 mg	Tablet	Oral use
United Kingdom		Flamingo Pharma (UK) Limited	Gliclazide 40 mg Tablets	gliclazide	40 mg	Tablet	Oral use
United Kingdom		HBS Healthcare Limited	Carbimazole 20 mg Tablets	carbimazole	20 mg	Tablet	Oral use
United Kingdom	Strides Arcolab International Limited		Omega 3-acid-ethyl esters 1000 mg soft capsules	omega-3-acid-ethyl esters 90	1000 mg	Capsule, soft	Oral use
United Kingdom		Generic Partners UK Limited	Vzole 50 mg film-coated tablets	voriconazol	50 mg	Tablet	Oral use
United Kingdom		Generic Partners UK Limited	Vzole 200 mg film-coated tablets	voriconazol	200 mg	Tablet	Oral use
United Kingdom		Dawa Limited	Carbimazole 5 mg Tablets	carbimazole	5 mg	Tablet	Oral use
United Kingdom		Dawa Limited	Carbimazole 20 mg Tablets	carbimazole	20 mg	Tablet	Oral use
United Kingdom		Essential-Healthcare Limited	Carbimazole 5 mg Tablets	carbimazole	5 mg	Tablet	Oral use
United Kingdom		Essential-Healthcare Limited	Carbimazole 20 mg Tablets	carbimazole	20 mg	Tablet	Oral use

ANNEX II

List of medicinal products and presentations

Member State EU/EEA	Marketing authorisation holder	Invented Name	Strength	Pharmaceutical form	Route of administration
France	Bristol-Myers Squibb 3, Rue Joseph Monier — BP 325, Rueil-Malmaison, 92506, France	Etopophos	100 mg	Powder for Solution for Injection	Intravenous Use
Germany	Bristol-Myers Squibb GmbH & Co. KGaA Arnulfstrasse 29, München, 80636,Germany	Etopophos	100 mg	Powder for Solution for Infusion	Intravenous Use
Germany	Bristol-Myers Squibb GmbH & Co. KGaA Arnulfstrasse 29, München, 80636,Germany	Etopophos	1000 mg	Powder for Solution for Infusion	Intravenous Use
Sweden	Bristol-Myers Squibb AB BOX 1172, 171 23 Solna, Sweden	Etopofos	100 mg	Powder for Solution for Infusion	Intravenous Use
United Kingdom	Bristol-Myers Squibb Pharmaceuticals Limited Uxbridge Business Park, Sanderson Road, Uxbridge, UB8 1 DH, United Kingdom	Etopophos	100 mg	Powder for Solution for Injection	Intravenous Use

