

Summary of Community decisions on marketing authorizations in respect of medicinal products from 1 October 2009 to 31 October 2009

(Decisions taken pursuant to Article 34 of Directive 2001/83/EC of the European Parliament and of the Council ⁽¹⁾ or Article 38 of Directive 2001/82/EC of the European Parliament and of the Council ⁽²⁾)

(2009/C 288/02)

- Issuing, maintenance or modification of a national marketing authorisation

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
1.10.2009	Simponi	Centocor B.V., Einsteinweg 101, 2333 CB Leiden, Nederland	This Decision is addressed to the Member States	5.10.2009
1.10.2009	Ivermectin	See Annex I	See Annex I	5.10.2009
1.10.2009	Topamax	See Annex II	See Annex II	5.10.2009
1.10.2009	Cimzia	UCB Pharma SA., Allée de la Recherche 60, 1070 Bruxelles, Belgique/ Researchdreef, 60, Brussel 1070, België	This Decision is addressed to the Member States	5.10.2009
2.10.2009	Avalox	See Annex III	See Annex III	6.10.2009
2.10.2009	Octegra	See Annex IV	See Annex IV	6.10.2009
5.10.2009	ChondroCelect	TiGenix NV, Romeinse straat 12/2, B-3001 Leuven, België	This Decision is addressed to the Member States	6.10.2009
6.10.2009	Fentrix	See Annex V	See Annex V	7.10.2009
15.10.2009	Meronem	See Annex VI	See Annex VI	19.10.2009
15.10.2009	Pulmotil AC	See Annex VII	See Annex VII	19.10.2009
15.10.2009	Pulmotil 40 VET Premix, Pulmotil 100 VET Premix, Pulmotil 200 VET Premix	See Annex VIII	See Annex VIII	19.10.2009
16.10.2009	Nimesulide	See Annex IX	See Annex IX	19.10.2009
19.10.2009	Augmentin	See Annex X	See Annex X	21.10.2009
23.10.2009	ILARIS	Novartis Europharm Limited, Wimbleshurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	This Decision is addressed to the Member States	26.10.2009
23.10.2009	ARCALYST	Regeneron UK Limited, 40 Bank Street, E14 5DS London, United Kingdom	This Decision is addressed to the Member States	26.10.2009

⁽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	Holder(s) of the marketing authorization	Member State concerned	Date of notification
30.10.2009	Fentrans	See Annex XI	See Annex XI	4.11.2009
30.10.2009	Matripain	See Annex XII	See Annex XII	4.11.2009
30.10.2009	Matrigesic	See Annex XIII	See Annex XIII	4.11.2009
30.10.2009	Fentador	See Annex XIV	See Annex XIV	4.11.2009
30.10.2009	Fentastad	See Annex XV	See Annex XV	4.11.2009

**LIST OF THE NAMES, STRENGTHS OF THE VETERINARY MEDICINAL PRODUCTS, ANIMAL SPECIES,
ROUTE OF ADMINISTRATION, RECOMMENDED DOSE AND MARKETING AUTHORISATION HOLDERS
IN THE MEMBER STATES**

