C/2024/7476

30.12.2024

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 November 2024 to 30 November 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/2024/7476)

— **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
22.11.2024	Metamizole	metamizole	See Annex	See Annex	25.11.2024

[1] OJ L 311, 28.11.2001, p. 67, ELI: https://data.europa.eu/eli/dir/2001/83/oj.
[2] OJ L 311, 28.11.2001, p. 1, ELI: https://data.europa.eu/eli/dir/2001/82/oj.
[3] OJ L 4, 7.1.2019, p. 43, ELI: https://data.europa.eu/eli/reg/2019/6/oj.

ANNEX

List of medicinal products and presentations

Member State in EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Austria	+pharma Arzneimittel Gmbh	Metamizol +pharma	metamizole	1 000mg	Film-coated tablet	Oral use
Austria	G.L. Pharma Gmbh	Metagelan	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Austria	G.L. Pharma Gmbh	Metagelan	metamizole	500mg	Film-coated tablet	Oral use
Austria	G.L. Pharma Gmbh	Metagelan	metamizole	500mg/ml	Oral drops, solution	Oral use
Austria	G.L. Pharma Gmbh	Metagelan	metamizole	500mg	Tablet	Oral use
Austria	Genericon Pharma Gesellschaft M.B.H.	Novakut	metamizole	1 000mg	Film-coated tablet	Oral use
Austria	Hcs Bvba	Metamizol Hcs	metamizole	500mg/ml	Solution for injection/ infusion	Intramuscular use | intravenous use
Austria	Kalceks	Metamizol Kalceks	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Austria	Opella Healthcare Austria Gmbh	Novalgin	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Austria	Opella Healthcare Austria Gmbh	Novalgin	metamizole	500mg	Film-coated tablet	Oral use
Austria	Opella Healthcare Austria Gmbh	Novalgin	metamizole	500mg/ml	Oral drops, solution	Oral use
Belgium	Opella Healthcare Belgium (Handelsnaam Sanofi Belgium)	Novalgine	metamizole	1 000mg/2ml	Solution for injection	Intramuscular use | intravenous use
Belgium	Opella Healthcare Belgium (Handelsnaam Sanofi Belgium)	Novalgine I.M./I.V.	metamizole	1 000mg/2ml	Solution for injection	Intramuscular use | intravenous use