ANNEX III

List of medicinal products and presentations

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical form	Route of administration
Austria	Bristol-Myers Squibb GesmbH Rivergate/Gate 1/5.OG, Handelskai 92, 1200 Vienna, Austria	Vepesid	100 mg	Capsule	Oral Use
Belgium	Bristol-Myers Squibb Belgium S.A. Chaussée De La Hulpe, 185, 1170 Bruxelles, Belgium	Vepesid	100 mg	Capsule, Soft	Oral Use
Croatia	Bristol-Myers Squibb spol. s.r.o. Budějovická 778/3, Michle, 140 00 Prague, Czech Republic	Vepesid	100 mg	Capsule, Soft	Oral Use
Denmark	Bristol-Myers Squibb AB BOX 1172, 171 23 Solna, Sweden	Vepesid	50 mg	Capsule, soft	Oral Use
Estonia	Bristol-Myers Squibb Gyogyszerkereskedelmi Kft. Lövőház u. 39, 1024 Budapest, Hungary	Vepesid	100 mg	Capsule, Soft	Oral Use
Finland	Bristol-Myers Squibb AB BOX 1172, 171 23 Solna, Sweden	Vepesid	50 mg	Capsule, Soft	Oral Use
Germany	Bristol-Myers Squibb GmbH & Co. KGaA Arnulfstrasse 29, München, 80636,Germany	Vepesid K	50 mg	Capsule	Oral Use
Germany	Bristol-Myers Squibb GmbH & Co. KGaA Arnulfstrasse 29, München, 80636,Germany	Vepesid K	100 mg	Capsule	Oral Use
Ireland	Bristol-Myers Squibb Holdings Limited t/a Bristol-Myers Pharmaceuticals, Swords, County Dublin, Ireland	Vepesid	50 mg	Capsules, Soft	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical form	Route of administration
Ireland	Bristol-Myers Squibb Holdings Limited t/a Bristol-Myers Pharmaceuticals, Swords, County Dublin, Ireland	Vepesid	100 mg	Capsules, Soft	Oral Use
Italy	Bristol-Myers Squibb S.R.L. Via Virgilio Maroso, 50, 00142 Rome, Italy	Vepesid	50 mg	Capsule, Soft	Oral Use
Italy	Bristol-Myers Squibb S.R.L. Via Virgilio Maroso, 50, 00142 Rome, Italy	Vepesid	100 mg	Capsule, Soft	Oral Use
Luxembourg	Bristol-Myers Squibb Belgium S.A. Chaussée De La Hulpe, 185, 1170 Bruxelles, Belgium	Vepesid	100 mg	Capsule, Soft	Oral Use
Netherlands	Bristol-Myers Squibb B.V. Orteliuslaan 1000, 3528 BD Utrecht, The Netherlands	Vepesid	50 mg	Capsule, Soft	Oral Use
Netherlands	Bristol-Myers Squibb B.V. Orteliuslaan 1000, Utrecht, 3528 BD, The Netherlands	Vepesid	100 mg	Capsule, Soft	Oral Use
Norway	Bristol-Myers Squibb AB BOX 1172, 171 23 Solna, Sweden	Vepesid	50 mg	Capsule, Soft	Oral Use
Romania	Bristol-Myers Squibb Gyogyszerkereskedelmi Kft. Lövőház u. 39, 1024 Budapest, Hungary	Vepesid	50 mg	Capsule, Soft	Oral Use
Romania	Bristol-Myers Squibb Gyogyszerkereskedelmi Kft. Lövőház u. 39, 1024 Budapest, Hungary	Vepesid	100 mg	Capsule, Soft	Oral Use
Slovenia	Bristol-Myers Squibb spol. s.r.o. Budějovická 778/3, Michle 140 00 Prague 4, Czech Republic	Vepesid	100 mg	Capsule, Soft	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical form	Route of administration
Spain	Bristol-Myers Squibb S.A. C/Quintanavides, 15, 28050 Madrid, Spain	Vepesid	50 mg	Capsule, Soft	Oral Use
Spain	Bristol-Myers Squibb S.A. C/Quintanavides, 15, 28050 Madrid, Spain	Vepesid	100 mg	Capsule, Soft	Oral Use
Sweden	Bristol-Myers Squibb AB BOX 1172, 171 23 Solna, Sweden	Vepesid	50 mg	Capsule, Soft	Oral Use
United Kingdom	Bristol-Myers Squibb Holdings Limited t/a Bristol-Myers Pharmaceuticals Uxbridge Business Park, Sanderson Road, Uxbridge, UB8 1 DH, United Kingdom	Vepesid	50 mg	Capsule, Soft	Oral Use
United Kingdom	Bristol-Myers Squibb Holdings Limited t/a Bristol-Myers Pharmaceuticals Uxbridge Business Park, Sanderson Road, Uxbridge, UB8 1 DH, United Kingdom	Vepesid	100 mg	Capsule, Soft	Oral Use

ANNEX IV

List of the names, pharmaceutical forms, strengths of the veterinary medicinal products, animal species, route of administration, applicants and marketing authorisation holders in the Member States

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Austria	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Gutal 1000 mg/g Arzneimittel-Vormischung zur Herstellung von Futterungsarzneimitteln für Ferkel	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Belgium	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Gutal 1000 mg/g premix voor gemedicineerd voeder	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Bulgaria	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Gutal 1000 mg/g premix for medicated feeding stuff for piglets	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Bulgaria	Andrés Pintaluba, S.A. Pol. Ind. Agro-Reus C/Prudenci Bertrana 5 43206 Reus (Tarragona) Spain	ZINCOPREMIX 1000 mg/g	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Cyprus	Laboratorios Calier, S.A. C/Barcelonès, 26 Pla del Ramassà Les Franqueses del Vallès 08520 Barcelona Spain	OXIDO DE ZINC CALIER 1000 mg/g, πρόμιγμα για φαρμακούχο ζωοτροφή για χοίρους	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Cyprus	Andrés Pintaluba, S.A. Pol. Ind. Agro-Reus C/Prudenci Bertrana 5 43206 Reus (Tarragona) Spain	ZINCOPREMIX 1000 MG/G πρόμιγμα για φαρμακούχο ζωοτροφή για χοίρους	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Cyprus	Vetpharma Animal Health, S.L. C/Les Corts, 23. 08028 Barcelona Spain	ZINTESTIN 1000 MG/G πρόμιγμα για φαρμακούχο ζωοτροφή για χοίρους	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Czech Republic	Trouw Nutrition Biofaktory s.r.o. Na Chvalce 2049 193 00 Praha 9 Horní Počernice Czech Republic	BIOZINK 600 mg/g premix pro medikaci krmiva pro selata	Zinc oxide	600 mg/g	Premix	Pigs (piglets)	Oral
Czech Republic	Tekro, spol. s r.o. Višňová 2/484 140 00 Praha 4 Czech Republic	MEDITEK Zn 500 mg/g perorální prášek	Zinc oxide	622 mg/g	Oral powder	Pigs (piglets)	Oral
Czech Republic	Tekro, spol. s r.o. Višňová 2/484 140 00 Praha 4 Czech Republic	MEDITEK Zn 500 mg/g premix pro medikaci krmiva	Zinc oxide	622 mg/g	Premix	Pigs (piglets)	Oral
Czech Republic	MIKROP ČEBÍN a.s. Čebín 416 664 23 Čebín Czech Republic	MIKROP — VLP ZINEK premix	Zinc oxide	492 mg/g	Premix	Pigs (piglets)	Oral