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Austria	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Animec injection Injektionsl�ng f�r Rinder und Schweine	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Austria	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bimectin	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Austria	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
Austria	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	Ivertin	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Austria	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec 10 mg/ml Injektionssuspension f�r Rinder, Schafe und Schweine	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Austria	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin – Injektionsl�sung f�r Tiere	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Austria	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
Austria	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC Injektionslösung Für Tiere: Rinder, Schafe, Schweine	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Austria	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin Injektionslösung für Rinder	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Belgium	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	BOVIMEC B	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Belgium	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	ECOMECTIN 10 MG/ML	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Belgium	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	IVERTIN CATTLE	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Belgium	MERIAL Belgium S.A. Bld Sylvain Dupuis 243 1070 Bruxelles Belgium	IVOMECE F	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Belgium	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Belgium	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC 1 % Solution injectable	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
Belgium	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC F solution injectable	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Belgium	MERIAL Belgium S.A. Bld Sylvain Dupuis 243 1070 Bruxelles Belgium	Ivomec	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
Belgium	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	QUALIMEC 10 MG/ML	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Belgium	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin Oplossing voor Injectie voor rundvee	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Bulgaria	Intervet International B.V. Wim de Korvrstraat 35, 5831 AA, Boxmeer, The Netherlands	Ivotan LA	Ivermectin 10 mg/ml	Cattle, Sheep, Goats, Pigs	Subcutaneous	Cattle, Sheep, Goats: 200 µg iver- mectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Bulgaria	Ceva Sante Animale La Ballastiere B.P. 126 33501 Libourne Cedex France	Cevamec 1 % injectable solution	Ivermectin 10 mg/ml	Cattle, Sheep, Goats, Pigs	Subcutaneous	Cattle, Sheep, Goats: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Bulgaria	Alfasan International B.V., P.O. Box 78, 3440 AB Woerden, The Netherlands	Alfamec 1 %	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Bulgaria	BIOVET JSC 39 Petar Rakov Str. 4550 Pesthera Bulgaria	Pandex 1 %	Ivermectin 10 mg/ml	Cattle, Sheep, Goats, Pigs	Subcutaneous	Cattle, Sheep, Goats: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Bulgaria	Centrovet Ltd. Av.Los Cerrillos 602 Santiago, Chile	Microdes Plus	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Bulgaria	Interchemie werken „de Adelaar“ BV Horsterweg 26A 5811 AC Castenray The Netherlands	Intermectin	Ivermectin 10 mg/ml	Cattle, Sheep, Goats, Pigs	Subcutaneous	Cattle, Sheep, Goats: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Bulgaria	Invesa International S.A. Esmeralda 19 08950 Esplugues de Llobregat Barcelona Spain	Promectine	Ivermectin 10 mg/ml	Cattle, pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Bulgaria	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Divamectin 1 % Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Cyprus	Panchris Feeds Ltd. P.O.Box 40261, 6302 Larnaca Cyprus	Bimectin Injection	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Cyprus	Vetagrica Ltd 3 Othellou Street, 2540 Dhali Industrial Estate Nicosia Cyprus	Ivomec Super Injection for Cattle	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Cyprus	Spyros Stavrinides Chemicals Ltd 28 Stasinou Avenue, 1060 Nicosia, Cyprus	Noromectin injection	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Czech Republic	Vétoquinol s.r.o., Zámečnicka 411, 288 02 Nymburk, Czech Republic	Biomectin 1 %	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Czech Republic	Bremer Pharma GmbH Cherbourger Str. 25 27540 Bremerhaven Germany	Bremamectin	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Czech Republic	CEVA Animal Health Slovakia, spol. s r.o. Račianska 77 83 102 BRATISLAVA Slovak Republic	Cevamec 1 % inj. ad us. vet.	Ivermectin 10 mg/ml	Cattle, Sheep, Goats, Pigs	Subcutaneous	Cattle, Sheep, Goats: 200 µg iver- mectin/kg bw Pigs: 300 µg ivermectin/kg bw
Czech Republic	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 1 %	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Czech Republic	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec 1 % inj. ad. us. vet.	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Czech Republic	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec Super inj. a.u.v.	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle, sheep	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Czech Republic	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Inj ad us vet	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Czech Republic	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec inj. ad us. vet.	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Czech Republic	Bioveta a.s., Komenského 212 683 23 Ivanovice na Hané Czech Republic	Biomec 10 mg/ml Injekční roztok	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Czech Republic	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin injekční roztok pro skot	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Denmark	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Vet	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Denmark	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec Vet	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Denmark	Bimeda (a division of Cross Vetpharm Group Limited) Broomhill Road Tallaght Dublin 24 Ireland	Bimec Vet	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Denmark	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomec vet.	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Denmark	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Ivermectin »Virbac« Vet., injektionsvæske, opløsning	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Denmark	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Coopermec Vet	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Denmark	Merial Norden A/S Mileparken 20 E 2740 Skovlunde Denmark	Ivomec vet., injektionsvæske 10 mg/ml	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Estonia	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Estonia	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec 1 % injection, süstelähus	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Estonia	Bimeda Chemical Export Ltd. (a division of Cross Vetpharm Group Limited), Broomhill Road Tallaght Dublin 24 Ireland	Bimectin injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Estonia	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Multi Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Estonia	Ceva Sante Animale La Ballastiere B.P. 126 33501 Libourne Cedex France	Cevamec 1 % injectable solution	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Estonia	Bremer Pharma GmbH Cherbourger Str. 25 27540 Bremerhaven Germany	Bremamectin	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Estonia	Vetoquinol Biowet Sp. z o.o., ul. Kosynierów Gdynskich 13-14, 66-400 Gorzów Wlkp., Poland	Biomectin 1 %	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Finland	Scanvet Eläinlääkkeet Oy PL 27 13721 PAROLA Finland	Animec vet	Ivermectin 10 mg/ml	Cattle, Reindeer, Pigs	Subcutaneous	Cattle, Reindeer: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Finland	Bimeda (a division of Cross Vetpharm Group Limited) Broomhill Road Tallaght Dublin 24 Ireland	Bimectin vet	Ivermectin 10 mg/ml	Cattle, Reindeer, Pigs	Subcutaneous	Cattle, Reindeer: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Finland	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec 10 mg/ml vet injektioneste, liuos	Ivermectin 10 mg/ml	Cattle, Reindeer, Pigs	Subcutaneous	Cattle, Reindeer: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Finland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Animec injection 10 mg/ml solution for injection	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Finland	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Vet 10mg/ml Solution for Injection	Ivermectin 10 mg/ml	Cattle, Reindeer, Pigs	Subcutaneous	Cattle, Reindeer: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Finland	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC VET 10 mg/ml injec- tioneste, liuos	Ivermectin 10 mg/ml	Cattle, Reindeer, Pigs	Subcutaneous	Cattle, Reindeer: 200 µg iver- mectin/kg bw Pigs: 300 µg ivermectin/kg bw
France	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
France	MERIAL 29 avenue Tony Garnier 69007 LYON France	IVOMEK D	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
France	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC SOLUTION INJECTA- BLE POUR BOVINS	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
France	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC D SOLUTION INJECTABLE	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
France	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC Solution Injectable pour Bovins Porçins Ovins	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
France	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	IVERMECTINE ECO 10 MG/ML SOLUTION I NJECTABLE	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
France	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	QUALIMEC 10 MG/ML SOLUTION INJECTABLE	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
France	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	IVERTIN BOVIN	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
France	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	CEVAMEC BOVINS OVINS SOLUTION INJECTABLE	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
France	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Magamectine iInjectable, solution injectable	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
France	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Medimec Injectable, Solution Injectable	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
France	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin 1 % Solution Injectable Bovine, Porcins	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
France	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectine Solution Injectable pour bovins	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
France	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Divamectin 1 % Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Germany	MERIAL GmbH Am Söldnermoos 6 D-85399 Hallbergmoos Germany	Ivomec	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Germany	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Chanectin Injektion	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Germany	Bimeda Chemical Export Ltd. (a division of Cross Vetpharm Group Limited), Broomhill Road Tallaght Dublin 24 Ireland	Diapec R	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Germany	Bimeda Chemical Export Ltd. (a division of Cross Vetpharm Group Limited), Broomhill Road Tallaght Dublin 24 Ireland	Wedemec R	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Germany	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Sumex Injektion für Rinder	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Germany	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 1 % Injektion	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Germany	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec Inektionslösung	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Greece	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin 1 % 1 % Ενέσιμο Διάλυμα	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Greece	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin 1 % 1 % Ενέσιμο Διάλυμα	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Greece	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Greece	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	ECOMECTIN	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Greece	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Greece	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland	Animec Inj. Sol.	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Greece	VETERIN ABEE Aspropyrgos Attikis 19300 Greece	VETERMEC	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Greece	PNG Gerolymatos S.A. 13, Asklipiou 145 68 KRYONERI, ATTICA Greece	VALANEQ	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Greece	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	MAXIMEC	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Greece	SCHERING PLOUGH SA 65,Ag Dimitriou 17455, Athens Greece	TIZOVAL	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Hungary	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland	Animec Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	Bayer Hungária Ltd. H-1123 Budapest Alkotás u. 50. Hungary	Baymec Trio 1 %	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	Vetoquinol Biowet Sp. z o.o., ul. Kosynierów Gdynskich 13-14, 66-400 Gorzów Wlkp., Poland	Biomectin 1 %	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	Ceva-Phylaxia Oltóanyag- termelő Zrt. Szállás u. 5 1107 Budapest Hungary	Cevamec 1 % injekció A.U.V	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	Divasa Farmavic Hungaria Ltd. H-6070 Izsák, Kossuth L. u. 60. Hungary	ECOMECTIN	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	Bremer Pharma GmbH. Werkstrasse 42 34414 Warburg-Scherfede Germany	FROMMECTIN	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Hungary	Invesa International S.A. Esmeralda 19 08950 Esplugues de Llobregat Barcelona Spain	IVERGEN PREMIUM LA	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	Veterina Polska Sp. Zo.o. Ul. Mogilska 80, 31546 Krakow Poland	Iverklin Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	IVERTIN	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	VMD Animal Health Ltd. Közraktár u. 22/b. II. 3., 1093 Budapest Hungary	IVERVETo 1 %	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec injekció A.U.V.	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec super injekció A.U.V.	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Hungary	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Vetimec 10 mg/ml solution for injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Ireland	C-Corp, 78 Coombe Road, New Malden, Surrey KT3 4QS, United Kingdom	Kilo-mec 1 % Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	C-Corp, 78 Coombe Road, New Malden, Surrey KT3 4QS, United Kingdom	Mastermectin 1 %	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	C-Corp, 78 Coombe Road, New Malden, Surrey KT3 4QS, United Kingdom	Coopermec 1 % Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec Injectable Solution	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec for Cattle Swine and Sheep 1 %	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec Super Solution for Injection	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Ireland	Merial Animal Health Limited Sandringham House Harlow Business Park Harlow Essex CM19 5TG United Kingdom	Panomec 1 % Solution for Injection for Cattle, Sheep and Pigs	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Ireland	Merial Animal Health Limited Sandringham House Harlow Business Park Harlow Essex CM19 5TG United Kingdom	Ivomec Classic Injection for Cattle and Sheep 1 % w/v	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Merial Animal Health Limited Sandringham House Harlow Business Park Harlow Essex CM19 5TG United Kingdom	Ivomec Super Injection for Cattle	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Ireland	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 1 % Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec 10 mg/ml Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Fatromectin 1 % Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Divamectin 1 % Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Chanimec Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Animec 1 % solution Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Chanectin Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Sumex Injection for Cattle, 1 %, Solution for injection for cattle	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Anisec Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Aniject Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Chaniject Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Sumiject Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Medimec Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Topimec Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bimectin 1,0 % w/v Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Mectaject 1 % Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bovimectin 1 % solution for injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Maximec Injection for Cattle & Sheep	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Trimectin Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bovimec 1 % w/v Solution for Injection for Cattle	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin 1 % Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Ireland	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Multi Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Primectin 1 % w/v Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin Solution for Injection	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Ireland	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Enovex Injection 1 % w/v	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin 1 % Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closiver Injection	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Iceland	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec vet.	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Italy	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Baymec 1 % Soluzione	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Italy	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Injection	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Italy	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	Ivertin cattle	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Italy	INTERVET PRODUCTIONS SRL Via Nettunense km 20, 300 04011 Aprilia Italy	Ivogell	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Italy	Merial Italia S.p.A. a Socio Unico, Via Vittor Pisani, 16 Milano Italy	Ivomec	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Italy	Merial Italia S.p.A. a Socio Unico, Via Vittor Pisani, 16 Milano Italy	Ivomec Plus	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Italy	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Maximec iniettable	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Italy	Fatro Via Emilia, 285 40064 Ozzano Emilia (Bologna) Italy	Tolomec	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Italy	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC Soluzione iniettabile	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Italy	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC F soluzione iniettabile	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Italy	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin Soluzione iniettabile per bovini	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Italy	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Divamectin 1 % Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Latvia	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland	Animec Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Latvia	Bimeda Chemical Export Ltd. (a division of Cross Vetpharm Group Limited), Broomhill Road Tallaght Dublin 24 Ireland	Bimectin Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Latvia	Vetoquinol Biowet Sp. z o.o., ul. Kosynierów Gdynskich 13-14, 66-400 Gorzów Wlkp., Poland	Biomectin 1 %	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Latvia	Ceva Sante Animale La Ballastiere B.P. 126 33501 Libourne Cedex France	Cevamec 1 %	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Latvia	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 10 mg/ml	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Latvia	MERIAL 29 avenue Tony Garnier 69007 LYON France	IVOMEK 1 % Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Latvia	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec Plus	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Latvia	Pharmaceutical Company PFO „VETOS-FARMA” sp. z.o.o., Dzierzoniwska street 21 58-260 Bielawa Poland	Iwermektyna 1 % Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Latvia	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Lithuania	MERIAL 29 avenue Tony Garnier 69007 LYON France	IVOMEC PLUS, injekcinis tirpalas	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
Lithuania	MERIAL 29 avenue Tony Garnier 69007 LYON France	IVOMEC 1 %, injekcinis tirpalas	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Lithuania	Vetoquinol Biowet Sp. z o.o., ul. Kosynierów Gdynskich 13-14, 66-400 Gorzów Wlkp., Poland	Biomectin 1 %, injekcinis tirpalas	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Lithuania	Ceva Sante Animale La Ballastiere B.P. 126 33501 Libourne Cedex France	Cevamec 1 %, injekcinis tirpalas	Ivermectin 10 mg/ml	Cattle, Sheep, Goats, Pigs	Subcutaneous	Cattle, Sheep, Goats: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Lithuania	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Injekcinis tirpalas	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Lithuania	Invesa International S.A. Esmeralda 19 08950 Esplugues de Llobregat Barcelona Spain	PROMECTINE	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Lithuania	Bimeda Chemical Export Ltd. (a division of Cross Vetpharm Group Limited), Broomhill Road Tallaght Dublin 24 Ireland	BIMECTIN	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Lithuania	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	ECOMECTIN 10 mg/ml	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Luxembourg	MERIAL Belgium S.A. Bld Sylvain Dupuis 243 1070 Bruxelles Belgium	Ivomec solution pour injection	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
Luxembourg	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 1 %	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
Luxembourg	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin 1 % inj.sol. bovine and porcine	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Luxembourg	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin 1 % solution for injection	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Luxembourg	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec 1 % solution for injection	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
Luxembourg	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec solution pour injection bovine	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Malta	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bimectin	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Malta	Laboratorios HIPRA S.A. Avda. La Selva, 135 17170 Amer, Girona Spain	Iveripra-I	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Malta	Interchemie werken „de Adelaar” BV Horsterweg 26A 5811 AC Castenray The Netherlands	Intermectin	Ivermectin 10 mg/ml	Cattle, Sheep, Goats, Pigs	Subcutaneous	Cattle, Sheep, Goats: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Malta	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Multi Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Malta	INDUSTRIAL VETERINARIA, S.A. C/ Esmeralda, 19 08950 Esplugues de Llobregat Barcelona Spain	Promectine	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
The Netherlands	Merial B.V. Kleermakerstraat 10 1991 JL Velsbroek The Netherlands	Ivomec	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
The Netherlands	Merial B.V. Kleermakerstraat 10 1991 JL Velsbroek The Netherlands	Ivomec Plus	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
The Netherlands	Merial B.V. Kleermakerstraat 10 1991 JL Velsbroek The Netherlands	Panomec Injectievloeistof	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
The Netherlands	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Animec Injection	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
The Netherlands	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Euomec Injectie	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
The Netherlands	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin Injectie	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
The Netherlands	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Injectie	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
The Netherlands	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Maximec Injectie	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
The Netherlands	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	Ivertin Cattle	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
The Netherlands	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bimectin Injectie	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
The Netherlands	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec F	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
The Netherlands	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ges-o-mec 10 mg/ml oplossing voor injectie	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
The Netherlands	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec 10 mg/g solution for injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
The Netherlands	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer The Netherlands	Iverveto 1 %	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Norway	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec vet, injeksjonsvæske, oppløsning 10 mg/ml	Ivermectin 10 mg/ml	Cattle, Sheep, Rein- deer, Pigs	Subcutaneous	Cattle, Sheep, Reindeer: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Norway	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Vet Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Norway	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC VET	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Poland	Vetoquinol Biowet Sp. z o.o., ul. Kosynierów Gdyńskich 13-14, 66-400 Gorzów Wlkp., Poland	Biomectin 1 %	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Poland	Ceva Sante Animale La Ballastiere B.P. 126 33501 Libourne Cedex France	Cevamec 1 %	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Poland	Drwalewskie Zakłady Przemysłu Bioweterynaryjnego S.A. ul. Grójecka 6 05-651 Drwalew Poland	Ivermina 1 % Inj	Ivermectin 10 mg/ml	Cattle, pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Poland	Pharmaceutical Company PFO „VETOS-FARMA” sp. z.o.o., Dzierzoniwska street 21 58-260 Bielawa Poland	Iwermektyna 1 % Iniekcja	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Poland	Agri- Biovet Sp. z o.o. ul. Smocza 27 01-048 Warsaw Poland	Pandex 1 %	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Poland	Scan Vet Poland Sp. z o.o. Skierszewo, ul. Kiszkowska 9 62-200 Gniezno Poland	Paramectin 1 %	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Poland	Przedsiębiorstwo Wielobranżowe Vet Agro Sp. z o.o. ul. Gliniana 32 20-616 Lublin Poland	Vetamectin	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Portugal	Bimeda (a division of Cross Vetpharm Group Limited) Broomhill Road Tallaght Dublin 24 Ireland	Tizoval Bovinos 1 %	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Portugal	Calier Portugal S.A Centro Empresarial Sintra-Estoril II, Ed. C, R. Pé de Mouro Estrada de Albarraque 2710 - 335 Sintra Portugal	Ivertin	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Portugal	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Chanectin Injectável	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Portugal	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Maximec Injectável para bovinos e ovinos 1 %	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
Portugal	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 1 % Sol Injectável	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Portugal	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Vectimax 10 mg/Ml Sol. Inj. Este é	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Portugal	Merial Portuguesa - Saúde Animal, Lda AV Maria Lamas, Lote 19 - BL - A Piso 2 Parque Industrial Comercial Serra das Minas 2635-432 Rio de Mouro Portugal	Ivomec F	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Portugal	Merial Portuguesa - Saúde Animal, Lda AV Maria Lamas, Lote 19 - BL - A Piso 2 Parque Industrial Comercial Serra das Minas 2635-432 Rio de Mouro Portugal	Ivomec 1 % Bovinos, Solução Injectável	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Portugal	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin Injectável 1 %	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Portugal	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Injectável 1 %	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Portugal	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec F, Solução Injectável 1mg/ml	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Portugal	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC, Solução injectavel	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Portugal	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin FF, solução injectável para bovinos	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Romania	ANTIBIOTICE IASI S.A. Str. Valea Lupului, nr. 1, Iaşi, jud. Iaşi Romania	Ivermectina 1 %	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	BIOWET GORZOW PHAR- MACEUTICALS COMPANY- Kosynierów Gdyńskich 13/14 ST., Gorzow WLPK Poland	Biomectin 1 %	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Romania	BIOVET JSC 39 Petar Rakov Str. 4550 Pesthera Bulgaria	Pandex 1 %	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	Bioveta a.s., Komenského 212 683 23 Ivanovice na Hané Czech Republic	Biomec inj.	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	Bremer Pharma GmbH Cherbourger Str. 25 27540 Bremerhaven Germany	Bremamectin	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	CEVA SANTE ANIMALE Str. Chindiei, nr. 5 Sector 4 040185 Bucureşti Romania	Cevamec 1 %	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	DAR AL DAWA VETERINARY & AGRI- CULTURAL INDUSTRIAL Co. LTD. Jordan NA UR 11710 PO BOX 285 Jordania	Ivodad 1 %	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	DUTCH FARM VETERINARY PHAR- MACEUTICALS B.V. Veemweg 1-3771 MT BARNEVELEND The Netherlands	Dufamec 1 % inj.	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 1 % injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	FARMAVET S.A. Str. Petricani 198, Chişinău Republica Moldova	Ivermectina 1 %	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Romania	HEMOFARM – HEMOVET Beogradski Put BB Vrsac Serbia	Ivermektin S	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	Laboratorios HIPRA S.A. Avda. La Selva, 135 17170 Amer, Girona Spain	Iveripra I	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	Interchemie werken „de Adelaar” BV Horsterweg 26A 5811 AC Castenray The Netherlands	Intermectin	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	INTERVET PRODUCTIONS SRL Via Nettunense km 20, 300 04011 Aprilia Italy	Ivogell	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	INTERVET ROMANIA S.R.L. Șoseaua de Centură, nr. 27- 28, 077040 Chiajna, Ilfov Romania	Ivotan LA	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec 1 %	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	PANTEX Ganzestaartsedijk 8 – 5525 KC Duizel The Netherlands	Panmectin 10	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	PASTEUR – Filiala Filipești Str. Principală, nr. 944, Fili- peștii de Pădure, Jud. Prahova Romania	Evomec	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	S.C. ROMVAC COMPANY S.A. Șos. Centurii, nr. 7, Voluntari Romania	Romivermectin B ₁ 1 %	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Romania	SYVA Av. Párroco Pablo Diez, 49 – 57 24010 – Leon Spain	Zoomectin	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	VMD Animal Health Ltd. Közraktár u. 22/b. II. 3., 1093 Budapest Hungary	Iverveto 1 % Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Slovak Republic	Vétoquinol s.r.o., Zámečnická 411, 288 02 Nymburk, Czech Republic	Biomectin	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Slovak Republic	CEVA Animal Health Slovakia, spol. s r.o. Račianska 77 83 102 BRATISLAVA Slovak Republic	Cevamec 1 % inj. ad us. vet.	Ivermectin 10 mg/ml	Cattle, Sheep, Goats, Pigs	Subcutaneous	Cattle, Sheep, Goats: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Slovak Republic	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Injection ad us vet	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Slovak Republic	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec 1 % inj. ad us.vet.	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Slovak Republic	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec Super inj. ad us.vet.	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
Slovak Republic	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Slovak Republic	Pharmagal spol.s.r.o. Murgašova 5 949 01 Nitra Slovak Republic	Galmectin	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Slovak Republic	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin injekčný roztok pre hovädzi dobytok	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Slovenia	VET4VET d.o.o. Gerbičeva 50, 1000 Ljubljana Slovenia	Animec Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Slovenia	VETERINA d.o.o., Dunajska 51, 1000 Ljubljana, Slovenia	Plus IVERKTIN 1 % solution for injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Slovenia	MERIAL 29 avenue Tony Garnier 69007 LYON France	IVOMEK solution for injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Spain	DIVASA FARMAVIC, S.A. Ctra. Sant Hipolit, km 71 08503 – Gurb-Vic Barcelona Spain	DIVAMECTIN 1 % SOLUCION	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
Spain	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin 1 % Solution Inyectable para Bovino y Porcino	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Spain	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC SOLUCIÓN INYECTABLE PARA BOVINOS	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Spain	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	TIZOVAL VACUNO INYECTABLE	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Spain	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	CHANECTIN INYECTABLE	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Spain	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin Inyectable	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Spain	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	IVERTIN BOVINO	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Spain	INDUSTRIAL VETERINARIA, S.A. C/ Esmeralda, 19 08950 Esplugues de Llobregat Barcelona Spain	PROMECTINE	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Spain	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	SUMEX INYECTABLE BOVINO	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Spain	Laboratorios HIPRA S.A. Avda. La Selva, 135 17170 Amer, Girona Spain	IVERIPRA-I	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Spain	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	ECOMECTIN 10 MG/ML SOLU- CION INYECTABLE	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Spain	Chemo Iberica Gran Vía Carlos III, 98 – 7ºth floor. 08028 Barcelona, Spain	BOVECTIN	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Spain	MERIAL LABORATORIOS S.A Tarragona, 161-Locales D/E 08014 Barcelona Spain	Ivomec Inyetable Para Vacuno	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Spain	MERIAL LABORATORIOS S.A Tarragona, 161-Locales D/E 08014 Barcelona Spain	Ivomec F Inyetable Para Vacuno	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Spain	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin Solucion inyetable para bovino	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Sweden	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec® vet.	Ivermectin 10 mg/ml	Cattle, Reindeer, Pigs	Subcutaneous	Cattle, Reindeer: 200 µg iver- mectin/kg bw Pigs: 300 µg ivermectin/kg bw
Sweden	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2 2080-104 Almeirim Portugal	Virbamec vet. 10 mg/ml injektions- vätska, lösning	Ivermectin 10 mg/ml	Cattle, Reindeer, Pigs	Subcutaneous	Cattle, Reindeer: 200 µg iver- mectin/kg bw Pigs: 300 µg ivermectin/kg bw
Sweden	Bimeda (a division of Cross Vetpharm Group Limited) Broomhill Road Tallaght Dublin 24 Ireland	Bimectin® vet.	Ivermectin 10 mg/ml	Cattle, Reindeer, Pigs	Subcutaneous	Cattle, Reindeer: 200 µg iver- mectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Sweden	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin vet Solution for Injection 10 mg/ml	Ivermectin 10 mg/ml	Cattle, Reindeer, Pigs	Subcutaneous	Cattle, Reindeer: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Sweden	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin, 10 mg/ml, Injektions-vätska, lösning	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Sweden	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec, 10 mg/ml, Injektions-vätska, lösning	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	Ivertin Cattle	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
United Kingdom	Merial Animal Health Limited Sandringham House Harlow Business Park Harlow Essex CM19 5TG United Kingdom	Ivomec Classic Injection for Cattle and Sheep	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
United Kingdom	Merial Animal Health Limited Sandringham House Harlow Business Park Harlow Essex CM19 5TG United Kingdom	Ivomec Super Injection for Cattle	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
United Kingdom	Merial Animal Health Limited Sandringham House Harlow Business Park Harlow Essex CM19 5TG United Kingdom	Panomec Injection for Cattle, Sheep and Pigs	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Animec Injection	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec Injectable Solution For Cattle and Swine	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec Injectable Solution for Cattle, Swine and Sheep	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec Super	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
United Kingdom	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Enovex Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
United Kingdom	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Multi Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
United Kingdom	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
United Kingdom	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin Multi Injection 1 % w/v Solution for Injection for Cattle, Sheep and Pigs	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bimectin 1 % w/v Solution for Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Ecomec 1 % Injection	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Qualimintic 1 % Injection	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	Alstoe Ltd Sheriff Hutton Industrial Park Sheriff Hutton York YO60 6RZ United Kingdom	Alstomec	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 10 mg/ml Solution for Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
United Kingdom	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec 10 mg/ml Solution for Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin Injection	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
United Kingdom	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closiver Injection	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
United Kingdom	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Norofas Solution for Injection	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw

**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	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 1232 Wien, Austria	Topamax 100 mg – Filmtabletten	100 milligram(s)	Film-coated tablet	Oral use
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 1232 Wien, Austria	Topamax 200 mg - Filmtabletten	200 milligram(s)	Film-coated tablet	Oral use
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 1232 Wien, Austria	Topamax 25 mg - Filmtabletten	25 milligram(s)	Film-coated tablet	Oral use
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 1232 Wien, Austria	Topamax 50 mg - Filmtabletten	50 milligram(s)	Film-coated tablet	Oral use
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 1232 Wien, Austria	Topamax 15 mg - Granulat in Kapseln	15 milligram(s)	granuals in capsule	Oral use
Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 1232 Wien, Austria	Topamax 25 mg - Granulat in Kapseln	25 milligram(s)	granuals in capsule	Oral use
Austria	Janssen-Cilag Pharma GmbH - Pfarrgasse 75 A-1232 Wien, Austria	Topamax 50 mg - Granulat in Kapseln	50 milligram(s)	granuals in capsule	Oral use
Belgium	Janssen-Cilag NV – BE Roderveldlaan 1 2600 Berchem, Belgium	Topamax 15 mg harde capsules	15 milligram(s)	Capsule, hard	Oral use
Belgium	Janssen-Cilag NV – BE Roderveldlaan 1 2600 Berchem, Belgium	Topamax 25 mg harde capsules	25 milligram(s)	Capsule, hard	Oral use
Belgium	Janssen-Cilag NV – BE Roderveldlaan 1 2600 Berchem, Belgium	Topamax 50 mg harde capsules	50 milligram(s)	Capsule, hard	Oral use
Belgium	Janssen-Cilag NV – BE Roderveldlaan 1 2600 Berchem, Belgium	Topamax 100 mg tabletten	100 milligram(s)	Tablet	Oral use
Belgium	Janssen-Cilag NV – BE Roderveldlaan 1 2600 Berchem, Belgium	Topamax 200 mg tabletten	200 milligram(s)	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Belgium	Janssen-Cilag NV – BE Roderveldlaan 1 2600 Berchem, Belgium	Topamax 25 mg tabletten	25 milligram(s)	Tablet	Oral use
Belgium	Janssen-Cilag NV – BE Roderveldlaan 1 2600 Berchem, Belgium	Topamax 50 mg tabletten	50 milligram(s)	Tablet	Oral use
Bulgaria	Johnson & Johnson, Prodaja medicinskih in farmacevtskih izdelkov, d.o.o. - SI Smartinska cesta 53, 1000 Ljubljana, Slovenia	TOPAMAX	15 milligram(s)	Capsule	Oral use
Bulgaria	Johnson & Johnson, Prodaja medicinskih in farmacevtskih izdelkov, d.o.o. - SI Smartinska cesta 53, 1000 Ljubljana, Slovenia	TOPAMAX	25 milligram(s)	Capsule	Oral use
Bulgaria	Johnson & Johnson, Prodaja medicinskih in farmacevtskih izdelkov, d.o.o. - SI Smartinska cesta 53, 1000 Ljubljana, Slovenia	TOPAMAX	100 milligram(s)	Tablet	Oral use
Bulgaria	Johnson & Johnson, Prodaja medicinskih in farmacevtskih izdelkov, d.o.o. - SI Smartinska cesta 53, 1000 Ljubljana, Slovenia	TOPAMAX	25 milligram(s)	Tablet	Oral use
Bulgaria	Johnson & Johnson, Prodaja medicinskih in farmacevtskih izdelkov, d.o.o. - SI Smartinska cesta 53, 1000 Ljubljana, Slovenia	TOPAMAX	50 milligram(s)	Tablet	Oral use
Cyprus	Janssen-Cilag International NV - BE Turnhoutseweg 30, 2340 Beerse, Belgium	TOPAMAX 100 mg tabs	100 milligram(s)	Tablet	Oral use
Cyprus	Janssen-Cilag International NV - BE Turnhoutseweg 30, 2340 Beerse, Belgium	TOPAMAX 200 mg tabs	200 milligram(s)	Tablet	Oral use
Cyprus	Janssen-Cilag International NV - BE Turnhoutseweg 30, 2340 Beerse, Belgium	TOPAMAX 25 mg tabs	25 milligram(s)	Film-coated tablet	Oral use
Cyprus	Janssen-Cilag International NV - BE Turnhoutseweg 30, 2340 Beerse, Belgium	TOPAMAX 50 mg tabs	50 milligram(s)	Film-coated tablet	Oral use
Cyprus	Janssen-Cilag International NV - BE Turnhoutseweg 30, 2340 Beerse, Belgium	TOPAMAX 15 mg Sprinkles	15 milligram(s)	Sprinkle capsule	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Cyprus	Janssen-Cilag International NV - BE Turnhoutseweg 30, 2340 Beerse, Belgium	TOPAMAX 25 mg Sprinkles	25 milligram(s)	Sprinkle capsule	Oral use
Cyprus	Janssen-Cilag International NV - BE Turnhoutseweg 30, 2340 Beerse, Belgium	TOPAMAX 50 mg Sprinkles	50 milligram(s)	Sprinkle capsule	Oral use
Czech Republic	Janssen-Cilag s.r.o Karla Engliše 3201/6 150 00 Praha 5	Topamax 100 mg	100 milligram(s)	Film-coated tablet	Oral use
Czech Republic	Janssen-Cilag s.r.o Karla Engliše 3201/6 150 00 Praha 5	Topamax 25 mg	25 milligram(s)	Film-coated tablet	Oral use
Czech Republic	Janssen-Cilag s.r.o Karla Engliše 3201/6 150 00 Praha 5	Topamax 50 mg	50 milligram(s)	Film-coated tablet	Oral use
Czech Republic	Janssen-Cilag s.r.o Karla Engliše 3201/6 150 00 Praha 5	Topamax 15 mg	15 milligram(s)	Capsule	Oral use
Czech Republic	Janssen-Cilag s.r.o Karla Engliše 3201/6 150 00 Praha 5	Topamax 25 mg	25 milligram(s)	Capsule	Oral use
Denmark	Janssen-Cilag A/S Hammerbakken 19, 3460 Birkerød, Denmark	Topimax	15 milligram(s)	Capsule, hard	Oral use
Denmark	Janssen-Cilag A/S Hammerbakken 19, 3460 Birkerød, Denmark	Topimax	25 milligram(s)	Capsule, hard	Oral use
Denmark	Janssen-Cilag A/S Hammerbakken 19, 3460 Birkerød, Denmark	Topimax	50 milligram(s)	Capsule, hard	Oral use
Denmark	Janssen-Cilag A/S Hammerbakken 19, 3460 Birkerød, Denmark	Topimax	100 milligram(s)	Film-coated tablet	Oral use
Denmark	Janssen-Cilag A/S Hammerbakken 19, 3460 Birkerød, Denmark	Topimax	200 milligram(s)	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Denmark	Janssen-Cilag A/S Hammerbakken 19, 3460 Birkerød, Denmark	Topimax	25 milligram(s)	Film-coated tablet	Oral use
Denmark	Janssen-Cilag A/S Hammerbakken 19, 3460 Birkerød, Denmark	Topimax	50 milligram(s)	Film-coated tablet	Oral use
Estonia	UAB Johnson & Johnson - LT Geležinio Vilko g. 18A LT-08104 Vilnius Lithuania	TOPAMAX 100 mg	100 milligram(s)	Film-coated tablet	Oral use
Estonia	UAB Johnson & Johnson - LT Geležinio Vilko g. 18A LT-08104 Vilnius Lithuania	TOPAMAX 200 mg	200 milligram(s)	Film-coated tablet	Oral use
Estonia	UAB Johnson & Johnson - LT Geležinio Vilko g. 18A LT-08104 Vilnius Lithuania	TOPAMAX 25 mg	25 milligram(s)	Film-coated tablet	Oral use
Estonia	UAB Johnson & Johnson - LT Geležinio Vilko g. 18A LT-08104 Vilnius Lithuania	TOPAMAX 50 mg	50 milligram(s)	Film-coated tablet	Oral use
Finland	Janssen-Cilag OY – FI Metsänneidonkuja 8 02130 Espoo Finland	Topimax 15 mg kapseli, kova	15 milligram(s)	Capsule, hard	Oral use
Finland	Janssen-Cilag OY – FI Metsänneidonkuja 8 02130 Espoo Finland	Topimax 100 mg tabletti, kalvopäällysteinen	100 milligram(s)	Film-coated tablet	Oral use
Finland	Janssen-Cilag OY – FI Metsänneidonkuja 8 02130 Espoo Finland	Topimax 200 mg tabletti, kalvopäällysteinen	200 milligram(s)	Film-coated tablet	Oral use
Finland	Janssen-Cilag OY – FI Metsänneidonkuja 8 02130 Espoo Finland	Topimax 25 mg tabletti, kalvopäällysteinen	25 milligram(s)	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Finland	Janssen-Cilag OY – FI Metsänneidonkuja 8 02130 Espoo Finland	Topimax 50 mg tabletti, kalvopäällysteinen	50 milligram(s)	Film-coated tablet	Oral use
Finland	Janssen-Cilag OY – FI Metsänneidonkuja 8 02130 Espoo Finland	Topimax 25 mg kapseli, kova	25 milligram(s)	Capsule, hard	Oral use
Finland	Janssen-Cilag OY – FI Metsänneidonkuja 8 02130 Espoo Finland	Topimax 50 mg kapseli, kova	50 milligram(s)	Capsule, hard	Oral use
France	Janssen-Cilag S.A. – FR 1 rue Camille Desmoulins, TSA 91003, 92787 ISSY-Les-Moulineaux Cedex 9 France	EPITOMAX 100 mg, COMPRIME PELLICULE	100 milligram(s)	Film-coated tablet	Oral use
France	Janssen-Cilag S.A. – FR 1 rue Camille Desmoulins, TSA 91003, 92787 ISSY-Les-Moulineaux Cedex 9 France	EPITOMAX 200 mg, COMPRIME PELLICULE	200 milligram(s)	Film-coated tablet	Oral use
France	Janssen-Cilag S.A. – FR 1 rue Camille Desmoulins, TSA 91003, 92787 ISSY-Les-Moulineaux Cedex 9 France	EPITOMAX 50 mg, COMPRIME PELLICULE	50 milligram(s)	Film-coated tablet	Oral use
France	Janssen-Cilag S.A. – FR 1 rue Camille Desmoulins, TSA 91003, 92787 ISSY-Les-Moulineaux Cedex 9 France	EPITOMAX 15 mg, GELULE	15 milligram(s)	Sprinkle capsule	Oral use
France	Janssen-Cilag S.A. – FR 1 rue Camille Desmoulins, TSA 91003, 92787 ISSY-Les-Moulineaux Cedex 9 France	EPITOMAX 25 mg, GELULE	25 milligram(s)	Sprinkle capsule	Oral use
France	Janssen-Cilag S.A. – FR 1 rue Camille Desmoulins, TSA 91003, 92787 ISSY-Les-Moulineaux Cedex 9 France	EPITOMAX 50 mg, GELULE	50 milligram(s)	Sprinkle capsule	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topiramate-Cilag 25 mg Hart- kapseln	25 milligram(s)	Capsule, hard	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topiramat-Janssen 25 mg Hart- kapseln	25 milligram(s)	Capsule, hard	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topiramat-Cilag 50 mg Hart- kapseln	50 milligram(s)	Capsule, hard	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topiramat-Janssen 50 mg Hart- kapseln	50 milligram(s)	Capsule, hard	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topamax 100 mg Filmtabletten	100 milligram(s)	Film-coated tablet	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topiramat-Janssen 100 mg Film- tabletten	100 milligram(s)	Film-coated tablet	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	TOPAMAX MIGRÄNE 100 mg Filmtabletten	100 milligram(s)	Film-coated tablet	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topiramat - Cilag 100 mg Film- tabletten	100 milligram(s)	Film-coated tablet	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topiramat-Cilag 100 mg Film-tab- letten	100 milligram(s)	Film-coated tablet	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topamax 200 mg Filmtabletten	200 milligram(s)	Film-coated tablet	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	TOPAMAX MIGRÄNE 200 mg Filmtabletten	200 milligram(s)	Film-coated tablet	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topiramat - Cilag 200 mg Film- tabletten	200 milligram(s)	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topiramat-Cilag 200 mg Filmtabletten	200 milligram(s)	Film-coated tablet	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topiramat-Janssen 200 mg Filmtabletten	200 milligram(s)	Film-coated tablet	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topamax 25 mg Filmtabletten	25 milligram(s)	Film-coated tablet	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	TOPAMAX MIGRÄNE 25 mg Filmtabletten	25 milligram(s)	Film-coated tablet	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topiramat-Cilag 25 mg Filmtabletten	25 milligram(s)	Film-coated tablet	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topiramat-Janssen 25 mg Filmtabletten	25 milligram(s)	Film-coated tablet	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topamax 50 mg Filmtabletten	50 milligram(s)	Film-coated tablet	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	TOPAMAX MIGRÄNE 50 mg Filmtabletten	50 milligram(s)	Film-coated tablet	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topiramat-Cilag 50 mg Filmtabletten	50 milligram(s)	Film-coated tablet	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topiramat-Janssen 50 mg Filmtabletten	50 milligram(s)	Film-coated tablet	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topamax 25 mg Kapseln	25 milligram(s)	Capsule hard	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	TOPAMAX MIGRÄNE 25 mg Hartkapseln	25 milligram(s)	Capsule	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	Topamax 50 mg Kapseln	50 milligram(s)	Capsule hard	Oral use
Germany	Janssen-Cilag GmbH - DE Raiffeisenstr. 8 41470 Neuss, Germany	TOPAMAX MIGRÄNE 50 mg Hartkapseln	50 milligram(s)	Capsule	Oral use
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. – GR 56 Eirinis Avenue 56, Pefki, 15121, Greece	TOPAMAC	100 milligram(s)	Film-coated tablet	Oral use
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. – GR 56 Eirinis Avenue 56, Pefki, 15121, Greece	TOPAMAC	200 milligram(s)	Film-coated tablet	Oral use
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. – GR 56 Eirinis Avenue 56, Pefki, 15121, Greece	TOPAMAC	25 milligram(s)	Film-coated tablet	Oral use
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. – GR 56 Eirinis Avenue 56, Pefki, 15121, Greece	TOPAMAC	50 milligram(s)	Film-coated tablet	Oral use
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. – GR 56 Eirinis Avenue 56, Pefki, 15121, Greece	TOPAMAC	15 milligram(s)	Capsule, hard	Oral use
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. – GR 56 Eirinis Avenue 56, Pefki, 15121, Greece	TOPAMAC	25 milligram(s)	Capsule, hard	Oral use
Greece	Janssen-Cilag Pharmaceutical S.A.C.I. – GR 56 Eirinis Avenue 56, Pefki, 15121, Greece	TOPAMAC	50 milligram(s)	Capsule, hard	Oral use
Hungary	Janssen-Cilag Kft. - HU 2045 Törökbálint Tó park, Hungary	Topamax 100 mg film-coated tablet	100 milligram(s)	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Hungary	Janssen-Cilag Kft. - HU 2045 Törökbálint Tó park, Hungary	Topamax 200 mg film-coated tablets	200 milligram(s)	Film-coated tablet	Oral use
Hungary	Janssen-Cilag Kft. - HU 2045 Törökbálint Tó park, Hungary	Topamax 25 mg film-coated tablet	25 milligram(s)	Film-coated tablet	Oral use
Hungary	Janssen-Cilag Kft. - HU 2045 Törökbálint Tó park, Hungary	Topamax 50 mg film-coated tablet	50 milligram(s)	Film-coated tablet	Oral use
Iceland	Janssen-Cilag AB - SE Box 7073 192 07 Sollentuna, Sverige	Topimax 15 mg hylki, hörð	15 milligram(s)	Capsule, hard	Oral use
Iceland	Janssen-Cilag AB - SE Box 7073 192 07 Sollentuna, Sverige	Topimax 25 mg hylki, hörð	25 milligram(s)	Capsule, hard	Oral use
Iceland	Janssen-Cilag AB - SE Box 7073 192 07 Sollentuna, Sverige	Topimax 50 mg hylki, hörð	50 milligram(s)	Capsule, hard	Oral use
Iceland	Janssen-Cilag AB - SE Box 7073 192 07 Sollentuna, Sverige	Topimax 100 mg filmuhúðaðar töflur	100 milligram(s)	Film-coated tablet	Oral use
Iceland	Janssen-Cilag AB - SE Box 7073 192 07 Sollentuna, Sverige	Topimax 200 mg filmuhúðaðar töflur	200 milligram(s)	Film-coated tablet	Oral use
Iceland	Janssen-Cilag AB - SE Box 7073 192 07 Sollentuna, Sverige	Topimax 25 mg filmuhúðaðar töflur	25 milligram(s)	Film-coated tablet	Oral use
Iceland	Janssen-Cilag AB - SE Box 7073 192 07 Sollentuna, Sverige	Topimax 50 mg filmuhúðaðar töflur	50 milligram(s)	Film-coated tablet	Oral use
Ireland	Janssen-Cilag Limited - GB Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	TOPAMAX 100 mg Tablets	100 milligram(s)	Film-coated tablet	Oral use
Ireland	Janssen-Cilag Limited - GB Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	TOPAMAX 200 mg Tablets	200 milligram(s)	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Ireland	Janssen-Cilag Limited - GB Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	TOPAMAX 25 mg Tablets	25 milligram(s)	Film-coated tablet	Oral use
Ireland	Janssen-Cilag Limited - GB Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	TOPAMAX 50 mg Tablets	50 milligram(s)	Film-coated tablet	Oral use
Ireland	Janssen-Cilag Limited - GB Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	TOPAMAX Sprinkle Capsules 15 mg.	15 milligram(s)	Sprinkle capsule	Oral use
Ireland	Janssen-Cilag Limited - GB Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	TOPAMAX Sprinkle Capsules 25 mg.	25 milligram(s)	Sprinkle capsule	Oral use
Ireland	Janssen-Cilag Limited - GB Saunderton High Wycombe Buckinghamshire HP14 4HJ United Kingdom	TOPAMAX Sprinkle Capsules 50 mg	50 milligram(s)	Sprinkle capsule	Oral use
Italy	Janssen-Cilag SpA – IT Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	TOPAMAX 15 mg capsule rigide, 60 capsule	15 milligram(s)	Capsule, hard	Oral use
Italy	Janssen-Cilag SpA – IT Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	TOPAMAX 100 mg compresse rivestite con film, 60 compresse	100 milligram(s)	Film-coated tablet	Oral use
Italy	J.C. Healthcare srl – IT Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	EPITOMAX 100 mg compresse rivestite con film, 60 compresse	100 milligram(s)	Film-coated tablet	Oral use