ELI: http://data.europa.eu/eli/C/2024/7476/oj

Member State in EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Belgium	Opella Healthcare Belgium (Handelsnaam Sanofi Belgium)	Novalgine	metamizole	500mg	Film-coated tablet	Oral use
Belgium	Opella Healthcare Belgium (Handelsnaam Sanofi Belgium)	Novalgine	metamizole	500mg/ml	Oral drops, solution	Oral use
Bulgaria	Adipharm Ead	Аналгин Макс	metamizole	1 000mg	Effervescent powder	Oral use
Bulgaria	Adipharm Ead	Фрешалгин	metamizole	500mg	Effervescent powder	Oral use
Bulgaria	Adipharm Ead	Спазмоблок Д	metamizole, pitofenone	500mg/ml, 5mg/ml	Oral drops, solution	Oral use
Bulgaria	Adipharm Ead	Бенлек Експрес	metamizole, thiamine, caffeine	500mg, 37,61mg, 50mg	Powder for oral solution	Oral use
Bulgaria	Adipharm Ead	Дро Спаз Комплекс	drotaverine, metamizole, caffeine	40mg, 400mg, 60mg	Powder for oral solution in sachet	Oral use
Bulgaria	Adipharm Ead	Спазмоблок	metamizole, pitofenone	500mg, 5mg	Powder for oral solution in sachet	Oral use
Bulgaria	Adipharm Ead	Бенлек	thiamine, metamizole, caffeine	38,75mg, 500mg, 50mg	Tablet	Oral use
Bulgaria	Adipharm Ead	Спазмоблок	pitofenone, fenpiverinium, metamizole	5mg, 0,1mg, 500mg	Tablet	Oral use
Bulgaria	Adipharm Ead	Фрешалгин	metamizole	500mg	Tablet	Oral use
Bulgaria	Bausch Health Ireland Limited	Амизолмет	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Bulgaria	Chemax Pharma Ltd	Диалгин	metamizole	500mg/ml	Oral drops, solution	Oral use
Bulgaria	Chemax Pharma Ltd	Диалгин За Деца	metamizole	500mg/ml	Oral drops, solution	Oral use
Bulgaria	Chemax Pharma Ltd	Диалгин	metamizole	1 000mg	Powder for oral solution	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Bulgaria	Chemax Pharma Ltd	Диалгин	metamizole	500mg	Powder for oral solution	Oral use
Bulgaria	Chemax Pharma Ltd	Диалгин Джуниор	metamizole	250mg	Powder for oral solution	Oral use
Bulgaria	Chemax Pharma Ltd	Диалгин Експрес	metamizole, caffeine	500mg, 50mg	Powder for oral solution	Oral use
Bulgaria	Danhson-Bg	Омалгин	metamizole	500mg/ml	Solution for injection	Intramuscular use
Bulgaria	Danhson-Bg	Спазмофарм	pitofenone, fenpiverinium, metamizole	4mg/2ml, 0,04mg/2ml, 1 000mg/2ml	Solution for injection	Intramuscular use
Bulgaria	Danhson-Bg	Омалгин Форте	thiamine, metamizole, caffeine	38,75mg, 500mg, 50mg	Tablet	Oral use
Bulgaria	Danhson-Bg	Омалгин	metamizole	500mg/ml	Oral drops, solution	Oral use
Bulgaria	Danhson-Bg	Мигренол	metamizole, paracetamol, phenobarbital, caffeine, codeine	150mg, 300mg, 15mg, 50mg, 10mg	Tablet	Oral use
Bulgaria	Danhson-Bg	Омалгин	metamizole	500mg	Tablet	Oral use
Bulgaria	Generica Ood	Генералгин	metamizole	500mg	Tablet	Oral use
Bulgaria	Hexal Ag	Hexalgin	metamizole	500mg	Oral solution	Oral use
Bulgaria	Inbiotech Ltd	Ангетоп	metamizole	500mg	Tablet	Oral use
Bulgaria	Kalceks	Метамизол Калцекс	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Bulgaria	Kupro94	Меалгин	metamizole	500mg/ml	Oral drops, solution	Oral use
Bulgaria	Sandoz Pharmaceuticals D.D.	Хексалгин За Деца	metamizole	500mg	Oral solution	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Bulgaria	Sopharma Ad	Спазмалгон	pitofenone, fenpiverinium, metamizole	4mg/2ml, 0,04mg/2ml, 1 000mg/2ml	Solution for injection	Intramuscular use
Bulgaria	Sopharma Ad	Аналгин	metamizole	1 000mg/2ml	Solution for injection	Intramuscular use | intravenous use
Bulgaria	Sopharma Ad	Аналгин Хин	metamizole	250mg	Film-coated tablet	Oral use
Bulgaria	Sopharma Ad	Темпалгин	metamizole, triacetonamine	500mg,20mg	Film-coated tablet	Oral use
Bulgaria	Sopharma Ad	Аналгин	metamizole	500mg/ml	Oral drops, solution	Oral use
Bulgaria	Sopharma Ad	Аналгин За Деца	metamizole	500mg/ml	Oral drops, solution	Oral use
Bulgaria	Sopharma Ad	Аналгин	metamizole	500mg	Tablet	Oral use
Bulgaria	Sopharma Ad	Паракофдал	metamizole, paracetamol, caffeine, codeine	300mg, 200mg, 30mg, 20mg	Tablet	Oral use
Bulgaria	Teva Pharma Ead	Беналгин Рапид	metamizole, thiamine, caffeine	500mg, 37,61mg, 50mg	Powder for oral solution	Oral use
Bulgaria	Teva Pharma Ead	Беналгин	thiamine, metamizole, caffeine	38,75mg, 500mg, 50mg	Tablet	Oral use
Bulgaria	Teva Pharma Ead	Проалгин	metamizole	500mg	Tablet	Oral use
Bulgaria	Teva Pharma Ead	Седалгин-Нео	metamizole, paracetamol, phenobarbital, caffeine, codeine	150mg, 300mg, 15mg, 50mg, 10mg	Tablet	Oral use
Bulgaria	Teva Pharma Ead	Спазмалгон	pitofenone, fenpiverinium, metamizole	5mg, 0,1mg, 500mg	Tablet	Oral use
Croatia	Alkaloid D.O.O.	Alkagin	metamizole	0,5g/ml	Solution for injection/ infusion	Intramuscular use | intravenous use