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Czech Republic	Andrés Pintaluba, S.A. Pol. Ind. Agro-Reus C/Prudenci Bertrana 5 43206 Reus (Tarragona) Spain	ZINCOPREMIX 1000 mg/g premix pro medikaci krmiva pro prasata	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Denmark	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Gutal	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Denmark	Vepidan ApS Østerbrogade 23 DK-9670 Løgstør Denmark	VetZink	Zinc oxide	1000 mg/g	Oral powder	Pigs (piglets)	Oral
Denmark	Vepidan ApS Østerbrogade 23 DK-9670 Løgstør Denmark	VetZink	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Denmark	Vilofarm A/S Sjellebrovej 10 DK-8544 Mørke Denmark	Vilocare	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Denmark	Vilofarm A/S Søagervej 9, Sdr. Onsild DK-9500 Hobro Denmark	Zicare	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Denmark	Vilofarm A/S Søagervej 9, Sdr. Onsild DK-9500 Hobro Denmark	Zicare	Zinc oxide	1000 mg/g	Oral powder	Pigs (piglets)	Oral
Denmark	ScanVet Animal Health A/S Kongevejen 66 DK-3480 Fredensborg Denmark	Zingovet	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Denmark	ScanVet Animal Health A/S Kongevejen 66 DK-3480 Fredensborg Denmark	Zingovet	Zinc oxide	1000 mg/g	Oral powder	Pigs (piglets)	Oral
Denmark	Vepidan ApS Østerbrogade 23 DK-9670 Løgstør Denmark	Zinkoxid Vepidan	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Estonia	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Gutal	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Finland	Vepidan ApS Østerbrogade 23 DK-9670 Løgstør Denmark	Vetzin vet. 1000 mg/g esisekoite lääkerehua varten	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
France	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	GUTAL PREMELANGE MEDICAMENTEUX POUR PORCELETS	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Germany	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Gutal	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Germany	aniMedica GmbH Im Südfeld 9 D-48308 Senden-Bösensell Germany	Enteroxid N AMV aniMedica	Zinc oxide Colistin sulfate	480 mg/g 25 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Germany	aniMedica GmbH Im Südfeld 9 D-48308 Senden-Bösensell Germany	aniMedica Enteroxid N	Zinc oxide Colistin sulfate	480 mg/g 25 mg/g	Powder for oral administration	Pigs (piglets)	Oral
Hungary	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Gutal 1000 mg/g gyógypremix malacok számára A.U.V.	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Hungary	Andrés Pintaluba, S.A. Pol. Ind. Agro-Reus C/Prudenci Bertrana 5 43206 Reus (Tarragona) Spain	ZINCOPREMIX 1000 mg/g gyógypremix sertések számára A.U.V.	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Hungary	Sintofarm S.p.A. Via Togliatti 5 42016 Guastalla (RE) Italy	ZINCOSINT G 1000 mg/g gyógypremix sertések részére A.U.V.	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Hungary	Dunavet-B Zrt. Dolgos u. 2 1126 Budapest Hungary	Zintestin Forte 1000 mg/g gyógypremix sertések részére A.U.V.	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Iceland	Vepidan ApS Østerbrogade 23 DK-9670 Løgstør Denmark	VetZin	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Ireland	DSM Nutritional Products (UK) Limited Delves Road Heanor Gate Industrial Estate Heanor Derbyshire, DE75 7SG United Kingdom	Pigzin Premix, 100 % w/w Premix for medicated feeding stuff.	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Ireland	Provimi Limited Eastern Avenue Lichfield Staffordshire WS13 7SE United Kingdom	ZincoTec — Zinc Oxide 100 % Premix for medicated Feeding Stuff.	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Ireland	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Gutal 1000 mg/g premix for medicated feeding stuff for piglets	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Italy	Laboratorios Calier, S.A. C/Barcelonès, 26 Pla del Ramassà Les Franqueses del Vallès 08520 Barcelona Spain	OXIDO DE ZINC	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Italy	Vetpharma Animal Health, S.L. C/Les Corts, 23. 08028 Barcelona Spain	ZINTESTIN	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Italy	Sintofarm S.p.A. Via Togliatti 5 42016 Guastalla (RE) Italy	ZINCOFARM G	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Italy	Andrés Pintaluba, S.A. Pol. Ind. Agro-Reus C/Prudenci Bertrana 5 43206 Reus (Tarragona) Spain	ZINCOPREMIX	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	GUTAL 1000 mg/g	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Latvia	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Gutal	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Lithuania	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	GUTAL 1 000 mg/g, vaistinis premiksas paršeliams	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
The Netherlands	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	GUTAL 1000 mg/g premix for piglets	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Norway	Vepidan ApS Østerbrogade 23 DK-9670 Løgstør Denmark	VetZin	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Poland	Vetoquinol Biowet Sp. z o. o. ul. Kosynierów Gdyńskich 13-14 66-400 Gorzów Wielkopolski Poland	Suibicol Premiks (30 g + 18,45 g)/100 g premiks do sporządzania paszy leczniczej dla świń	Zinc oxide Sulfaguanidinum	30 g/100 g 18,45 g/100 g	Premix for medicated feeding stuff	Pigs (piglets)	Oral