Italy	Janssen-Cilag SpA – IT Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	TOPAMAX 200 mg compresse rivestite con film, 60 compresse	200 milligram(s)	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Italy	J.C. Healthcare srl – IT Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	EPITOMAX 200 mg compresse rivestite con film, 60 compresse	200 milligram(s)	Film-coated tablet	Oral use
Italy	Janssen-Cilag SpA – IT Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	TOPAMAX 25 mg compresse rivestite con film, 60 compresse	25 milligram(s)	Film-coated tablet	Oral use
Italy	J.C. Healthcare srl – IT Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	EPITOMAX 25 mg compresse rivestite con film, 60 compresse	25 milligram(s)	Film-coated tablet	Oral use
Italy	Janssen-Cilag SpA – IT Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	TOPAMAX 300 mg compresse rivestite con film, 60 compresse	300 milligram(s)	Film-coated tablet	Oral use
Italy	J.C. Healthcare srl – IT Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	EPITOMAX 300 mg compresse rivestite con film, 60 compresse	300 milligram(s)	Film-coated tablet	Oral use
Italy	Janssen-Cilag SpA – IT Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	TOPAMAX 400 mg compresse rivestite con film, 60 compresse	400 milligram(s)	Film-coated tablet	Oral use
Italy	J.C. Healthcare srl – IT Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	EPITOMAX 400 mg compresse rivestite con film, 60 compresse	400 milligram(s)	Film-coated tablet	Oral use
Italy	Janssen-Cilag SpA – IT Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	TOPAMAX 50 mg compresse rivestite con film, 60 compresse	50 milligram(s)	Film-coated tablet	Oral use
Italy	J.C. Healthcare srl – IT Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	EPITOMAX 50 mg compresse rivestite con film, 60 compresse	50 milligram(s)	Film-coated tablet	Oral use
Italy	Janssen-Cilag SpA – IT Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	TOPAMAX 25 mg capsule rigide, 60 capsule	25 milligram(s)	Capsule, hard	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Italy	Janssen-Cilag SpA – IT Via Michelangelo Buonarroti n. 23 Cologno Monzese, 20093, Milano, Italy	TOPAMAX 50 mg capsule rigide, 60 capsule	50 milligram(s)	Capsule, hard	Oral use
Latvia	UAB Johnson & Johnson - LT Šeimyniškių g.1A, LT-09312 Vilnius, Lithuania	Topamax 100 mg coated tablets	100 milligram(s)	Coated tablet	Oral use
Latvia	UAB Johnson & Johnson - LT Šeimyniškių g.1A, LT-09312 Vilnius, Lithuania	Topamax 25 mg coated tablets	25 milligram(s)	Coated tablet	Oral use
Latvia	UAB Johnson & Johnson - LT Šeimyniškių g.1A, LT-09312 Vilnius, Lithuania	Topamax 50 mg coated tablets	50 milligram(s)	Coated tablet	Oral use
Latvia	UAB Johnson & Johnson - LT Šeimyniškių g.1A, LT-09312 Vilnius, Lithuania	Topamax 15 mg sprinkle capsules	15 milligram(s)	Sprinkle capsule	Oral use
Latvia	UAB Johnson & Johnson - LT Šeimyniškių g.1A, LT-09312 Vilnius, Lithuania	Topamax 25 mg sprinkle capsules	25 milligram(s)	Sprinkle capsule	Oral use
Lithuania	UAB Johnson & Johnson Šeimyniškių g. 1A, LT-09312 Vilnius, Lithuania	Topamax	100 milligram(s)	Tablet	Oral use
Lithuania	UAB Johnson & Johnson Šeimyniškių g. 1A, LT-09312 Vilnius, Lithuania	Topamax	200 milligram(s)	Tablet	Oral use
Lithuania	UAB Johnson & Johnson Šeimyniškių g. 1A, LT-09312 Vilnius, Lithuania	Topamax	25 milligram(s)	Tablet	Oral use
Lithuania	UAB Johnson & Johnson Šeimyniškių g. 1A, LT-09312 Vilnius, Lithuania	Topamax	50 milligram(s)	Tablet	Oral use
Luxembourg	Janssen-Cilag NV – BE Roderveldlaan 1 2600 Berchem, Belgium	Topamax gélules 15 mg	15 milligram(s)	Capsule, hard	Oral use
Luxembourg	Janssen-Cilag NV – BE Roderveldlaan 1 2600 Berchem, Belgium	Topamax comprimés 100 mg	100 milligram(s)	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Luxembourg	Janssen-Cilag NV – BE Roderveldlaan 1 2600 Berchem, Belgium	Topamax comprimés 200 mg	200 milligram(s)	Tablet	Oral use
Luxembourg	Janssen-Cilag NV – BE Roderveldlaan 1 2600 Berchem, Belgium	Topamax comprimés 25 mg	25 milligram(s)	Tablet	Oral use
Luxembourg	Janssen-Cilag NV – BE Roderveldlaan 1 2600 Berchem, Belgium	Topamax comprimés 50 mg	50 milligram(s)	Tablet	Oral use
Luxembourg	Janssen-Cilag NV – BE Roderveldlaan 1 2600 Berchem, Belgium	Topamax gélules 25 mg	25 milligram(s)	Capsule, hard	Oral use
Luxembourg	Janssen-Cilag NV – BE Roderveldlaan 1 2600 Berchem, Belgium	Topamax gélules 50 mg	50 milligram(s)	Capsule, hard	Oral use
Malta	Janssen-Cilag International NV - BE Turnhoutseweg 30, B-2340 Beerse, Belgium	Topamax	100 milligram(s)	Tablet	Oral use
Malta	Janssen-Cilag International NV - BE Turnhoutseweg 30, B-2340 Beerse, Belgium	Topamax	200 milligram(s)	Tablet	Oral use
Malta	Janssen-Cilag International NV - BE Turnhoutseweg 30, B-2340 Beerse, Belgium	Topamax	25 milligram(s)	Tablet	Oral use
Malta	Janssen-Cilag International NV - BE Turnhoutseweg 30, B-2340 Beerse, Belgium	Topamax	50 milligram(s)	Tablet	Oral use
Malta	Janssen-Cilag International NV - BE Turnhoutseweg 30, B-2340 Beerse, Belgium	Topamax	15 milligram(s)	Hard capsule	Oral use
Malta	Janssen-Cilag International NV - BE Turnhoutseweg 30, B-2340 Beerse, Belgium	Topamax	25 milligram(s)	Hard capsule	Oral use
Malta	Janssen-Cilag International NV - BE Turnhoutseweg 30, B-2340 Beerse, Belgium	Topamax	50 milligram(s)	Hard capsule	Oral use
Netherlands	Janssen-Cilag BV – NL Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Topamax omhulde tabletten 100 mg, omhulde tabletten	100 milligram(s)	Coated tablet	Oral use
Netherlands	Janssen-Cilag BV – NL Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Topamax omhulde tabletten 200 mg, omhulde tabletten	200 milligram(s)	Coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Netherlands	Janssen-Cilag BV – NL Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Topamax omhulde tabletten 25 mg, omhulde tabletten	25 milligram(s)	Coated tablet	Oral use
Netherlands	Janssen-Cilag BV – NL Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Topamax omhulde tabletten 50 mg, omhulde tabletten	50 milligram(s)	Coated tablet	Oral use
Netherlands	Janssen-Cilag BV – NL Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Topamax Sprinkle capsules 15 mg, capsules	15 milligram(s)	Capsule	Oral use
Netherlands	Janssen-Cilag BV – NL Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Topamax Sprinkle capsules 25 mg, capsules	25 milligram(s)	Capsule	Oral use
Netherlands	Janssen-Cilag BV – NL Dr. Paul Janssenweg 150 PO Box 90240 5000 LT Tilburg The Netherlands	Topamax Sprinkle capsules 50 mg, capsules	50 milligram(s)	Capsule	Oral use
Norway	Janssen-Cilag AS – NO Hoffsveien 1D 0275 Oslo Norway	Topimax 15 mg Kapsel, hard	15 milligram(s)	Capsule, hard	Oral use
Norway	Janssen-Cilag AS – NO Hoffsveien 1D 0275 Oslo Norway	Topimax 25 mg Kapsel, hard	25 milligram(s)	Capsule, hard	Oral use
Norway	Janssen-Cilag AS – NO Hoffsveien 1D 0275 Oslo Norway	Topimax 50 mg Kapsel, hard	50 milligram(s)	Capsule, hard	Oral use
Norway	Janssen-Cilag AS – NO Hoffsveien 1D 0275 Oslo Norway	Topimax 100 mg Tabletter filmdrasjert	100 milligram(s)	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Norway	Janssen-Cilag AS – NO Hoffsveien 1D 0275 Oslo Norway	Topimax 200 mg Tabletter filmdrasjert	200 milligram(s)	Film-coated tablet	Oral use
Norway	Janssen-Cilag AS – NO Hoffsveien 1D 0275 Oslo Norway	Topimax 25 mg Tabletter filmdrasjert	25 milligram(s)	Film-coated tablet	Oral use
Norway	Janssen-Cilag AS – NO Hoffsveien 1D 0275 Oslo Norway	Topimax 50 mg Tabletter filmdrasjert	50 milligram(s)	Film-coated tablet	Oral use
Poland	Janssen-Cilag International NV - BE Turnhoutseweg 30 B-2340 Beerse Belgium	Topamax 100 mg tabletki powlekane	100 milligram(s)	Film-coated tablet	Oral use
Poland	Janssen-Cilag International NV - BE Turnhoutseweg 30 B-2340 Beerse Belgium	Topamax 200 mg tabletki powlekane	200 milligram(s)	Film-coated tablet	Oral use
Poland	Janssen-Cilag International NV - BE Turnhoutseweg 30 B-2340 Beerse Belgium	Topamax 25 mg tabletki powlekane	25 milligram(s)	Film-coated tablet	Oral use
Poland	Janssen-Cilag International NV - BE Turnhoutseweg 30 B-2340 Beerse Belgium	Topamax 50 mg tabletki powlekane	50 milligram(s)	Film-coated tablet	Oral use
Poland	Janssen-Cilag International NV - BE Turnhoutseweg 30 B-2340 Beerse Belgium	Topamax 15 mg kapsulki	15 milligram(s)	Capsule	Oral use
Poland	Janssen-Cilag International NV - BE Turnhoutseweg 30 B-2340 Beerse Belgium	Topamax 25 mg kapsulki	25 milligram(s)	Capsule	Oral use
Portugal	Janssen-Cilag Farmacêutica, Lda. – PT Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo 2734-503 Barcarena Portugal	Topamax	100 milligram(s)	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Portugal	Janssen-Cilag Farmacêutica, Lda. – PT Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo 2734-503 Barcarena Portugal	Topamax	200 milligram(s)	Film-coated tablet	Oral use
Portugal	Janssen-Cilag Farmacêutica, Lda. – PT Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo 2734-503 Barcarena Portugal	Topamax	25 milligram(s)	Film-coated tablet	Oral use
Portugal	Janssen-Cilag Farmacêutica, Lda. – PT Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo 2734-503 Barcarena Portugal	Topamax	50 milligram(s)	Film-coated tablet	Oral use
Portugal	Janssen-Cilag Farmacêutica, Lda. – PT Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo 2734-503 Barcarena Portugal	Topamax	15 milligram(s)	capsule, hard	Oral use
Portugal	Janssen-Cilag Farmacêutica, Lda. – PT Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo 2734-503 Barcarena Portugal	Topamax	25 milligram(s)	capsule, hard	Oral use
Portugal	Janssen-Cilag Farmacêutica, Lda. – PT Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo 2734-503 Barcarena Portugal	Topamax	50 milligram(s)	capsule, hard	Oral use
Romania	Johnson & Johnson, d.o.o. – SI Smartinska cesta 53, Ljubljana, Slovenia	TOPAMAX 100 tablets	100 milligram(s)	Tablet	Oral use
Romania	Johnson & Johnson, d.o.o. – SI Smartinska cesta 53, Ljubljana, Slovenia	TOPAMAX 200 tablets	200 milligram(s)	Tablet	Oral use
Romania	Johnson & Johnson, d.o.o. – SI Smartinska cesta 53, Ljubljana, Slovenia	TOPAMAX 25 tablets	25 milligram(s)	Tablet	Oral use
Romania	Johnson & Johnson, d.o.o. – SI Smartinska cesta 53, Ljubljana, Slovenia	TOPAMAX 50 tablets	50 milligram(s)	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Romania	Johnson & Johnson, d.o.o. – SI Smartinska cesta 53, Ljubljana, Slovenia	TOPAMAX sprinkle caps	50 milligram(s)	Sprinkle capsule	Oral use
Slovak Republic	Johnson & Johnson, s.r.o – SK Plynárenská 7/B 824 78 Bratislava Slovak Republic	Topamax 15 mg cps	15 milligram(s)	Prolonged-release capsule, hard	Oral use
Slovak Republic	Johnson & Johnson, s.r.o – SK Plynárenská 7/B 824 78 Bratislava Slovak Republic	Topamax 25 mg cps	25 milligram(s)	Prolonged-release capsule, hard	Oral use
Slovak Republic	Johnson & Johnson, s.r.o – SK Plynárenská 7/B 824 78 Bratislava Slovak Republic	Topamax 100	100 milligram(s)	Film-coated tablet	Oral use
Slovak Republic	Johnson & Johnson, s.r.o – SK Plynárenská 7/B 824 78 Bratislava Slovak Republic	Topamax 200	200 milligram(s)	Film-coated tablet	Oral use
Slovak Republic	Johnson & Johnson, s.r.o – SK Plynárenská 7/B 824 78 Bratislava Slovak Republic	Topamax 25	25 milligram(s)	Film-coated tablet	Oral use
Slovak Republic	Johnson & Johnson, s.r.o – SK Plynárenská 7/B 824 78 Bratislava Slovak Republic	Topamax 50	50 milligram(s)	Film-coated tablet	Oral use
Slovenia	Johnson & Johnson, Prodaja medicinskih in farmaceutskih izdelkov, d.o.o. – SI Šmartinska 53, Ljubljana, Slovenia	TOPAMAX 100 mg filmsko obložene tablete	100 milligram(s)	Film-coated tablet	Oral use
Slovenia	Johnson & Johnson, Prodaja medicinskih in farmaceutskih izdelkov, d.o.o. – SI Šmartinska 53, Ljubljana, Slovenia	TOPAMAX 200 mg filmsko obložene tablete	200 milligram(s)	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Slovenia	Johnson & Johnson, Prodaja medicinskih in farmacevtskih izdelkov, d.o.o. – SI Šmartinska 53, Ljubljana, Slovenia	TOPAMAX 25 mg filmsko obložene tablete	25 milligram(s)	Film-coated tablet	Oral use
Slovenia	Johnson & Johnson, Prodaja medicinskih in farmacevtskih izdelkov, d.o.o. – SI Šmartinska 53, Ljubljana, Slovenia	TOPAMAX 50 mg filmsko obložene tablete	50 milligram(s)	Film-coated tablet	Oral use
Slovenia	Johnson & Johnson, Prodaja medicinskih in farmacevtskih izdelkov, d.o.o. – SI Šmartinska 53, Ljubljana, Slovenia	TOPAMAX 15 mg kapsule	15 milligram(s)	hard capsule	Oral use
Spain	Janssen-Cilag S.A. – ES Paseo de las DoceEstrellas, 5-7 28042 Madrid, Spain	TOPAMAX 100 mg Comprimidos recubiertos	100 milligram(s)	Coated tablet	Oral use
Spain	Janssen-Cilag S.A. – ES Paseo de las DoceEstrellas, 5-7 28042 Madrid, Spain	TOPAMAX 200 mg Comprimidos recubiertos	200 milligram(s)	Coated tablet	Oral use
Spain	Janssen-Cilag S.A. – ES Paseo de las DoceEstrellas, 5-7 28042 Madrid, Spain	TOPAMAX 25 mg Comprimidos recubiertos	25 milligram(s)	Coated tablet	Oral use
Spain	Janssen-Cilag S.A. – ES Paseo de las DoceEstrellas, 5-7 28042 Madrid, Spain	TOPAMAX 50 mg Comprimidos recubiertos	50 milligram(s)	Coated tablet	Oral use
Spain	Janssen-Cilag S.A. – ES Paseo de las DoceEstrellas, 5-7 28042 Madrid, Spain	TOPAMAX DISPERSABLE 15 mg, cápsulas	15 milligram(s)	Sprinkle capsule	Oral use
Spain	Janssen-Cilag S.A. – ES Paseo de las DoceEstrellas, 5-7 28042 Madrid, Spain	TOPAMAX DISPERSABLE 25 mg, cápsulas	25 milligram(s)	Sprinkle capsule	Oral use
Spain	Janssen-Cilag S.A. – ES Paseo de las DoceEstrellas, 5-7 28042 Madrid, Spain	TOPAMAX DISPERSABLE 50 mg, cápsulas	50 milligram(s)	Sprinkle capsule	Oral use
Sweden	Janssen-Cilag AB – SE Box 7073 192 07 Sollentuna, Sverige	Topimax 15 mg kapslar, hårda	15 milligram(s)	Capsule, hard	Oral use
Sweden	Janssen-Cilag AB – SE Box 7073 192 07 Sollentuna, Sverige	Topimax 25 mg kapslar, hårda	25 milligram(s)	Capsule, hard	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
Sweden	Janssen-Cilag AB – SE Box 7073 192 07 Sollentuna, Sverige	Topimax 50 mg kapslar, hårda	50 milligram(s)	Capsule, hard	Oral use
Sweden	Janssen-Cilag AB – SE Box 7073 192 07 Sollentuna, Sverige	Topimax 100 mg tabletter, filmdragerade	100 milligram(s)	Film-coated tablet	Oral use
Sweden	Janssen-Cilag AB – SE Box 7073 192 07 Sollentuna, Sverige	Topimax 200 mg tabletter, filmdragerade	200 milligram(s)	Film-coated tablet	Oral use
Sweden	Janssen-Cilag AB – SE Box 7073 192 07 Sollentuna, Sverige	Topimax 25 mg tabletter, filmdragerade	25 milligram(s)	Film-coated tablet	Oral use
Sweden	Janssen-Cilag AB – SE Box 7073 192 07 Sollentuna, Sverige	Topimax 50 mg tabletter, filmdragerade	50 milligram(s)	Film-coated tablet	Oral use
United Kingdom	Janssen-Cilag Limited – GB Saunderton High-Wycombe Buckinghamshire HP14 4HJ United Kingdom	TOPAMAX 100 mg Tablets	100 milligram(s)	Tablet	Oral use
United Kingdom	Janssen-Cilag Limited – GB Saunderton High-Wycombe Buckinghamshire HP14 4HJ United Kingdom	TOPAMAX 200 mg Tablets	200 milligram(s)	Tablet	Oral use
United Kingdom	Janssen-Cilag Limited – GB Saunderton High-Wycombe Buckinghamshire HP14 4HJ United Kingdom	TOPAMAX 25 mg Tablets	25 milligram(s)	Tablet	Oral use
United Kingdom	Janssen-Cilag Limited – GB Saunderton High-Wycombe Buckinghamshire HP14 4HJ United Kingdom	TOPAMAX 50 mg Tablets	50 milligram(s)	Tablet	Oral use
United Kingdom	Janssen-Cilag Limited – GB Saunderton High-Wycombe Buckinghamshire HP14 4HJ United Kingdom	TOPAMAX Sprinkle Capsules 15 mg	15 milligram(s)	Sprinkle capsule	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Janssen-Cilag Limited – GB Saunderton High-Wycombe Buckinghamshire HP14 4HJ United Kingdom	TOPAMAX Sprinkle Capsules 25 mg	25 milligram(s)	Sprinkle capsule	Oral use
United Kingdom	Janssen-Cilag Limited – GB Saunderton High-Wycombe Buckinghamshire HP14 4HJ United Kingdom	TOPAMAX Sprinkle Capsules 50 mg	50 milligram(s)	Sprinkle capsule	Oral use