Member State in EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Croatia	Bausch Health Ireland Limited	Metamizolnatrij Hidrat Bausch Health	metamizole	500mg	Film-coated tablet	Oral use
Croatia	Pliva Hrvatska D.O.O.	Analgin	metamizole	500mg	Tablet	Oral use
Czech Republic	Auxilto Healthcare S.R.O.	Metamizol Auxilto	metamizole	500mg	Film-coated tablet	Oral use
Czech Republic	Bausch Health Ireland Limited	Emitazem	metamizole	500mg	Film-coated tablet	Oral use
Czech Republic	Bb Pharma A.S.	Analgin	pitofenone, fenpiverinium, metamizole	2mg/ml, 0,02mg/ml, 500mg/ml	Solution for injection	Intravenous use
Czech Republic	Kalceks	Metamizole Kalceks	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Czech Republic	Krka, D.D., Novo Mesto	Algominal	metamizole	500mg	Film-coated tablet	Oral use
Czech Republic	Medreg S.R.O.	Metamizol Medreg	metamizole	500mg	Tablet	Oral use
Czech Republic	Noridem Enterprises Ltd	Metamizole Noridem	metamizole	500mg/ml	Solution for injection/ infusion	Intramuscular use | intravenous use
Czech Republic	Opella Healthcare Czech S.R.O	Novalgin	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Czech Republic	Opella Healthcare Czech S.R.O	Novalgin	metamizole	500mg	Film-coated tablet	Oral use
Czech Republic	Stada Arzneimittel Ag	Metamizol Stada	metamizole	500mg/ml	Oral drops, solution	Oral use
Czech Republic	Stada Arzneimittel Ag	Metamizol Stada	metamizole	500mg	Tablet	Oral use
Czech Republic	Teva B.V	Metamizol Teva	metamizole	500mg	Tablet	Oral use
Czech Republic	Teva Czech Industries S.R.O	Algifen Neo	metamizole, pitofenone	500mg/ml, 5mg/ml	Oral drops, solution	Oral use

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Member State in EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Czech Republic	Zentiva, K.S.	Afexil	metamizole	500mg/ml	Solution for injection	Intravenous use
Czech Republic	Zentiva, K.S.	Afexil	metamizole	500mg	Film-coated tablet	Oral use
Czech Republic	Zentiva, K.S.	Algifen	metamizole, pitofenone, fenpiverinium	527mg, 5,25mg, 0,1mg	Tablet	Oral use
Germany	1 A Pharma Gmbh	Novaminsulfon 500	metamizole	500mg	Film-coated tablet	Oral use
Germany	1 A Pharma Gmbh	Novaminsulfon Tropfen	metamizole	500mg/ml	Oral drops, solution	Oral use
Germany	A. Nattermann & Cie. Gmbh	Novalgin	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Germany	A. Nattermann & Cie. Gmbh	Novalgin	metamizole	500mg	Film-coated tablet	Oral use
Germany	A. Nattermann & Cie. Gmbh	Novalgin Tropfen	metamizole	500mg/ml	Oral drops, solution	Oral use
Germany	A. Nattermann & Cie. Gmbh	Novalgin	metamizole	50mg/ml	Syrup	Oral use
Germany	A. Nattermann & Cie. Gmbh	Novalgin	metamizole	0,3g	Suppository	Rectal use
Germany	A. Nattermann & Cie. Gmbh	Novalgin	metamizole	1g	Suppository	Rectal use
Germany	A. Nattermann & Cie. Gmbh	Novalgin Für Erwachsene	metamizole	1g	Suppository	Rectal use
Germany	A. Nattermann & Cie. Gmbh	Novalgin Für Kinder	metamizole	0,3g	Suppository	Rectal use
Germany	Abanta Pharma Gmbh	Analgin	metamizole	500mg	Tablet	Oral use
Germany	Abz-Pharma Gmbh	Novaminsulfon	metamizole	50g/100ml	Oral drops, solution	Oral use
Germany	Abz-Pharma Gmbh	Metamizole Abz	metamizole	500mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Germany	Aliud Pharma Gmbh	Metamizol Al	metamizole	500mg/ml	Oral drops, solution	Oral use
Germany	Aristo Pharma Gmbh (Art 57)	Metamizol Aristo	metamizole	1 000mg	Film-coated tablet	Oral use
Germany	Aristo Pharma Gmbh (Art 57)	Metamizol Aristo	metamizole	500mg/ml	Oral drops, solution	Oral use
Germany	Aristo Pharma Gmbh (Art 57)	Metamizol Aristo	metamizole	500mg	Tablet	Oral use
Germany	Berlin-Chemie Ag	Berlosin	metamizole	500mg	Tablet	Oral use
Germany	Berlin-Chemie Ag	Berlosin	metamizole	1 000mg	Suppository	Rectal use
Germany	Carinopharm Gmbh	Analgin Ampullen	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Germany	Hameln Pharma Gmbh	Metamizol Hameln	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Germany	Heumann Pharma Gmbh & Co. Generica Kg	Metamizol Heumann	metamizole	500mg/ml	Oral drops, solution	Oral use
Germany	Heumann Pharma Gmbh & Co. Generica Kg	Metamizol Heumann	metamizole	500mg	Tablet	Oral use
Germany	Hexal Ag	Metamizol Hexal	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Germany	Hexal Ag	Metamizol Hexal	metamizole	500mg	Film-coated tablet	Oral use
Germany	Hexal Ag	Metamizol Hexal	metamizole	500mg/ml	Oral solution	Oral use
Germany	Kalceks	Metamizol Kalceks	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Germany	Ratiopharm Gmbh	Novaminsulfon	metamizole	1g/2ml	Solution for injection	Intramuscular use | intravenous use