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Poland	Laboratorios Calier, S.A. C/Barcelonès, 26 Pla del Ramassà Les Franqueses del Vallès 08520 Barcelona Spain	Tlenek cynku Calier 1000 mg/1 g, premiks do sporządzania paszy leczniczej dla świń	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Poland	Andrés Pintaluba, S.A. Pol. Ind. Agro-Reus C/Prudenci Bertrana 5 43206 Reus (Tarragona) Spain	Zincopremix 1000 mg/g premiks do sporządzania paszy leczniczej dla świń	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Poland	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Gutal 1000 g/kg premix for medicated feeding staff	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Poland	Vetoquinol Biowet Sp. z o. o. ul. Kosynierów Gdyńskich 13-14 66-400 Gorzów Wielkopolski Poland	Suibicol proszek	Zinc oxide Sulfaguanidine	30 g/100 g 18,45 g/100 g	Oral powder	Pigs (piglets)	Oral
Portugal	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Gutal 1000 mg/g premix for medicated feeding stuff for piglets	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Portugal	Andrés Pintaluba, S.A. Pol. Ind. Agro-Reus C/Prudenci Bertrana 5 43206 Reus (Tarragona) Spain	APSAMIX ZINC 1000 mg/g medicated premix for pigs	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Portugal	CALIER PORTUGAL, S.A. Centro Empresarial Sintra-Estoril II, Ed. C, R. Pé de Mouro Estrada de Albarraque 2710 — 335 Sintra Portugal	OXIDO DE ZINCO CALIER 1000 mg/g Pré-mistura medicamentosa para suínos (leitões)	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Portugal	Vetlima S.A. Centro Empresarial da Rainha, Lote 27 2050-501 Vila Nova da Rainha Portugal	Vetazinco 1000 mg/g Prémistura medicamentosa para suínos (leitões)	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Romania	Andrés Pintaluba, S.A. Pol. Ind. Agro-Reus C/Prudenci Bertrana 5 43206 Reus (Tarragona) Spain	Zincopremix 1000 mg/g premix pentru furaje medicamentate la porcine	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Romania	Sintofarm S.p.A. Via Togliatti 5 42016 Guastalla (RE) Italy	Zincosint G 1000 mg/g premix pentru furaje medicamentate la porcine	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Romania	S.C. CRIDA PHARM S.R.L. 2 Intrarea Vagonetului, Bl. 101, Ap. 47 sector 6, Bucharest Romania	Colistop premix 1000 mg/g premix medicamentat pentru purcei dupa intarcare	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Slovak Republic	Andrés Pintaluba, S.A. Pol. Ind. Agro-Reus C/Prudenci Bertrana 5 43206 Reus (Tarragona) Spain	Zincopremix 1000 mg/g premix na medikovanie kŕmnej zmesi pre ošípané	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Slovak Republic	Tekro, spol. s r.o. Višňová 2/484 140 00 Praha 4 Czech Republic	Tekrozink 500 mg/g perorálny prášok	Zinc oxide	622 mg/g (500 mg zinc/g)	Pulvis for oral use	Pigs (piglets)	Oral
Slovak Republic	Tekro, spol. s r.o. Višňová 2/484 140 00 Praha 4 Czech Republic	Tekrozink 500 mg/g premix na medikáciu krmiva	Zinc oxide	622 mg/g (500 mg zinc/g)	Premix for medicated feedingstuff	Pigs (piglets)	Oral
Slovak Republic	Trouw Nutrition Biofaktory s.r.o. Na Chvalce 2049 193 00 Praha 9 Horní Počernice Czech Republic	Biozink 600 mg/g premix na medikáciu krmiva	Zinc oxide	600 mg/g	Premix for medicated feedingstuff	Pigs (piglets)	Oral