**LIST OF THE NAMES, PHARMACEUTICAL FORM(S), STRENGTH(S) OF THE MEDICINAL PRODUCT(S),
ROUTE(S) OF ADMINISTRATION, APPLICANT(S) / MARKETING AUTHORISATION HOLDER(S) IN THE
MEMBER STATES**

Member State EU/EEA	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Austria	Bayer Austria GmbH Herbststraße 6-10 1160 Wien Austria		Avelox 400 mg - Infusionslösung	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Belgium	Bayer SA-NV Avenue Louise 143 Louizalaan B-1050 Brussel Belgium		Avelox	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Cyprus		Bayer Hellas S.A. Sorou 18-20 151 25 Marousi - Athens Greece	Avelox	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Czech Republic		Bayer HealthCare AG Kaiser Wilhelm Allee 51368 Leverkusen Germany	Avelox 400 mg/ 250 ml infuzní roztok	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Denmark	Bayer HealthCare AG Kaiser Wilhelm Allee 51368 Leverkusen Germany		Avelox	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Estonia	Bayer HealthCare AG Kaiser Wilhelm Allee 51368 Leverkusen Germany		Avelox	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Finland	Bayer HealthCare AG Kaiser Wilhelm Allee 51368 Leverkusen Germany		Avelox	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
France		Bayer Santé 13, rue Jean Jaurès 92807 Puteaux Cedex France	Izilox 400 mg / 250 ml, solution pour perfusion	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml

Member State EU/EEA	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Germany	Bayer Vital GmbH Kaiser Wilhelm Allee 51368 Leverkusen Germany		Avalox 400 mg / 250 ml Infusionslösung	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Greece	Bayer Hellas S.A. Sorou 18-20 151 25 Marousi - Athens Greece		Avelox	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Hungary	Bayer Hungária Kft Alkotás ut.50 1123 Budapest Hungary		Avelox	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Ireland	Bayer Limited The Atrium Blackthorn Road Dublin 18 Ireland		Avelox	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Italy		Bayer HealthCare AG Kaiser Wilhelm Allee 51368 Leverkusen Germany	Avalox	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Látvia	Bayer HealthCare AG Kaiser Wilhelm Allee 51368 Leverkusen Germany		Avelox	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Lithuania	Bayer HealthCare AG Kaiser Wilhelm Allee 51368 Leverkusen Germany		Avelox	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Luxembourg	Bayer SA-NV Avenue Louise 143 Louizalaan B-1050 Brussel Belgium		Avelox	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Malta	Bayer HealthCare AG Kaiser Wilhelm Allee 51368 Leverkusen Germany		Avalox 400 mg/250 ml Solution for Infusion	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml

Member State EU/EEA	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Netherlands	Bayer BV Energieweg 1 3641 RT Mijdrecht Netherlands		Avelox 400 mg/250 ml oplossing voor infusie	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Poland		Bayer HealthCare AG Kaiser Wilhelm Allee 51368 Leverkusen Germany	Avelox	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Portugal		BayHealth - Comercialização de Produtos Farmacêuticos Unipessoal, Lda. Rua Quinta do Pinheiro, 5 2794-003 Carnaxide Portugal	Avelox	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Slovak Republic	Bayer HealthCare AG Kaiser Wilhelm Allee 51368 Leverkusen Germany		AVELOX 400 mg/250 ml infúzny roztok	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Slovenia	BAYER d.o.o. Bravničarjeva 13 1000 Ljubljana Slovenia		Avelox 400 mg/250 ml raztopina za infundiranje	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Spain		Bayer HealthCare AG Kaiser Wilhelm Allee 51368 Leverkusen Germany	Muzolil	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Sweden	Bayer HealthCare AG Kaiser Wilhelm Allee 51368 Leverkusen Germany		Avelox	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
United Kingdom		Bayer plc Bayer House Strawberry Hill Newbury Berkshire RG14 1JA United Kingdom	Avelox	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml

ANNEX IV

**LIST OF THE NAMES, PHARMACEUTICAL FORM(S), STRENGTH(S) OF THE MEDICINAL PRODUCT(S),
ROUTE(S) OF ADMINISTRATION, APPLICANT(S) / MARKETING AUTHORISATION HOLDER(S) IN THE
MEMBER STATES**

Member State EU/EEA	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Austria	Bayer HealthCare AG 51368 Leverkusen Germany		Octegra 400 mg - Infusionslösung	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Belgium	Bayer HealthCare AG 51368 Leverkusen Germany		Proflox	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
France		Bayer HealthCare AG 51368 Leverkusen Germany	Octegra 400 mg / 250 ml, solution pour perfusion	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Germany	Bayer HealthCare AG 51368 Leverkusen Germany		Octegra 400 mg / 250 ml Infusionslösung	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Greece	Elpen Pharmaceutical Co, Inc 95, Marathonos Avenue 190-09 Pikermi Greece		Octegra	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Luxembourg	Bayer HealthCare AG 51368 Leverkusen Germany		Proflox	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Netherlands	Bayer HealthCare AG 51368 Leverkusen Germany		Octegra 400 mg/ 250 ml oplossing voor infusie	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml
Portugal		Bialfar - Produtos Farma- cêuticos S.A. À Av. da Siderurgia Nacional 4745-457 S. Mamede do Coronado Portugal	Proflox	400 mg	Solution for infusion	Intravenous use	400 mg / 250 ml

**LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE
OF ADMINISTRATION, APPLICANT IN THE MEMBER STATES**

Member State EU/EEA	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Austria		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanyl Helm 25 Mikrogramm/h Transdermales Pflaster	25 µg/h	transdermal patch	transdermal route
Austria		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanyl Helm 50 Mikrogramm/h Transdermales Pflaster	50 µg/h	transdermal patch	transdermal route
Austria		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanyl Helm 75 Mikrogramm/h Transdermales Pflaster	75 µg/h	transdermal patch	transdermal route
Austria		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanyl Helm 100 Mikrogramm/h Transdermales Pflaster	100 µg/h	transdermal patch	transdermal route
Belgium		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanyl Helm Pharmaceuticals 25 µg/h Pleister voor transdermaal gebruik/Dispositif transdermique/ transdermales Pflaster	25 µg/h	transdermal patch	transdermal route
Belgium		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanyl Helm Pharmaceuticals 50 µg/h Pleister voor transdermaal gebruik/Dispositif transdermique/ transdermales Pflaster	50 µg/h	transdermal patch	transdermal route
Belgium		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanyl Helm Pharmaceuticals 75 µg/h Pleister voor transdermaal gebruik/Dispositif transdermique/ transdermales Pflaster	75 µg/h	transdermal patch	transdermal route
Belgium		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanyl Helm Pharmaceuticals 100 µg/h Pleister voor trans- dermaal gebruik/Dispositif trans- dermique/transdermales Pflaster	100 µg/h	transdermal patch	transdermal use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Germany		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentrix 25 µg/h Transdermales Pflaster	25 µg/h	transdermal patch	transdermal use
Germany		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentrix 50 µg/h Transdermales Pflaster	50 µg/h	transdermal patch	transdermal use
Germany		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentrix 75 µg/h Transdermales Pflaster	75 µg/h	transdermal patch	transdermal use
Germany		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentrix 100 µg/h Transdermales Pflaster	100 µg/h	transdermal patch	transdermal use
Italy		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanyl Helm 25 µg/h cerotto transdermico	25 µg/h	transdermal patch	transdermal use
Italy		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanyl Helm 50 µg/h cerotto transdermico	50 µg/h	transdermal patch	transdermal use
Italy		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanyl Helm 75 µg/h cerotto transdermico	75 µg/h	transdermal patch	transdermal use
Italy		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanyl Helm 100 µg/h cerotto transdermico	100 µg/h	transdermal patch	transdermal use
Netherlands		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentrix 25 µg/h Pleister voor transderaal gebruik	25 µg/h	transdermal patch	transdermal use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Netherlands		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentrix 50 µg/h Pleister voor transderaal gebruik	50 µg/h	transdermal patch	transdermal use
Netherlands		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentrix 75 µg/h Pleister voor transderaal gebruik	75 µg/h	transdermal patch	transdermal use
Netherlands		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentrix 100 µg/h Pleister voor transderaal gebruik	100 µg/h	transdermal patch	transdermal use
Portugal		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanilo Helm	25 µg/h	transdermal patch	transdermal use
Portugal		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanilo Helm	50 µg/h	transdermal patch	transdermal use
Portugal		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanilo Helm	75 µg/h	transdermal patch	transdermal use
Portugal		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanilo Helm	100 µg/h	transdermal patch	transdermal use
Slovenia		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanil HELM 25 mikrogramov/h transdermalni obliži	25 µg/h	transdermal patch	transdermal use
Slovenia		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanil HELM 50 mikrogramov/h transdermalni obliži	50 µg/h	transdermal patch	transdermal use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Slovenia		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanil HELM 75 mikrogramov/h transdermalni obliži	75 µg/h	transdermal patch	transdermal use
Slovenia		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanil HELM 100 mikrogramov/ h transdermalni obliži	100 µg/h	transdermal patch	transdermal use
Spain		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanilo Matrix Helm 25 micro- gramos/hora parches transdérmicos EFG	25 µg/h	transdermal patch	transdermal use
Spain		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanilo Matrix Helm 50 micro- gramos/hora parches transdérmicos EFG	50 µg/h	transdermal patch	transdermal use
Spain		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanilo Matrix Helm 75 micro- gramos/hora parches transdérmicos EFG	75 µg/h	transdermal patch	transdermal use
Spain		Helm Pharmaceuticals GmbH Nordkanalstrasse 28 20097 Hamburg Germany	Fentanilo Matrix Helm 100 micro- gramos/hora parches transdérmicos EFG	100 µg/h	transdermal patch	transdermal use