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Member State in EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Germany	Ratiopharm Gmbh	Novaminsulfon-Ratiopharm	metamizole	2 500mg/5ml	Solution for injection	Intramuscular use | intravenous use
Germany	Ratiopharm Gmbh	Novaminsulfon	metamizole	500mg/ml	Oral drops, solution	Oral use
Germany	Ratiopharm Gmbh	Metamizol Ratiopharm	metamizole	500mg	Tablet	Oral use
Germany	Ratiopharm Gmbh	Novaminsulfon	metamizole	500mg	Tablet	Oral use
Germany	Stada Arzneimittel Ag	Metamizol Stada	metamizole	500mg	Tablet	Oral use
Germany	Stadapharm Gmbh	Metamizol Stada	metamizole	500mg/ml	Oral drops, solution	Oral use
Germany	Tad Pharma Gmbh	Metamizol Tad	metamizole	500mg/ml	Solution for injection/ infusion	Intramuscular use | intravenous use
Germany	Winthrop Arzneimittel Gmbh	Novaminsulfon Injekt Lichtenstein	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Germany	Winthrop Arzneimittel Gmbh	Novaminsulfon Lichtenstein	metamizole	500mg	Film-coated tablet	Oral use
Germany	Winthrop Arzneimittel Gmbh	Novaminsulfon Lichtenstein	metamizole	500mg/ml	Oral drops, solution	Oral use
Germany	Winthrop Arzneimittel Gmbh	Novaminsulfon Lichtenstein	metamizole	1g	Suppository	Rectal use
Germany	Zentiva Pharma Gmbh	Metamizol Zentiva	metamizole	500mg	Film-coated tablet	Oral use
Germany	Zentiva Pharma Gmbh	Metamizol Zentiva	metamizole	500mg/ml	Oral drops, solution	Oral use
Hungary	Gedeon Richter Plc.	Flamborin	metamizole	500mg/ml	Oral drops, solution	Oral use
Hungary	Gedeon Richter Plc.	Flamborin	metamizole	500mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Hungary	Goodwill Pharma Nyrt.	Metapyrin	metamizole	500mg	Film-coated tablet	Oral use
Hungary	Kalceks	Metamizole Kalceks	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Hungary	Magnapharm Hungary Kft	Algozone	metamizole	500mg	Tablet	Oral use
Hungary	Meditop Pharmaceutical Co. Ltd.	Metamizol Meditop	metamizole	500mg	Tablet	Oral use
Hungary	Meditop Pharmaceutical Co. Ltd.	Nodoryl	metamizole	500mg	Tablet	Oral use
Hungary	Meditop Pharmaceutical Co. Ltd.	Nodoryl Complex	drotaverine, metamizole, caffeine	20mg, 200mg, 30mg	Tablet	Oral use
Hungary	Meditop Pharmaceutical Co. Ltd.	Nodoryl Complex	drotaverine, metamizole, caffeine	40mg, 400mg, 60mg	Tablet	Oral use
Hungary	Meditop Pharmaceutical Co. Ltd.	Nodoryl Dolo	metamizole	250mg	Tablet	Oral use
Hungary	Meditop Pharmaceutical Co. Ltd.	Nodoryl Forte	metamizole	500mg	Tablet	Oral use
Hungary	Naturland Magyarország Kft.	Analgetica Fono Viii.	metamizole, caffeine	450mg, 50mg	Tablet	Oral use
Hungary	Naturland Magyarország Kft.	Analgeticum Fono Vii.	metamizole, caffeine	0,5g, 0,05g	Suppository	Rectal use
Hungary	Naturland Magyarország Kft.	Analgeticum Forte Fono Vii.	metamizole, caffeine, codeine	0,9g, 0,05g, 0,02873g	Suppository	Rectal use
Hungary	Naturland Magyarország Kft.	Noraminophenazoni Fono Vii. Naturland	metamizole	100mg	Suppository	Rectal use
Hungary	Naturland Magyarország Kft.	Noraminophenazoni Fono Vii. Naturland	metamizole	200mg	Suppository	Rectal use