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Slovenia	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Gutal 1000 mg/g predmešanica za pripravo zdravilne krmne mešanice za pujske	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Spain	Industrial Veterinaria, S.A. Esmeralda, 19 E-08950 Esplugues de Llobregat (Barcelona) Spain	ZETAPREX	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Spain	Andrés Pintaluba, S.A. Pol. Ind. Agro-Reus C/Prudenci Bertrana 5 43206 Reus (Tarragona) Spain	ZINCOPREMIX 1000 MG/G	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Spain	Laboratorios Support Pharma, S.L. General Alvarez de Castro, 39 28010 Madrid Spain	ZINCOSINT G 100 MG/G PREMIX	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Spain	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Gutal 1.000 mg/g premezcla medicamentosa para lechones	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Laboratorios Calier, S.A. C/Barcelonès, 26 Pla del Ramassà Les Franqueses del Vallès 08520 Barcelona Spain	ÓXIDO DE ZINC CALIER 1000 mg/g PREMEZCLA MEDICAMENTOSA PARA CERDOS	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Spain	Vetpharma Animal Health, S.L. C/Les Corts, 23. 08028 Barcelona Spain	ZINTESTIN 1000 mg/g Premezcla medicamentosa para porcino	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Spain	Andrés Pintaluba, S.A. Pol. Ind. Agro-Reus C/Prudenci Bertrana 5 43206 Reus (Tarragona) Spain	APSAMIX ZINC 1000 mg/g premezcla medicamentosa para porcino	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Spain	Andrés Pintaluba, S.A. Pol. Ind. Agro-Reus C/Prudenci Bertrana 5 43206 Reus (Tarragona) Spain	ZINCOTRAX	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
Sweden	Vepidan ApS Østerbrogade 23 DK-9670 Løgstør Denmark	Vetzin vet	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Sweden	Biovet ApS Kongevejen 66 3480 Fredensborg Denmark	Zingovet	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
United Kingdom	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Gutal 1000 mg/g premix for medicated feeding stuff for piglets	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
United Kingdom	DSM Nutritional Products (UK) Limited Delves Road Heanor Gate Industrial Estate Heanor Derbyshire, DE75 7SG United Kingdom	Pigzin Premix, 100 % w/w Premix for Medicated Feeding Stuff	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral
United Kingdom	SCA NuTec (Provimi Ltd) Eastern Avenue Lichfield Staffordshire WS13 7SE United Kingdom	ZincoTec Zinc Oxide 100 % Premix for Medicated Feeding Stuff	Zinc oxide	1000 mg/g	Premix for medicated feeding stuff	Pigs (piglets)	Oral

ANNEX V

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, Marketing Authorisation Holders in the Member States

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Austria	Janssen-Cilag Pharma GmbH Vorgartenstraße 206B AT-1020 Vienna Austria	Haldol	2 mg/ml	Oral solution	Oral use	2 mg/ml
Austria	Janssen-Cilag Pharma GmbH Vorgartenstraße 206B AT-1020 Vienna Austria	Haldol	150 mg/30 ml	Solution for injection	Intramuscular use	5 mg/ml
Austria	Janssen-Cilag Pharma GmbH Vorgartenstraße 206B AT-1020 Vienna Austria	Haldol	1 mg	Tablet	Oral use	N/A
Austria	Janssen-Cilag Pharma GmbH Vorgartenstraße 206B AT-1020 Vienna Austria	Haldol	10 mg	Tablet	Oral use	N/A
Belgium	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	30 mg/15 ml	Oral solution	Oral use	2 mg/ml
Belgium	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	60 mg/30 ml	Oral solution	Oral use	2 mg/ml