**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	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Austria	AstraZeneca Österreich GmbH, Schwarzenbergplatz 7 A-1037 Wien Austria	Optinem i.v. 500 mg - Trockenstechampullen	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/20ml
Austria	AstraZeneca Österreich GmbH, Schwarzenbergplatz 7 A-1037 Wien Austria	Optinem i.v. 1 g - Trockenstechampullen	1 g	Powder for solution for injection or infusion	Intravenous use	1 g /30 ml
Belgium	NV AstraZeneca SA Rue Egide Van Ophemstraat 110 1180 Brussel Belgium	MeroneM IV 500 mg	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/20 ml
Belgium	NV AstraZeneca SA Rue Egide Van Ophemstraat 110 1180 Brussel Belgium	MeroneM IV 1 g	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/30 ml
Bulgaria	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	MeroneM	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/20 ml
Bulgaria	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	MeroneM	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/30 ml
Cyprus	AstraZeneca UK Ltd. Silk Road Business Park 1 Macclesfield Cheshire SK10 2NA United Kingdom	MeroneM	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/20 ml

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Cyprus	AstraZeneca UK Ltd. Silk Road Business Park 1 Macclesfield Cheshire SK10 2NA United Kingdom	Meronem	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/30 ml
Czech Republic	AstraZeneca UK Ltd. Silk Road Business Park 1 Macclesfield Cheshire SK10 2NA United Kingdom	Meronem	500 mg	Powder for solution for injection	Intravenous use	500 mg/20 ml
Czech Republic	AstraZeneca UK Ltd. Silk Road Business Park 1 Macclesfield Cheshire SK10 2NA United Kingdom	Meronem	1 g	Powder for solution for injection	Intravenous use	1 g/30 ml
Denmark	AstraZeneca A/S Roskildevej 22 2620 Albertslund Denmark	Meronem	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/20 ml
Denmark	AstraZeneca A/S Roskildevej 22 2620 Albertslund Denmark	Meronem	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/30 ml
Estonia	AstraZeneca UK Limited 15 Stanhope Gate London W1K 1LN United Kingdom	Meronem	500mg	Powder for solution for injection or infusion	Intravenous use	500 mg/10 ml
Estonia	AstraZeneca UK Limited 15 Stanhope Gate London W1K 1LN United Kingdom	Meronem	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/20 ml
Finland	AstraZeneca Oy Luomanportti 3 FI-02200 Espoo Finland	Meronem 500 mg	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/20 ml

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Finland	AstraZeneca Oy Luomanportti 3 FI-02200 Espoo Finland	Meronem 1 g	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/30 ml
France	AstraZeneca 1, Place Renault 92844 RUEIL-MALMAISON Cédex France	Meronem 500 mg poudre pour solution injectable IV	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/20 ml
France	AstraZeneca 1, Place Renault 92844 RUEIL-MALMAISON Cédex France	Meronem 1 g poudre pour solution injectable IV	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/30 ml
Germany	AstraZeneca GmbH Tinsdaler Weg 183 22880 Wedel Germany	Meronem 500 mg	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/10 ml 5 mg / ml
Germany	AstraZeneca GmbH Tinsdaler Weg 183 22880 Wedel Germany	Meronem 1 000 mg	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/20 ml 5 mg / ml
Greece	"CANA" SA Pharmaceutical laboratories 446 Irakliou Ave. 14122 Iraklio Attikis Greece	Meronem	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/20 ml
Greece	"CANA" SA Pharmaceutical laboratories 446 Irakliou Ave 14122 Iraklio Attikis Greece	Meronem	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/30 ml
Hungary	AstraZeneca Kft. H-2045 Törökbálint Park u. 3. Hungary	Meronem 500 mg intravenas injekcio	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/20 ml

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Hungary	AstraZeneca Kft. H-2045 Törökbálint Park u. 3. Hungary	Meronem 1 g intravenas injekcio	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/30 ml
Iceland	AstraZeneca UK Ltd. Alderley Park Macclesfield Cheshire SK10 4TG United Kingdom	Meronem 500 mg stungulyfs-/innrennslistofn, lausn.	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/20 ml
Iceland	AstraZeneca UK Ltd. Alderley Park Macclesfield Cheshire SK10 4TG United Kingdom	Meronem 1 g stungulyfs-/innrennslistofn, lausn.	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/30 ml
Ireland	AstraZeneca UK Limited 600 Capability Green Luton Bedfordshire LU1 3LU United Kingdom	Meronem IV 0.5 g powder for solution for injection or infusion.	0,5 g	Powder for solution for injection or infusion.	Intravenous use	500 mg/20 ml
Ireland	AstraZeneca UK Limited 600 Capability Green Luton Bedfordshire LU1 3LU United Kingdom	Meronem IV 1 g powder for solution for injection or infusion.	1 g	Powder for solution for injection or infusion.	Intravenous use	1 g/30 ml
Italy	AstraZeneca S.p.A. Palazzo Volta Via F. Sforza 20080 Basiglio (MI) Italy	MERREM	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg
Italy	AstraZeneca S.p.A. Palazzo Volta Via F. Sforza 20080 Basiglio (MI) Italy	MERREM	1 g	Powder for solution for injection or infusion	Intravenous use	1 g
Italy	AstraZeneca S.p.A. Palazzo Volta Via F. Sforza 20080 Basiglio (MI) Italy	MERREM	500 mg	Powder and solvent for solution for injection	Intramuscular use	500 mg/2 ml (not marketed)

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Italy	AstraZeneca S.p.A. Palazzo Volta Via F. Sforza 20080 Basiglio (MI) Italy	MERREM	250 mg	Powder and solvent for solution for injection or infusion	Intravenous use	250 mg/5 ml (not marketed)
Italy	AstraZeneca S.p.A. Palazzo Volta Via F. Sforza 20080 Basiglio (MI) Italy	MERREM	500 mg	Powder and solvent for solution for injection or infusion	Intravenous use	500 mg/10 ml (not marketed)
Italy	AstraZeneca S.p.A. Palazzo Volta Via F. Sforza 20080 Basiglio (MI) Italy	MERREM	1 g	Powder and solvent for solution for injection or infusion	Intravenous use	1 g/20 ml (not marketed)
Italy	AstraZeneca S.p.A. Palazzo Volta Via F. Sforza 20080 Basiglio (MI) Italy	MERREM	250 mg	Powder and solvent for solution for infusion	Intravenous use	250 mg/100 ml (not marketed)
Italy	AstraZeneca S.p.A. Palazzo Volta Via F. Sforza 20080 Basiglio (MI) Italy	MERREM	500 mg	Powder and solvent for solution for infusion	Intravenous use	500 mg/100 ml (not marketed)
Italy	AstraZeneca S.p.A. Palazzo Volta Via F. Sforza 20080 Basiglio (MI) Italy	MERREM	1 g	Powder and solvent for solution for infusion	Intravenous use	1 g/100 ml (not marketed)
Latvia	AstraZeneca UK Ltd. Silk Road Business Park 1 Macclesfield Cheshire SK10 2NA United Kingdom	Meronem 500 mg	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/20 ml

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Latvia	AstraZeneca UK Ltd. Silk Road Business Park 1 Macclesfield Cheshire SK10 2NA United Kingdom	Meronem 1 g	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/30 ml
Lithuania	AstraZeneca UK Ltd. Silk Road Business Park 1 Macclesfield Cheshire SK10 2NA United Kingdom	Meronem IV	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/10 ml
Lithuania	AstraZeneca UK Ltd. Silk Road Business Park 1 Macclesfield Cheshire SK10 2NA United Kingdom	Meronem IV	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/20 ml
Luxembourg	NV AstraZeneca SA Rue Egide Van Ophemstraat 110 1180 Brussel Belgium	Meronem IV 500 mg	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/20 ml
Luxembourg	NV AstraZeneca SA Rue Egide Van Ophemstraat 110 1180 Brussel Belgium	Meronem IV 1 g	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/30 ml
Malta	AstraZeneca UK Ltd. Silk Road Business Park 1 Macclesfield Cheshire SK10 2NA United Kingdom	Meronem IV 0,5 g powder for solution for injection or infusion.	0,5 g	Powder for solution for injection or infusion	Intravenous use	500 mg/20 ml
Malta	AstraZeneca UK Ltd. Silk Road Business Park 1 Macclesfield Cheshire SK10 2NA United Kingdom	Meronem IV 1 g powder for solution for injection or infusion.	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/30 ml
Netherlands	AstraZeneca BV at the Louis Pasteurlaan 5 2719 EE, Zoetermeer, Netherlands	Meronem i.v.	250 mg	Powder for solution for injection or infusion	Intravenous use	In the process of being cancelled

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Netherlands	AstraZeneca BV at the Louis Pasteurlaan 5 2719 EE, Zoetermeer, Netherlands	Meronom i.v.	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/20 ml
Netherlands	AstraZeneca BV at the Louis Pasteurlaan 5 2719 EE, Zoetermeer, Netherlands	Meronom i.v.	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/30 ml
Norway	AstraZeneca AS Hoffsveien 70 B/Postboks 200 Vinderen 0319 OSLO Norway	Meronom	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/20 ml
Norway	AstraZeneca AS Hoffsveien 70 B/Postboks 200 Vinderen 0319 OSLO Norway	Meronom	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/30 ml
Poland	AstraZeneca UK Ltd. Silk Road Business Park 1 Macclesfield Cheshire SK10 2NA United Kingdom	Meronom	500 mg	Powder for solution for injection	Intravenous use	500 mg/20 ml
Poland	AstraZeneca UK Ltd. Silk Road Business Park 1 Macclesfield Cheshire SK10 2NA United Kingdom	Meronom	1 g	Powder for solution for injection	Intravenous use	1 g/30 ml
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, n.º 7, Valejas 2745-663 Barcarena, Portugal	Meronom	500 mg	Powder for solution for injection	Intramuscular use	500 mg/2 ml (not marketed)

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, n.º 7, Valejas 2745-663 Barcarena, Portugal	Meronem	500 mg	Powder for solution infusion	Intravenous use	500 mg/20 ml
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, n.º 7, Valejas 2745-663 Barcarena, Portugal	Meronem	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/30 ml
Romania	AstraZeneca UK Limited 600 Capability Green Luton Bedfordshire LU1 3LU United Kingdom	Meronem i.v. 500 mg	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/20 ml
Romania	AstraZeneca UK Limited 600 Capability Green Luton Bedfordshire LU1 3LU United Kingdom	Meronem i.v. 1 g	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/30 ml
Slovak Republic	AstraZeneca UK Ltd. Silk Road Business Park 1 Macclesfield Cheshire SK10 2NA United Kingdom	Meronem 500 mg i.v.	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/20 ml
Slovenia	AstraZeneca UK Limited 15 Stanhope Gate London W1K 1LN United Kingdom	Meronem 500 mg prasek za raztopino za injiciranje ali infundiranje	500 mg	Powder for solution for injection or infusion	Intravenous use	50 mg/ml
Slovenia	AstraZeneca UK Limited 15 Stanhope Gate London W1K 1LN United Kingdom	Meronem 1 g prasek za raztopino za injiciranje ali infundiranje	1 g	Powder for solution for injection or infusion	Intravenous use	50 mg/ml

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Spain	AstraZeneca Farmacéutica Spain, S.A. C/ Serrano Galvache 56 Edificio Roble 28033 Madrid Spain	Meronem I.V., 500	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/20 ml
Spain	AstraZeneca Farmacéutica Spain, S.A. C/ Serrano Galvache 56 Edificio Roble 28033 Madrid Spain	Meronem I.V., 1 000	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/30 ml
Sweden	AstraZeneca AB 151 85 Södertälje Sweden	Meronem	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/10 ml for injection or variable concentration for infusion
Sweden	AstraZeneca AB 151 85 Södertälje Sweden	Meronem	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/20 ml for injection or variable concentration for infusion
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton Bedfordshire LU1 3LU United Kingdom	Meronem IV 500 mg	500 mg	Powder for solution for injection or infusion	Intravenous use	500 mg/20 ml
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton Bedfordshire LU1 3LU United Kingdom	Meronem IV 1 g	1 g	Powder for solution for injection or infusion	Intravenous use	1 g/30 ml

**LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE VETERINARY MEDICINAL
PRODUCTS, ANIMAL SPECIES, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS
IN THE MEMBER STATES**

Member State	Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Route of administration
Austria	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Pulmotil AC	Oral solution	Tilmicosin 250 mg/ml	Chickens Turkeys Pigs Calves	Oral
Belgium	Eli Lilly Benelux N.V. Elanco Animal Health Rue del'Etuve 52-Bte 1Stoofstraat 52 1000 Brussel Belgium	Pulmotil AC	Oral solution	Tilmicosin 250 mg/ml	Chickens Turkeys Pigs Calves	Oral
Cyprus	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmotil AC	Oral solution	Tilmicosin 250 mg/ml	Chickens Pigs	Oral
Czech Republic	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmotil AC sol. ad us. vet.	Oral solution	Tilmicosin 250 mg/ml	Chickens (broilers) Pigs Calves	Oral
Germany	Lilly Deutschland GmbH Teichweg 3 35396 Gießen Germany	Pulmotil AC	Oral solution	Tilmicosin 250 mg/ml	Cattle (calves) Pigs for fattening Chickens	Oral
Greece	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmotil AC	Oral solution	Tilmicosin 250 mg/ml	Chickens Turkeys Pigs Calves	Oral
Spain	Elanco Valquímica, S.A. Avenida de la Industria, 30 28108 – Alcobendas Madrid Spain	PULMOTIL AC	Oral solution	Tilmicosin 250 mg/ml	Pigs Poultry (except laying hens) Turkeys Cattle	Oral