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Member State in EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Hungary	Noridem Enterprises Ltd	Metamizol Noridem	metamizole	500mg/ml	Solution for injection/ infusion	Intramuscular use | intravenous use
Hungary	Opella Healthcare Commercial Kft.	Algopyrin	metamizole	1g/2ml	Solution for injection	Intramuscular use | intravenous use
Hungary	Opella Healthcare Commercial Kft.	Algopyrin Neo	metamizole	500mg	Film-coated tablet	Oral use
Hungary	Opella Healthcare Commercial Kft.	Algopyrin	metamizole	500mg	Tablet	Oral use
Hungary	Opella Healthcare Commercial Kft.	Quarelin	drotaverine, metamizole, caffeine	40mg, 400mg, 60mg	Tablet	Oral use
Hungary	Pannonpharma Kft.	Panalgorin	metamizole	1g/2ml	Solution for injection	Intramuscular use | intravenous use
Hungary	Pannonpharma Kft.	Panalgorin	metamizole	500mg	Tablet	Oral use
Hungary	Parma Produkt Kft	Analgetica Fono Viii.	metamizole, caffeine	450mg, 50mg	Tablet	Oral use
Hungary	Parma Produkt Kft	Analgeticum Fono Viii	metamizole, caffeine	500mg, 50mg	Suppository	Rectal use
Hungary	Parma Produkt Kft	Analgeticum Forte Fono Viii	codeine, metamizole, caffeine	30mg, 900mg, 50mg	Suppository	Rectal use
Hungary	Parma Produkt Kft	Metamizoli Fonoviii. Parma	metamizole	100mg	Suppository	Rectal use
Hungary	Parma Produkt Kft	Metamizoli Fonoviii. Parma	metamizole	200mg	Suppository	Rectal use
Hungary	Stada Arzneimittel Ag	Dolosped	metamizole	500mg	Tablet	Oral use
Hungary	Stada Arzneimittel Ag	Metamizol Stada	metamizole	500mg	Tablet	Oral use
Hungary	Teva Gyógyszergyár Zrt	Optalgin	metamizole	500mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Hungary	Teva Gyógyszergyár Zrt	Optalgin Neo	metamizole	500mg	Tablet	Oral use
Hungary	Zaklady Farmaceutyczne Polpharma S.A.	Pyralgina	metamizole	1 000mg	Film-coated tablet	Oral use
Hungary	Zentiva, K.S.	Nofebran	metamizole	500mg	Film-coated tablet	Oral use
Italy	Abc Farmaceutici S.P.A.	Metamizolo Sodico Abc	metamizole	500mg/ml	Oral drops, solution	Oral use
Italy	Opella Healthcare Italy S.R.L.	Novalgina	metamizole	1g/2ml	Solution for injection	Intramuscular use | intravenous use
Italy	Opella Healthcare Italy S.R.L.	Novalgina	metamizole	500mg/ml	Oral drops, solution	Oral use
Italy	So.Se.Pharm S.R.L.	Piralgin	metamizole	500mg/ml	Oral drops, solution	Oral use
Latvia	Actavis Group Ptc Ehf.	Spasmalgon	pitofenone, fenpiverinium, metamizole	5mg, 0,1mg, 500mg	Tablet	Oral use
Latvia	Kalceks	Metamizole Sodium Kalceks	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Latvia	Sopharma Ad	Analgin	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Latvia	Sopharma Ad	Tempalgin	metamizole, triacetonamine	500mg, 20mg	Film-coated tablet	Oral use
Latvia	Sopharma Ad	Analgin	metamizole	500mg	Tablet	Oral use
Lithuania	Bausch Health Ireland Limited	Metamizole Sodium Bausch Health	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Lithuania	Kalceks	Metamizole Sodium Kalceks	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use

Member State in EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Lithuania	Pharmaswiss Česká Republika S.R.O.	Analginas	metamizole	1g/2ml	Solution for injection	Intramuscular use | intravenous use
Lithuania	Pharmaswiss Česká Republika S.R.O.	Analginas	metamizole	500mg	Tablet	Oral use
Lithuania	Sopharma Ad	Analgin	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Lithuania	Sopharma Ad	Analgin	metamizole	500mg	Tablet	Oral use
Luxembourg	Opella Healthcare Belgium (Handelsnaam Sanofi Belgium)	Novalgine I.M./I.V.	metamizole	1 000mg/2ml	Solution for injection	Intramuscular use | intravenous use
Luxembourg	Opella Healthcare Belgium (Handelsnaam Sanofi Belgium)	Novalgine	metamizole	500mg	Film-coated tablet	Oral use
Luxembourg	Opella Healthcare Belgium (Handelsnaam Sanofi Belgium)	Novalgine	metamizole	500mg/ml	Oral drops, solution	Oral use
Netherlands	Allgen Pharmaceuticals & Generics Bv	Dolamizol	metamizole	250mg	Tablet	Oral use
Netherlands	Allgen Pharmaceuticals & Generics Bv	Dolamizol	metamizole	500mg	Tablet	Oral use
Netherlands	Kalceks	Metamizol Kalceks	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Poland	Adamed Pharma S.A.	Vemonis Intense	drotaverine, metamizole, caffeine	40mg, 400mg, 60mg	Film-coated tablet	Oral use
Poland	Adamed Pharma S.A.	Vemonis Ultra	drotaverine, metamizole, caffeine	80mg, 400mg, 60mg	Film-coated tablet	Oral use
Poland	Aristo Pharma Sp. Z O.O.	Axonalgin	metamizole	1 000mg	Film-coated tablet	Oral use
Poland	Bausch Health Ireland Limited	Pyreoxing	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use