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Belgium	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	200 mg/100 ml	Oral solution	Oral use	2 mg/ml
Belgium	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	300 mg/30 ml	Oral solution	Oral use	10 mg/ml
Belgium	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	1000 mg/100 ml	Oral solution	Oral use	10 mg/ml
Belgium	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	5 mg/ml	Solution for injection	Intramuscular use; Intravenous use	5 mg/ml
Belgium	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	2 mg	Tablet	Oral use	N/A
Belgium	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	5 mg	Tablet	Oral use	N/A
Belgium	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	20 mg	Tablet	Oral use	N/A

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Cyprus	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, Belgium	Haldol	30 mg/15 ml	Oral solution	Oral use	2 mg/ml
Cyprus	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, Belgium	Haldol	5 mg/ml	Solution for injection	Intramuscular use	5 mg/ml
Cyprus	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, Belgium	Haldol	5 mg	Tablet	Oral use	N/A
Denmark	JANSSEN-CILAG A/S Bregnerødvej 133 3460 Birkerød Denmark	Serenase	2 mg/ml	Oral solution	Oral use	2 mg/ml
Denmark	JANSSEN-CILAG A/S Bregnerødvej 133 3460 Birkerød Denmark	Serenase	5 mg/ml	Solution for injection	Intramuscular use; Intravenous use	5 mg/ml
Denmark	JANSSEN-CILAG A/S Bregnerødvej 133 3460 Birkerød Denmark	Serenase	2 mg	Tablet	Oral use	N/A
Denmark	JANSSEN-CILAG A/S Bregnerødvej 133 3460 Birkerød Denmark	Serenase	5 mg	Tablet	Oral use	N/A

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Denmark	JANSSEN-CILAG A/S Bregnerødvej 133 3460 Birkerød Denmark	Serenase	20 mg	Tablet	Oral use	N/A
Finland	Janssen-Cilag Oy Vaisalantie 2 02130 Espoo Finland	Serenase	2 mg/ml	Oral solution	Oral use	2 mg/ml
Finland	Janssen-Cilag Oy Vaisalantie 2 02130 Espoo	Serenase	5 mg/ml	Solution for injection	Intramuscular use	5 mg/ml
Finland	Janssen-Cilag Oy Vaisalantie 2 02130 Espoo Finland	Serenase	1 mg	Tablet	Oral use	N/A
Finland	Janssen-Cilag Oy Vaisalantie 2 02130 Espoo Finland	Serenase	4 mg	Tablet	Oral use	N/A
Finland	Janssen-Cilag Oy Vaisalantie 2 02130 Espoo Finland	Serenase	10 mg	Tablet	Oral use	N/A

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
France	Janssen-Cilag 1, rue Camille Desmoulins, TSA 91003 F-92787 Issy Les Moulineaux, Cedex 9 France	Haldol	2 mg/ml in bottles of 15 ml, 30 ml, 100 ml and 195 ml	Oral solution	Oral use	2 mg/ml
France	Janssen-Cilag 1, rue Camille Desmoulins, TSA 91003 F-92787 Issy Les Moulineaux, Cedex 9 France	Haldol	5 mg/ml	Solution for injection	Intramuscular use	5 mg/ml
France	Janssen-Cilag 1, rue Camille Desmoulins, TSA 91003 F-92787 Issy Les Moulineaux, Cedex 9 France	Haldol	1 mg	Tablet	Oral use	N/A
France	Janssen-Cilag 1, rue Camille Desmoulins, TSA 91003 F-92787 Issy Les Moulineaux, Cedex 9 France	Haldol	5 mg	Tablet	Oral use	N/A
Germany	Janssen-Cilag GmbH Johnson & Johnson Platz 1 41470 Neuss Germany	Haldol-Janssen	2 mg/ml in bottles of 30 ml and 100 ml)	Oral solution	Oral use	2 mg/ml
Germany	Janssen-Cilag GmbH Johnson & Johnson Platz 1 41470 Neuss Germany	Haldol-Janssen	5 mg/ml	Solution for injection	Intramuscular use	5 mg/ml
Germany	Janssen-Cilag GmbH Johnson & Johnson Platz 1 41470 Neuss Germany	Haldol-Janssen	1 mg	Tablet	Oral use	N/A