Member State	Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Route of administration
France	Lilly France SA Département Elanco Santé Animale 13 Rue Pagès 92158 Suresnes Cedex France	PULMOTIL AC	Oral solution	Tilmicosin 250 mg/ml	Pigs Calves Chickens Turkeys	Oral
Hungary	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmotil AC oral solution	Oral solution	Tilmicosin 250 mg/ml	Cattle (calf) Pigs Chickens Turkeys	Oral
Ireland	Elanco Animal Health Eli Lilly and Company Ltd Priestley Road Basingstoke Hampshire RG24 9NL United Kingdom	Pulmotil AC	Oral Solution	Tilmicosin 250 mg/ml	Chicken Turkeys Pigs	Oral
United Kingdom	Elanco Animal Health Eli Lilly and Company Ltd Priestley Road Basingstoke Hampshire RG24 9NL United Kingdom	Pulmotil AC	Oral solution	Tilmicosin 250 mg/ml	Chickens Turkeys	Oral
Italy	Eli Lilly Italia Elanco Animal Health Via A. Gramsci, 731-733 50019 Sesto Fiorentino Florence Italia	Pulmotil AC	Oral Solution	Tilmicosin 250 mg/ml	Chickens Turkeys Pigs Calves	Oral
Luxembourg	Eli Lilly Benelux N.V. Elanco Animal Health Rue del'Etuve 52-Bte 1Stoofstraat 52 1000 Brussel Belgium	Pulmotil AC	Oral Solution	Tilmicosin 250 mg/ml	Chickens Turkeys Pigs Calves	Oral
The Netherlands	Eli Lilly Nederland B.V. Elanco Animal Health Grootslag 1-5 3991 RA Houten The Netherlands	Pulmotil AC	Oral solution	Tilmicosin 250 mg/ml	Chicken Turkey Pig Calves	Oral

Member State	Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Route of administration
Portugal	Lilly Portugal - Produtos Farmacêuticos, Lda Rua Dr. António Loureiro Borges, 1-piso 1, Arquiparque, Miraflores 1495-016 Algés Portugal	Pulmotil AC	Oral Solution	Tilmicosin 250 mg/ml	Chickens Turkeys Pigs Calves	Oral
Poland	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmotil AC	Oral solution	Tilmicosin 250 mg/ml	Chickens Pigs Calves	Oral
Slovak Republic	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmotil AC	Oral solution	Tilmicosin 250 mg/ml	Chickens Pigs Calves	Oral
Romania	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmotil AC	Oral solution	Tilmicosin 250 mg/ml	Pigs Broilers Calves	Oral

**LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE VETERINARY MEDICINAL
PRODUCTS, ANIMAL SPECIES, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS
IN THE MEMBER STATE**

40 g tilmicosin per 1 000 g

Member State	Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Route of administration
Belgium	Eli Lilly Benelux N.V. Elanco Animal Health Rue de l'Etuve 52 Stoofstraat 52 1000 Brussel Belgium	Pulmotil 40 VET Premix	Premix for medicated feeding stuff	40 g tilmicosin per 1 000 g	Pigs	Oral
Germany	Lilly Deutschland GmbH Teichweg 3 35396 Gießen Germany	Pulmotil G 40 AMV	Premix for medicated feeding stuff	40 g tilmicosin per 1 000 g	Pigs	Oral
Germany	Lilly Deutschland GmbH Teichweg 3 35396 Gießen Germany	Pulmotil G 40 Granulat	Premix for medicated feeding stuff	40 g tilmicosin per 1 000 g	Pigs	Oral
Denmark	Eli Lilly Danmark A/S Elanco Animal Health Nybrovej 110 2800 Lyngby Denmark	Pulmotil Vet	Premix for medicated feeding stuff	40 g tilmicosin per 1 000 g	Pigs	Oral
Spain	Elanco Valquímica, S.A. Avenida de la Industria, 30 28108 – Alcobendas Madrid Spain	PULMOTIL 40	Premix for medicated feeding stuff	40 g tilmicosin per 1 000 g	Pigs	Oral
France	Lilly France SA Départament Elanco Santé Animale 13 Rue Pagès 92158 Suresnes Cedex France	Pulmotil Tilmicosine 40 Porcins	Premix for medicated feeding stuff	40 g tilmicosin per 1 000 g	Pigs	Oral

Member State	Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Route of administration
Ireland	Elanco Animal Health Eli Lilly and Company Ltd Priestley Road Basingstoke Hampshire RG24 9NL United Kingdom	Pulmotil G40 Premix	Premix for medicated feeding stuff	40 g tilmicosin per 1 000 g	Pigs	Oral
The Netherlands	Eli Lilly Nederland B.V. Elanco Animal Health Grootslag 1-5 3991 RA Houten The Netherlands	Pulmotil G40 premix	Premix for medicated feeding stuff	40 g tilmicosin per 1 000 g	Pigs	Oral
Portugal	Lilly Portugal — Produtos Farmacêuticos, Lda Rua Dr. António Loureiro Borges, 1-piso 1, Arquiparque, Miraflores 1495-016 Algés Portugal	PULMOTIL G40 Pré Mistura para alimento medicamentoso	Premix for medicated feeding stuff	40 g tilmicosin per 1 000 g	Pigs	Oral

100 g tilmicosin per 1 000 g

Member State	Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Route of administration
Austria	Richter Pharma AG Feldgasse 19 4600 Wels Austria	PULMOTIL Prämix 10 % — Granulat für Schweine	Premix for medicated feeding stuff	100 g tilmicosin per 1 000 g	Pigs	Oral
Belgium	Eli Lilly Benelux N.V. Elanco Animal Health Rue de l'Etuve 52 Stoofstraat 52 1000 Brussel Belgium	Pulmotil 100 VET Premix	Premix for medicated feeding stuff	100 g tilmicosin per 1 000 g	Pigs	Oral
Belgium	Eli Lilly Benelux N.V. Elanco Animal Health Rue de l'Etuve 52-Bte Stoofstraat 52 1000 Brussel Belgium	Pulmotil 100 Granules	Premix for medicated feeding stuff	100 g tilmicosin per 1 000 g	Pigs	Oral

Member State	Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Route of administration
Germany	Lilly Deutschland GmbH Teichweg 3 35396 Gießen Germany	Pulmotil G 100 AMV	Premix for medicated feeding stuff	100 g tilmicosin per 1 000 g	Pigs	Oral
Germany	Lilly Deutschland GmbH Teichweg 3 35396 Gießen Germany	Pulmotil G 100	Premix for medicated feeding stuff	100 g tilmicosin per 1 000 g	Pigs	Oral
Denmark	Eli Lilly Danmark A/S Elanco Animal Health Nybrovej 110 2800 Lyngby Denmark	Pulmotil Vet	Premix for medicated feeding stuff	100 g tilmicosin per 1 000 g	Pigs	Oral
Denmark	Eli Lilly Danmark A/S Elanco Animal Health Nybrovej 110 2800 Lyngby Denmark	Pulmotil Vet Oralt pulver	Premix for medicated feeding stuff	100 g tilmicosin per 1 000 g	Pigs	Oral
Spain	Elanco Valquímica, S.A. Avenida de la Industria, 30 28108 – Alcobendas Madrid Spain	PULMOTIL 100	Premix for medicated feeding stuff	100 g tilmicosin per 1 000 g	Pigs	Oral
Ireland	Elanco Animal Health Eli Lilly and Company Ltd Priestley Road Basingstoke Hampshire RG24 9NL United Kingdom	Pulmotil G100 Premix	Premix for medicated feeding stuff	100 g tilmicosin per 1 000 g	Pigs	Oral
Italy	Eli Lilly Italia Elanco Animal Health Via A. Gramsci, 731-733 50019 Sesto Fiorentino Florence Italia	PULMOTIL G100 PREMIX	Premix for medicated feeding stuff	100 g tilmicosin per 1 000 g	Pigs	Oral

Member State	Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Route of administration
Luxembourg	Eli Lilly Benelux N.V. Elanco Animal Health Rue de l'Etuve 52-Bte 1 Stoofstraat 52 1000 Brussel Belgium	Pulmotil 100 Vet Premix	Premix for medicated feeding stuff	100 g tilmicosin per 1 000 g	Pigs	Oral
The Netherlands	Eli Lilly Nederland B.V. Elanco Animal Health Grootslag 1-5 3991 RA Houten The Netherlands	Pulmotil G100 premix	Premix for medicated feeding stuff	100 g tilmicosin per 1 000 g	Pigs	Oral
Portugal	Lilly Portugal — Produtos Farmacêuticos, Lda Rua Dr. António Loureiro Borges, 1-piso 1, Arquip- arque, Miraflores 1495-016 Algés Portugal	PULMOTIL G100 Pré Mistura para alimento medicamentoso	Premix for medicated feeding stuff	100 g tilmicosin per 1 000 g	Pigs	Oral
United Kingdom	Elanco Animal Health Eli Lilly and Company Ltd Priestley Road Basingstoke Hampshire RG24 9NL United Kingdom	Pulmotil G100 Premix	Premix for medicated feeding stuff	100 g tilmicosin per 1 000 g	Pigs	Oral

200 g tilmicosin per 1 000 g

Member State	Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Route of administration
Austria	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Pulmotil Prämix 20 %	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Pigs, Rabbit	Oral
Belgium	Eli Lilly Benelux N.V. Elanco Animal Health Rue de l'Etuve 52 Stoofstraat 52 1000 Brussel Belgium	Pulmotil 200 VET Premix	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Pigs, Rabbits	Oral

Member State	Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Route of administration
Czech Republic	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	PULMOTIL 200 prm. ad us. vet.	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Pigs	Oral
Cyprus	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmotil G200 Premix	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Pigs	Oral
Germany	Lilly Deutschland GmbH Teichweg 3 35396 Gießen Germany	Pulmotil G 20 % AMV	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Pigs	Oral
Germany	Lilly Deutschland GmbH Teichweg 3 35396 Gießen Germany	Pulmotil G 20 %	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Pigs	Oral
Denmark	Eli Lilly Danmark A/S Elanco Animal Health Nybrovej 110 2800 Lyngby Denmark	Pulmotil Vet	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Pigs	Oral
Greece	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmotil 200 medicated premix	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Pigs	Oral
Spain	Elanco Valquímica, S.A. Avenida de la Industria, 30 28108 – Alcobendas Madrid Spain	PULMOTIL 200	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Pigs	Oral

Member State	Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Route of administration
Hungary	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmotil G 200 premix	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Pigs	Oral
Ireland	Elanco Animal Health Eli Lilly and Company Ltd Priestley Road Basingstoke Hampshire RG24 9NL United Kingdom	Pulmotil G200 Premix	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Pigs	Oral
Italy	Eli Lilly Italia Elanco Animal Health Via A. Gramsci, 731-733 50019 Sesto Fiorentino Florence Italia	PULMOTIL G200 PREMIX	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Pigs, Rabbits	Oral
Latvia	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmotil 200 premix	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Pigs	Oral
Luxembourg	Eli Lilly Benelux N.V. Elanco Animal Health Rue de l'Etuve 52-Bte 1Stoofstraat 52 1000 Brussel Belgium	Pulmotil 200 Vet Premix	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Pigs, Rabbits	Oral
The Netherlands	Eli Lilly Nederland B.V. Elanco Animal Health Grootslag 1-5 3991 RA Houten The Netherlands	Pulmotil G200 premix	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Pigs	Oral

Member State	Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Route of administration
Poland	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmontil 200	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Pigs	Oral
Portugal	Lilly Portugal — Produtos Farmacêuticos, Lda Rua Dr. António Loureiro Borges, 1-piso 1, Arquip- arque, Miraflores 1495-016 Algés Portugal	PULMOTIL G200 Pré Mistura para alimento medicamentoso	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Pigs	Oral
Romania	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmotil 200 Vet Premix	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Pigs	Oral
Slovak Republic	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	PULMOTIL G 200	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Fattening pigs	Oral
United Kingdom	Elanco Animal Health Eli Lilly and Company Ltd Priestley Road Basingstoke Hampshire RG24 9NL United Kingdom	Pulmotil G200 Premix	Premix for medicated feeding stuff	200 g tilmicosin per 1 000 g	Pigs	Oral

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, AND MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES AND NORWAY AND ICELAND

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Austria	CSC Pharmaceuticals Handels GmbH, Heiligenstädter Str. 395 b, A-1190 Vienna	Aulin 100 mg - Tabletten	100 mg	Tablet	oral use
Austria	CSC Pharmaceuticals Handels GmbH, Heiligenstädter Str. 395 b, A-1190 Vienna	Aulin 100 mg - Granulat	100 mg	Granules for oral suspension	oral use
Austria	CSC Pharmaceuticals Handels GmbH, Heiligenstädter Str. 395 b, A-1190 Vienna	Aulin 100 mg - Suppositorien	100 mg	Suppository	rectal use
Austria	CSC Pharmaceuticals Handels GmbH, Heiligenstädter Str. 395 b, A-1190 Vienna	Aulin 200 mg - Suppositorien	200 mg	Suppository	rectal use
Austria	CSC Pharmaceuticals Handels GmbH, Heiligenstädter Str. 395 b, A-1190 Vienna	Mesulid 100 mg - Tabletten	100 mg	Tablet	oral use
Austria	CSC Pharmaceuticals Handels GmbH, Heiligenstädter Str. 395 b, A-1190 Vienna	Mesulid 100 mg - Granulat	100 mg	Granules for oral suspension	oral use
Austria	CSC Pharmaceuticals Handels GmbH, Heiligenstädter Str. 395 b, A-1190 Vienna	Mesulid 100 mg - Suppositirien	100 mg	Suppository	rectal use
Austria	CSC Pharmaceuticals Handels GmbH, Heiligenstädter Str. 395 b, A-1190 Vienna	Mesulid 200 mg - Suppositorien	200 mg	Suppository	rectal use
Belgium	THERABEL PHARMA S.A., Rue E.Van Ophem, 108 B-1180 Uccle	AULIN 100 MG	100 mg	Tablet	oral use
Belgium	THERABEL PHARMA S.A., Rue E.Van Ophem, 108 B-1180 Uccle	AULIN 100 MG	100 mg	Granules for oral suspension	oral use
Belgium	THERABEL PHARMA S.A., Rue E.Van Ophem, 108 B-1180 Uccle	MESULID	100 mg	Granules for oral suspension	oral use
Belgium	THERABEL PHARMA S.A., Rue E.Van Ophem, 108 B-1180 Uccle	MESULID 100 MG	100 mg	Tablet	oral use
Bulgaria	Tchaika Pharma Sofia 1172 1, G. M. Dimitrov Blvd	AllGone	100 mg	Effervescent tablet	oral use
Bulgaria	Sopharma Sofia 122016, Iliensko shosse	Ameolin	100 mg	Tablet	oral use
Bulgaria	CSC Pharmaceuticals Sofia 159210, Assen Jordanov street		100 mg	Tablet	oral use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Bulgaria	CSC Pharmaceuticals Sofia 159210, Assen Jordanov street	Aulin 100	100 mg	Granules	oral use
Bulgaria	Inbioteh Sofia 1000 5, Triaditza street 'Sofia palace'	Biolin	100 mg	Tablet	oral use
Bulgaria	ZentivaSofia 140725, N.Vaptzarov Blvd	Coxtral	100 mg	Tablet	oral use
Bulgaria	Actavis Sofia 1000 2, Kniaginia Maria Luisa Blvd	Enetra	100 mg	Tablet	oral use
Bulgaria	Medochemie Sofia 111320, Fr. Jolio Currie street	Aponil	100 mg	Tablet	oral use
Bulgaria	CSC Pharmaceuticals Sofia 159210, Assen Jordanov street	Nimed	100 mg	Tablet	oral use
Bulgaria	Laboratori Guidotti S.p.A.(Menarini Group) Sofia 111317, Kosta Lultchev street	Nimesil	100 mg	Granules	oral use
CZ - Czech Republic	MEDICOM INTERNATIONAL S.R.O., Páteřní 7 635 00 Brno, Czech Republic	AULIN	100 mg	Granules for oral solution	Oral use
CZ - Czech Republic	MEDICOM INTERNATIONAL S.R.O., Páteřní 7 635 00 Brno, Czech Republic	AULIN	100 mg	Tablet	Oral use
CZ - Czech Republic	ZENTIVA, a.s. Empiria Palace Na strži 63 140 62 Praha 4, Czech Republic	COXTRAL 100 MG TABLETY	100 mg	Tablet	Oral use
CZ - Czech Republic	CSC Pharmaceuticals Handels GmbH Gewer- bestrasse 18-20 A-2102 Bisamberg, Austria	MESULID	100 mg	Granules for oral solution	Oral use
CZ - Czech Republic	MEDICOM INTERNATIONAL S.R.O., Páteřní 7 635 00 Brno, Czech Republic	NIMED	100 mg	Tablet	Oral use
CZ - Czech Republic	LABORATORI GUIDOTTI S.p.A., Via Livornese 897, I - 56010 La Vettola, PISA, Italy	NIMESIL	100 mg	Granules for oral suspension	Oral use
Cyprus	MEDOCHEMIE LTD, POBOX 51409, 3505 LEMESOS, CYPRUS	APONIL	100 mg	Tablet	ORAL
Cyprus	CDL PHARMACEUTICAL LTD, POBOX 40981, 6308 LARNACA, CYPRUS	ELINAP	100 mg	Tablet	ORAL
Cyprus	CHR. K. UNIMED LTD, 21 DAVLOU, PLATI, 2114 AGLANTZIA, LEFKOSIA, CYPRUS	FLOGOSTOP	100 mg	Tablet	ORAL