Member State in EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Poland	Bausch Health Ireland Limited	Pyreox	metamizole	500mg	Film-coated tablet	Oral use
Poland	Chemax Pharma Ltd	Dialginum	metamizole	500mg	Powder for oral solution in sachet	Oral use
Poland	Chemax Pharma Ltd	Dialginum	metamizole	1 000mg	Powder for oral solution in sachet	Oral use
Poland	Dr. Max Pharma S.R.O.	Metamizol Dr. Max	metamizole	500mg	Tablet	Oral use
Poland	Fresenius Kabi Polska Sp. Z O.O.	Metamizole Kabi	metamizole	1 000mg	Solution for injection	Intramuscular use | intravenous use
Poland	Kalceks	Metamizole Kalceks	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Poland	Promedo Pharma Products Gmbh	Metamizol Promedo	metamizole	500mg	Tablet	Oral use
Poland	Solinea Sp. Z O.O. Sp. K.	Benlek	metamizole, thiamine, caffeine	500mg, 38,75mg, 50mg	Tablet	Oral use
Poland	Sopharma Warszawa Sp. Z O.O.	Spasmalgon	pitofenone, fenpiverinium, metamizole	2mg/ml, 0,02mg/ml, 500mg/ml	Solution for injection	Intramuscular use
Poland	Sopharma Warszawa Sp. Z O.O.	Re-Algin	metamizole	500mg	Tablet	Oral use
Poland	Sun-Farm Sp. Z.O.O.	Metamizol-Sf	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Poland	Sun-Farm Sp. Z.O.O.	Pyretolek	metamizole	500mg	Film-coated tablet	Oral use
Poland	Wrocławskie Zakłady Zielarskie 'herbapol' S.A.	Scopolan Compositum	metamizole, hyoscine	250mg, 10mg	Coated tablet	Oral use
Poland	Zaklady Farmaceutyczne Polpharma S.A.	Pyralgin	metamizole	1g/2ml	Solution for injection	Intramuscular use | intravenous use
Poland	Zaklady Farmaceutyczne Polpharma S.A.	Pyralgina Max	metamizole	1 000mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Poland	Zaklady Farmaceutyczne Polpharma S.A.	Pyralgina Plus	drotaverine, metamizole, caffeine	40mg, 400mg, 60mg	Film-coated tablet	Oral use
Poland	Zaklady Farmaceutyczne Polpharma S.A.	Pyralgina Ból I Gorączka	metamizole	500mg	Granules for oral solution	Oral use
Poland	Zaklady Farmaceutyczne Polpharma S.A.	Pyralgin	metamizole	25mg	Oral drops, solution	Oral use
Poland	Zaklady Farmaceutyczne Polpharma S.A.	Pyralgina	metamizole	500mg	Tablet	Oral use
Poland	Zentiva, K.S.	Pixalzina	metamizole	500mg	Film-coated tablet	Oral use
Portugal	Aristo Pharma Gmbh (Art 57)	Metamizol Aristo	metamizole	1 000mg	Film-coated tablet	Oral use
Portugal	Boehringer Ingelheim Portugal, Lda.	Nolotil	metamizole	2000mg/5ml	Solution for injection	Intramuscular use | intravenous use
Portugal	Boehringer Ingelheim Portugal, Lda.	Nolotil	metamizole	575mg	Capsule	Oral use
Portugal	Faes Farma Portugal, S.A.	Metamizol Vitória	metamizole	575mg	Capsule, hard	Oral use
Portugal	Laboratórios Basi – Indústria Farmacêutica, S.A.	Metamizol Basi	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Portugal	Sidefarma - Sociedade Industrial De Expansão Farmacêutica, S.A.	Dolocalma	metamizole	575mg	Capsule, hard	Oral use
Portugal	Towa Pharmaceutical S.A.	Metamizol Magnésico Tolife	metamizole	575mg	Capsule, hard	Oral use
Romania	Antibiotice Sa	Novocalmin	metamizole	500mg	Tablet	Oral use
Romania	Antibiotice Sa	Piafen	pitofenone, metamizole, fenpipramide	5mg, 500mg, 0,1mg	Tablet	Oral use
Romania	Antibiotice Sa	Novocalmin	metamizole	300mg	Suppository	Rectal use
Romania	Arena Group S.A	Sintocalmin	metamizole	500mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Romania	Bioeel Manufacturing S.R.L.	Alvotor	metamizole	500mg/ml	Oral drops, solution	Oral use
Romania	Chemax Pharma Ltd	Algostop	metamizole	1 000mg	Powder for oral solution in sachet	Oral use
Romania	Chemax Pharma Ltd	Algostop	metamizole	500mg	Powder for oral solution in sachet	Oral use
Romania	Farmacom Sa	Metamizol	metamizole	500mg	Tablet	Oral use
Romania	Gemax Pharma S.R.O.	Metamizol Gemax Pharma	metamizole	500mg	Tablet	Oral use
Romania	Kalceks	Metamizol Kalceks	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Romania	Labormed Pharma S.A.	Algozone	metamizole	500mg	Tablet	Oral use
Romania	Laropharm Srl	Alindor	metamizole	500mg	Tablet	Oral use
Romania	Opella Healthcare Romania Srl	Quarelin	drotaverine, metamizole, caffeine	40mg, 400mg, 60mg	Tablet	Oral use
Romania	S.C. Sanosan S.R.L.	Metamizol Sodic Sanosan	metamizole	500mg	Tablet	Oral use
Romania	S.C. Santa S.A.	Algiotop	metamizole	500mg	Tablet	Oral use
Romania	Sc Centrofarm Sa	Centralgin	metamizole	500mg	Tablet	Oral use
Romania	Sc Sintofarm Sa	Centralgin	metamizole	500mg	Tablet	Oral use
Romania	Sopharma Ad	Metamizol Sodic Sopharma	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Romania	Stada Arzneimittel Ag	Locamin	metamizole	500mg/ml	Oral drops, solution	Oral use
Romania	Tis Farmaceutic Sa	Tisalgin	metamizole	300mg	Suppository	Rectal use
Romania	Zentiva S.A.	Algifen	metamizole, pitofenone, fenpiverinium	2,5g/5ml, 0,01g/5ml, 0g/5ml	Solution for injection	Intramuscular use | intravenous use