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Germany	Janssen-Cilag GmbH Johnson & Johnson Platz 1 41470 Neuss Germany	Haldol-Janssen	2 mg	Tablet	Oral use	N/A
Germany	Janssen-Cilag GmbH Johnson & Johnson Platz 1 41470 Neuss Germany	Haldol-Janssen	5 mg	Tablet	Oral use	N/A
Germany	Janssen-Cilag GmbH Johnson & Johnson Platz 1 41470 Neuss Germany	Haldol-Janssen	10 mg	Tablet	Oral use	N/A
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave, Pefki Athens GR-151 21 Greece	Aloperidin	30 mg/15 ml	Oral Drops, Solution	Oral use	2 mg/ml
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave, Pefki Athens GR-151 21 Greece	Aloperidin	150 mg/15 ml 300 mg/30 ml	Oral Drops, Solution	Oral use	10 mg/ml
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave, Pefki Athens GR-151 21 Greece	Aloperidin	5 mg/ml (BTx5AMP x1ML, BTx50AMP x1ML)	Solution for injection	Intramuscular use	5 mg/ml

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave, Pefki, Athens GR-151 21 Greece	Aloperidin	1 mg	Tablet	Oral use	N/A
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave, Pefki, Athens GR-151 21 Greece	Aloperidin	2 mg	Tablet	Oral use	N/A
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave, Pefki, Athens GR-151 21 Greece	Aloperidin	5 mg	Tablet	Oral use	N/A
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave, Pefki, Athens GR-151 21 Greece	Aloperidin	10 mg	Tablet	Oral use	N/A
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. 56 Eirinis Ave, Pefki, Athens GR-151 21 Greece	Aloperidin	20 mg	Tablet	Oral use	N/A
Iceland	Janssen-Cilag AB Box 4042 16904 Solna Sweden	Haldol	5 mg/ml	Solution for injection	Intramuscular use	5 mg/ml

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Iceland	Janssen-Cilag AB Box 4042 16904 Solna Sweden	Haldol	1 mg	Tablet	Oral use	N/A
Iceland	Janssen-Cilag AB Box 4042 16904 Solna Sweden	Haldol	4 mg	Tablet	Oral use	N/A
Italy	Janssen-Cilag SpA Via M.Buonarroti, 23 I-20093 Cologno Monzese MI, Italy	Haldol	60 mg/30 ml	Oral drops,	Oral use	2 mg/ml
Italy	Janssen-Cilag SpA Via M.Buonarroti, 23 I-20093 Cologno Monzese MI, Italy	Haldol	300 mg/30 ml	Oral drops, solution	Oral use	10 mg/ml
Italy	Janssen-Cilag SpA Via M.Buonarroti, 23 I-20093 Cologno Monzese MI, Italy	Haldol	5 mg/ml	Solution for injection	Intramuscular use	5 mg/ml
Italy	Janssen-Cilag SpA Via M.Buonarroti, 23 I-20093 Cologno Monzese MI, Italy	Haldol	1 mg	Tablet	Oral use	N/A

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Italy	Janssen-Cilag SpA Via M.Buonarroti, 23 I-20093 Cologno Monzese MI, Italy	Haldol	5 mg	Tablet	Oral use	N/A
Luxembourg	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	30 mg/15 ml	Oral solution	Oral use	2 mg/ml
Luxembourg	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	60 mg/30 ml	Oral solution	Oral use	2 mg/ml
Luxembourg	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	200 mg/100 ml	Oral solution	Oral use	2 mg/ml
Luxembourg	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	300 mg/30 ml	Oral solution	Oral use	10 mg/ml
Luxembourg	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	1000 mg/100 ml	Oral solution	Oral use	10 mg/ml

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Luxembourg	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	5 mg/ml	Solution for injection	Intramuscular use; Intravenous use	5 mg/ml
Luxembourg	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	2 mg	Tablet	Oral use	N/A
Luxembourg	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	5 mg	Tablet	Oral use	N/A
Luxembourg	Janssen-Cilag NV Antwerpseweg 15-17 B-2340 Beerse Belgium	Haldol	20 mg	Tablet	Oral use	N/A
Malta	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse Belgium	Haldol	5 mg	Tablet	Oral use	N/A
The Netherlands	Janssen-Cilag BV Dr. Paul Janssenweg 150 5026 RH Tilburg The Netherlands	Haldol druppels 2 mg/ml	60 mg/30 ml	Oral solution	Oral use	2 mg/ml
The Netherlands	Janssen-Cilag BV Dr. Paul Janssenweg 150 5026 RH Tilburg The Netherlands	Haldol oplossing voor injectie 5 mg/ml	5 mg/ml	Solution for injection	Intramuscular use; Intravenous use	5 mg/ml