Member State in EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Romania	Zentiva S.A.	Algocalmin	metamizole	0,525g/ml	Solution for injection	Intramuscular use | intravenous use
Romania	Zentiva S.A.	Algifen	metamizole, pitofenone, fenpiverinium	500mg, 5mg, 0,1mg	Tablet	Oral use
Romania	Zentiva S.A.	Algocalmin	metamizole	500mg	Tablet	Oral use
Romania	Zentiva, K.S.	Algocalmin	metamizole	500mg	Film-coated tablet	Oral use
Romania	Zentiva, K.S.	Algocalmin	metamizole	500mg/ml	Oral drops, solution	Oral use
Slovakia	Bausch Health Ireland Limited	Emitazem	metamizole	500mg	Film-coated tablet	Oral use
Slovakia	Bb Pharma A.S.	Analgin Inj	metamizole, pitofenone, fenpiverinium	500mg/ml, 2mg/ml, 0,02mg/ml	Solution for injection	Intramuscular use | intravenous use
Slovakia	Kalceks	Metamizole Kalceks	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Slovakia	Medreg S.R.O.	Metamizol Medreg	metamizole	500mg	Tablet	Oral use
Slovakia	Opella Healthcare Slovakia S.R.O.	Novalgin	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Slovakia	Opella Healthcare Slovakia S.R.O.	Novalgin	metamizole	500mg	Film-coated tablet	Oral use
Slovakia	Opella Healthcare Slovakia S.R.O.	Quarelin	drotaverine, metamizole, caffeine	40mg, 400mg, 60mg	Tablet	Oral use
Slovakia	Stada Arzneimittel Ag	Metamizol Stada	metamizole	500mg/ml	Oral drops, solution	Oral use
Slovakia	Stada Arzneimittel Ag	Metamistad	metamizole	500mg	Tablet	Oral use
Slovakia	Teva B.V	Algifen Neo	pitofenone, metamizole	5mg/ml, 500mg/ml	Oral drops, solution	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Slovakia	Teva B.V	Metamizol Teva	metamizole	500mg	Tablet	Oral use
Slovakia	Zentiva, K.S.	Nofebran	metamizole	500mg/ml	Solution for injection	Intravenous use
Slovakia	Zentiva, K.S.	Nofebran	metamizole	500mg	Film-coated tablet	Oral use
Slovakia	Zentiva, K.S.	Algifen	metamizole, pitofenone, fenpiverinium	500mg, 5,25mg, 0,1mg	Tablet	Oral use
Slovenia	Alkaloid-Int D.O.O.	Analgin	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Slovenia	Alkaloid-Int D.O.O.	Analgin	metamizole	500mg	Tablet	Oral use
Slovenia	Kalceks	Natrijev Metamizolat Kalceks	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Slovenia	Krka, D.D., Novo Mesto	Natrijev Metamizolat Krka	metamizole	500mg/ml	Solution for injection/ infusion	Intramuscular use | intravenous use
Slovenia	Krka, D.D., Novo Mesto	Algominal	metamizole	500mg	Film-coated tablet	Oral use
Slovenia	Stada Arzneimittel Ag	Metamizol Stada	metamizole	500mg/ml	Oral drops, solution	Oral use
Slovenia	Stada Arzneimittel Ag	Metamizol Stada	metamizole	500mg	Tablet	Oral use
Spain	Ababor Pharmaceuticals, S.L.	Metamizol Ababor	metamizole	575mg	Capsule, hard	Oral use
Spain	Aristo Pharma Gmbh (Art 57)	Turbet	metamizole	1 000mg	Film-coated tablet	Oral use
Spain	Aristo Pharma Iberia, S.L.	Metamizol Aristo	metamizole	575mg	Capsule, hard	Oral use
Spain	Boehringer Ingelheim Espana S.A.	Nolotil	metamizole	500mg/ml	Solution for injection/ infusion	Intramuscular use | intravenous use