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
The Netherlands	Janssen-Cilag BV Dr. Paul Janssenweg 150 5026 RH Tilburg The Netherlands	Haldol tabletten 10 mg	10 mg	Tablet	Oral use	N/A
Norway	JANSSEN-CILAG AS Drammensveien 288 0283 Oslo Norway	Haldol	5 mg/ml	Solution for injection	Intramuscular use	5 mg/ml
Norway	JANSSEN-CILAG AS Drammensveien 288 0283 Oslo Norway	Haldol	1 mg	Tablet	Oral use	N/A
Norway	JANSSEN-CILAG AS Drammensveien 288 0283 Oslo Norway	Haldol	4 mg	Tablet	Oral use	N/A
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A, Queluz de Baixo 2734 503 Barcarena Portugal	Haldol	2 mg/ml	Oral solution	Oral use	2 mg/ml
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A, Queluz de Baixo 2734 503 Barcarena Portugal	Haldol	1 mg	Tablet	Oral use	N/A
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A, Queluz de Baixo 2734 503 Barcarena Portugal	Haldol	2 mg	Tablet	Oral use	N/A

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A, Queluz de Baixo 2734 503 Barcarena Portugal	Haldol	5 mg	Tablet	Oral use	N/A
Portugal	Janssen Farmacêutica Portugal, Lda. Estrada Consiglieri Pedroso, 69 A, Queluz de Baixo 2734 503 Barcarena Portugal	Haldol	10 mg	Tablet	Oral use	N/A
Romania	Janssen Pharmaceutica N.V. Turnhoutseweg 30, B-2340 Beerse Belgium	Haldol	5 mg	Tablet	Oral use	N/A
Sweden	Janssen-Cilag AB Box 4042 16904 Solna Sweden	Haldol	200 mg/100 ml	Oral solution	Oral use	2 mg/ml
Sweden	Janssen-Cilag AB Box 4042 16904 Solna Sweden	Haldol	5 mg/ml	Solution for injection	Intramuscular use	5 mg/ml
Sweden	Janssen-Cilag AB Box 4042 16904 Solna Sweden	Haldol	1 mg	Tablet	Oral use	NA
Sweden	Janssen-Cilag AB Box 4042 16904 Solna Sweden	Haldol	4 mg	Tablet	Oral use	NA

Member State EU/EEA	Marketing authorisation holder	Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
United Kingdom	Janssen-Cilag Limited 50-100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG United Kingdom	Haldol	2 mg/ml	Oral solution	Oral use	N/A
United Kingdom	Janssen-Cilag Limited 50-100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG United Kingdom	Haldol	5 mg/ml	Solution for injection	Intramuscular use	5 mg/ml
United Kingdom	Janssen-Cilag Limited 50-100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG United Kingdom	Haldol	10 mg/2 ml	Solution for injection	Intramuscular use	5 mg/ml

ANNEX VI

List of the names, pharmaceutical forms, strengths of the veterinary medicinal products, animal species, routes of administration, applicant/marketing authorisation holder in the Member States

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Pharmaceutical form	Strength	Animal species	Route of administration
France	Zoetis France 23-25 Avenue du Dr Lannelongue 75014 Paris France	SOLU-MEDROL 120 MG	Methylprednisolone hydrogen succinate	Lyophilisate and diluent for solution for injection	120 mg per bottle	Cattle, cats, dogs	Intramuscular or intravenous
France	Zoetis France 23-25 Avenue du Dr Lannelongue 75014 Paris France	SOLU-MEDROL 500 MG	Methylprednisolone hydrogen succinate	Lyophilisate and diluent for solution for injection	500 mg per bottle	Cattle, cats, dogs	Intramuscular or intravenous
Germany ([1])	CP-Pharma Handelsgesellschaft mbH Ostlandring 13 D-31303 Burgdorf Germany	Solupred 125 mg Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	Methylprednisolone hydrogen succinate	Powder and solvent	500 mg per bottle	Cattle, cats, dogs	Intramuscular or intravenous

([1]) Marketing authorisation not granted for target species cattle.