Member State in EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Spain	Boehringer Ingelheim Espana S.A.	Nolotil	metamizole	575mg	Capsule, hard	Oral use
Spain	Industria Química Y Farmaceútica Vir, S.A.	Metamizol Aiko Farmacéutica	metamizole	575mg	Capsule, hard	Oral use
Spain	Industria Química Y Farmaceútica Vir, S.A.	Metamizol Vir	metamizole	575mg	Capsule, hard	Oral use
Spain	Kalceks	Metamizol Kalceks	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Spain	Kern Pharma, S.L.	Metamizol Kern Pharma	metamizole	575mg	Capsule, hard	Oral use
Spain	Laboratorio Stada, S.L.	Metamizol Stada	metamizole	575mg	Capsule, hard	Oral use
Spain	Laboratorios Alter, S.A.	Metamizol Alter	metamizole	575mg	Capsule, hard	Oral use
Spain	Laboratórios Basi – Indústria Farmacêutica, S.A.	Metamizol Basi	metamizole	500mg/ml	Solution for injection	Intramuscular use | intravenous use
Spain	Laboratorios Cinfa S.A.	Metamizol Cinfa	metamizole	575mg	Capsule, hard	Oral use
Spain	Laboratorios Combix, S.L.U.	Metamizol Combix	metamizole	575mg	Capsule, hard	Oral use
Spain	Laboratorios Ern, S.A.	Metalgial	metamizole	500mg/ml	Oral drops, solution	Oral use
Spain	Laboratorios Normon, S.A.	Metamizol Normon	metamizole	2g/5ml	Solution for injection/ infusion	Intramuscular use | intravenous use | oral use
Spain	Laboratorios Normon, S.A.	Metamizol Normon	metamizole	575mg	Capsule	Oral use
Spain	Laboratorios Normon, S.A.	Metamizol Normon	metamizole	500mg/ml	Oral drops, solution	Oral use
Spain	Mabo-Farma, S.A	Algi-Mabo	metamizole	2g	Solution for injection/ infusion	Intramuscular use | intravenous use | oral use

Member State in EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Spain	Mabo-Farma, S.A	Algi-Mabo	metamizole	500mg	Capsule, hard	Oral use
Spain	Mabo-Farma, S.A	Metamizol Mabo	metamizole	575mg	Capsule, hard	Oral use
Spain	Opella Healthcare Spain, S.L	Buscopresc Compositum	metamizole, hyoscine	2,5g/5ml, 0,02g/5ml	Solution for injection	Intramuscular use | intravenous use
Spain	Tarbis Farma, S.L.	Metamizol Tarbis	metamizole	575mg	Capsule, hard	Oral use
Spain	Tecnimede España Ind. Fca., S.A.	Metamizol Tecnigen	metamizole	575mg	Capsule, hard	Oral use
Spain	Teva Pharma S.L.U.,	Metamizol Ratiopharm	metamizole	575mg	Capsule	Oral use
Spain	Teva Pharma S.L.U.,	Metamizol Teva-Ratiopharm	metamizole	575mg	Capsule, hard	Oral use
Spain	Towa Pharmaceutical S.A.	Metamizol Pensa	metamizole	575mg	Capsule, hard	Oral use
Spain	Towa Pharmaceutical S.A.	Metamizol Pensa Pharma	metamizole	575mg	Capsule, hard	Oral use
Spain	Viatris Pharmaceuticals, S.L.U.	Metamizol Viatris	metamizole	575mg	Capsule, hard	Oral use