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Cyprus	PT HADJIGEORGIOU CO LTD, POBOX 53158, 3301 LEMESOS, CYPRUS	NIMELIDE	100 mg	Tablet	ORAL
Cyprus	CODAL SYNTO LTD, POBOX 51785, 3508 LEMESOS, CYPRUS	NIMM	100 mg	Tablet	ORAL
Cyprus	THE STAR MEDICINES IMPORTERS & CO LTD, POBOX 50151, 3601 LEMESOS, CYPRUS	RITAMINE	100 mg	Tablet	ORAL
Cyprus	COSMED HOLDINGS LTD, P.O.BOX 42145, 6531 LARNACA, CYPRUS	SPECILID	100 mg	Tablet	ORAL
Estonia	Zentiva a.s. U Kabelovny 130 Dolni Mecholupy 102 37 Praque 10	COXTRAL	100 mg	Tablet	oral use
France	THERABEL LUCIEN PHARMA 123 rue Jules Guesde 92309 LEVALLOIS-PERRET Cedex France	NEXEN	100 mg	Tablet	Oral
France	THERABEL LUCIEN PHARMA 123 rue Jules Guesde 92309 LEVALLOIS-PERRET Cedex France	NEXEN	100 mg	Granules for oral solution	Oral
France	HELSINN BIREX PHARMACEUTICALS Ltd Damastown Mulhuddart DUBLIN 15 IRELAND	OXETIAN	100 mg	Tablet	Oral
France	HELSINN BIREX PHARMACEUTICALS Ltd Damastown Mulhuddart DUBLIN 15 IRELAND	OXETIAN	100 mg	Granules for oral solution	Oral
Greece	BOEHRINGER INGELHEIM HELLAS S.A. 5TH Km PAEANIAS-MARKOPOULO AVENUE KOROPI, ATTIKIS, 19400	MESULID	100 mg	Tablet	ORAL
Greece	BOEHRINGER INGELHEIM HELLAS S.A. 5TH Km PAEANIAS-MARKOPOULO AVENUE KOROPI, ATTIKIS, 19400	MESULID	200 mg	Suppository	RECTAL
Greece	BOEHRINGER INGELHEIM HELLAS S.A. 5TH Km PAEANIAS-MARKOPOULO AVENUE KOROPI, ATTIKIS, 19400	MESULID	100 mg	Granules for oral solution	ORAL

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Greece	FARMEDIA A.E. ATHINAS 22 & APOLLONOS GERAKAS, ATTIKIS, 15344	MULTIFORMIL	100 mg	Tablet	ORAL
Greece	PHARMATHEN INTERNATIONAL S.A. GREECE, DERVENAKIWN 4, PALLINI, ATTIKIS 15351	BIOXIDOL	100 mg	Tablet	ORAL
Greece	ALET PHARMACEUTICALS M. ALEXANDER 121, AGIA VARVARA, 12351	SPECILID	100 mg	Tablet	ORAL
Greece	BIOSPRAY ABEE 18TH Km MARATHONOS AVENUE, PALLINI, 15344	FLOGOSTOP	100 mg	Tablet	ORAL
Greece	BIOMEDICA-CHEMICA A.E. G. LYRA 25, KATW KIFISSIA	NIMESULIDE/BIOMEDICA CHEMICA	100 mg	Tablet	ORAL
Greece	LEOVAN, M. LEWN & SIA EE ARGONAFTWN 22, ARGYROUPOLI, 16452	RISTOLZIT	100 mg	Tablet	ORAL
Greece	NORMA HELLAS A.E. MENANDROU 54, ATHENS, 10431	MYXINA	100 mg	Tablet	ORAL
Greece	GENEPHARM A.E. 18TH Km MARATHONOS AVENUE, PALLINI, ATTIKIS, 15351	NIMELIDE	100 mg	Tablet	ORAL
Greece	BROS EPE AVGIS & GALLINIS 15, N. KIFISSIA	DISCORID	100 mg	Tablet	ORAL
Greece	RAFARM AEBE KORINTHOU 12, N. PSYCHIKO, 15451	VENTOR	100 mg	Tablet	ORAL
Greece	RAFARM AEBE KORINTHOU 12, N. PSYCHIKO, 15451	VENTOR	100 mg	Granules for oral solution	ORAL
Greece	ARMEDICA A.E. AGIAS MARKELLIS 17, ATHENS, 11855	ALENCAS	100 mg	Tablet	ORAL
Greece	GAP A.E. AGISILAOU 46, AGIOS DIMITRIOS, 17341	G-REVM	100 mg	Tablet	ORAL
Greece	VIOFAR EPE ETHNIKIS ANTISTASEOS & TRIFYLLIAS, AHARNAI, 13671	VOLONTEN	100 mg	Tablet	ORAL
Greece	KLEVA EPE PARNITHOS AVENUE 189, AHARNAI, ATTIKIS, 13671	ELINAP	100 mg	Powder for oral solution	ORAL

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Greece	KLEVA EPE PARNITHOS AVENUE 189, AHARNAI, ATTIKIS, 13671	ELINAP	100 mg	Tablet	ORAL
Greece	MINERVA PHARMAKEFTIKI A.E. KIFISSOU AVENUE 132, PERISTERI, 12131	MIN-A-PON	100 mg	Tablet	ORAL
Greece	ANFARM HELLAS A.E. K. PALEOLOGOU & PERIKLEOUS 27, HALANDRI, 15232	LEMESIL	100 mg	Tablet	ORAL
Greece	ELPEN A.E. PHARMACEUTICAL INDUSTRY, MARATHONOS AVENUE 95, PIKERMİ, 19009	ROLAKET	100 mg	Tablet	ORAL
Greece	ELPEN A.E. PHARMACEUTICAL INDUSTRY, MARATHONOS AVENUE 95, PIKERMİ, 19009	ROLAKET	200 mg	Suppository	RECTAL
Greece	ANTOR EPE P. MAVROMIHALI 1, VRILISSIA, 15235	MELIMONT	100 mg	Tablet	ORAL
Greece	HELP ABEE VALAORITOU 10, METAMORFOSI, ATTIKIS, 14452	MOSUOLIT	100 mg	Tablet	ORAL
Greece	FINIXFARM EPE DERVENAKION 38 & SAHINI, GERAkas, 15344	KARTAL	100 mg	Tablet	ORAL
Greece	PHARMACEUTICAL INDUSTRY PROEL EPAM. G. KORONIS DİLOU 9, PERISTERI, ATTIKIS, 12134	FLADALGIN	100 mg	Tablet	ORAL
Greece	REMEK PHARMACEUTICALS ABEE PENTELIS 34, PALAİO FALIRO, ATTIKIS, 17564	MESUPON	100 mg	Tablet	ORAL
Greece	FARMANIC CHEMIPHARMA S.A. FYLIS 137, KAMATERO, ATTIKIS, 13451	CHEMISULIDE	100 mg	Tablet	ORAL
Greece	REMEDINA ABEE GOUNARI 25 & AREOS, KAMATERO, ATTIKIS, 13451	AMOCETIN	100 mg	Tablet	ORAL
Greece	COSMOPHARM EPE P.O. BOX 42, KORINTHOS, 20100	LIZEPAT	100 mg	Tablet	ORAL
Greece	DEMO ABEE 21ST Km NATIONAL HIGHWAY ATHENS-LAMIA, 14565	RITAMINE	100 mg	Tablet	ORAL

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Greece	BALU EPE 30 Km ATHENS-LAVRION, MARKOPOULO	NIBERAN	100 mg	Tablet	ORAL
Greece	SANDOZ GMBH, KUNDL, AUSTRIA BIOCHEMIESTRASSE 10, A-6250, KUNDL AUSTRIA	NIMESULIDE / HEXAL	100 mg	Tablet	ORAL
Greece	SANDOZ GMBH, KUNDL, AUSTRIA BIOCHEMIESTRASSE 10, A-6250, KUNDL AUSTRIA	NIMESULIDE / HEXAL	100 mg	Powder for oral solution	ORAL
Greece	VELKA HELLAS AEBE KAPODISTRIOU & KORINTHOU 12, NEO PSYCHIKO, 15451	NAOFID	100 mg	Tablet	ORAL
Greece	DOCTUM A.E. K.T. GIOKARIS & SIA 1 Km PAEANIAS-MARKOPOULOU AVENUE, PAEANIA, ATTIKIS, 19002	ERLECIT	100 mg	Tablet	ORAL
Greece	VOCATE PHARMAKEFTIKI A.E. GOUNARI 150, GLYFADA, 16674	TRANZICALM	100 mg	Tablet	ORAL
Greece	MEDICHROM A.E. 6 Km MARKOPOULOU-KOROPI AVENUE, MARKOPOULO, MESOGEION, 19003	NIMESUL	100 mg	Tablet	ORAL
Greece	FARAN ABEE PRODUCTION AND TRADING MEDICINES AVEROF 19A, ATHENS, 10433	AFLOGEN	100 mg	Tablet	ORAL
Greece	GEROLYMATOS P.N. AEBE ASKLEPIOU, KRYONERI, ATTIKIS	EDRIGYL	100 mg	Tablet	ORAL
Greece	GEROLYMATOS P.N. AEBE ASKLEPIOU, KRYONERI, ATTIKIS	EDRIGYL	100 mg	Granules for oral solution	ORAL
Greece	GEROLYMATOS P.N. AEBE ASKLEPIOU, KRYONERI, ATTIKIS	EDRIGYL	200 mg	Suppository	RECTAL
Greece	S.J.A. PHARM O.E. ARKOLEON 11, KATO PATISSIA, 10445	CLIOVYL	100 mg	Tablet	ORAL
Greece	COUP ABEE AGIAS VARVARAS 53-55, DAFNI, ATHENS, 17235	MELICAT	100 mg	Tablet	ORAL
Greece	PHARMACYPRIA HELLAS A.E. PASTER 6, AMPELOKIPOI, 11521	LALIDE	100 mg	Tablet	ORAL
Greece	PHARMACYPRIA HELLAS A.E. PASTER 6, AMPELOKIPOI, 11521	LALIDE	50 mg /5 ml	Oral suspension	ORAL

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Greece	INTERMED ABEE KALYFTAKI 27, ATHENS	DOLOSTOP	100 mg	Tablet	ORAL
Greece	INTERMED ABEE KALYFTAKI 27, ATHENS	DOLOSTOP	100 mg	Effervescent tablets	ORAL
Greece	INTERMED ABEE KALYFTAKI 27, ATHENS	DOLOSTOP	100 mg	Granules for oral solution	ORAL
Greece	INTERMED ABEE KALYFTAKI 27, ATHENS	DOLOSTOP	200 mg	Suppository	RECTAL
Greece	EVAGGELOS KALOFOLIAS & SIA O.E. MENANDROU 54, ATHENS, 10431	ALGOVER	100 mg	Tablet	ORAL
Greece	FARMILIA E.E. FAVIEROU 48, ATHENS	AUROMELID	100 mg	Tablet	ORAL
Greece	AURORA PHARMACEUTICALS EPE EVROU & MESSINIAS, GERAkas, 15344	SUDINET	100 mg	Tablet	ORAL
Greece	LEOVAN M. LEON & SIA E.E. ARGONAFTON 22, ARGYROUPOLI, 16452	LASAZIN	100 mg	Tablet	ORAL
Greece	PHARMACHEM EPE YMITOU 73, VRILISSIA, ATTIKIS, 15235	NIMESULIDE / PHARMACHEM	100 mg	Tablet	ORAL
Greece	ANTONIOS POLYCHRONIS OF MARINOu IONIAS 29, NEO PSYCHIKO, 15451	OMNIBUS	100 mg	Tablet	ORAL
Greece	ZWITTER PHARMACEUTICALS EPE, GREECE PENTELIS AVENUE 34-36, ATHENS, 15234	RHEMID	100 mg	Tablet	ORAL
Greece	MED-ONE S.A., HELLAS PARNITHOS AVENUE 211, AHARNAI, 13671	ALGOSULID	100 mg	Tablet	ORAL
Greece	MED-ONE S.A., HELLAS PARNITHOS AVENUE 211, AHARNAI, 13671	ALGOSULID	100 mg	Powder for oral solution	ORAL
Greece	LAMDA PHARMAKEFTIKI A.E. EVRIPIDOU 18, ATHENS, 10559	NIMESORAL	100 mg	Tablet	ORAL
Greece	MEDARTE FARMAKEFTIKI ABEE SPYROU VRETTou 10, METAMORFOSI, 14452	NIMESULIDE / MEDICON	100 mg	Tablet	ORAL
Greece	FARMAMUST EPE PANTAZOPOULOU SQUARE 7, KOLONOS, ATTIKIS, 10443	LOVIREM	100 mg	Tablet	ORAL

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Greece	B.I. FARMA A.E. ARISTOTELOUS 79-81, ATHENS, 10434	NIMESULIDE / B.I. FARMA	100 mg	Tablet	ORAL
Greece	LAVIPHARM HELLAS A.E. AGIAS MARINAS, PAEANIA, ATTIKIS, 19002	AULIN	100 mg	Tablet	ORAL
Greece	LAVIPHARM HELLAS A.E. AGIAS MARINAS, PAEANIA, ATTIKIS, 19002	AULIN	200 mg	Suppository	RECTAL
Greece	LAVIPHARM HELLAS A.E. AGIAS MARINAS, PAEANIA, ATTIKIS, 19002	AULIN	100 mg	Granules for oral solution	ORAL
Hungary	Chinoin Zrt.1045 Budapest, Tó u.1-5	Winsulid	100 mg	Granules	oral
Hungary	Chinoin Zrt.1045 Budapest, Tó u.1-5	Winsulid	100 mg	Tablet	oral
Hungary	Sanofi-Aventis 1045 Budapest, Tó u.1-5	Mesulid	100 mg	Granules	oral
Hungary	Sanofi-Aventis 1045 Budapest, Tó u.1-5	Mesulid	100 mg	Tablet	oral
Hungary	PannonPharma Gyógyszergyártó Kft. 1016 Budapest Derék u.2	Nimelid	100 mg	Tablet	oral
Hungary	Eurodrug Lab.BV 4032 Debrecen,Bartha Boldizsár u. 7	Nidol	100 mg	Tablet	oral
Hungary	Lab.Guidotti S.p.A. 2040 Budaörs,Terrapark, Neumann János u.1/B tömb, D ép	Xilox	100 mg	Granules	oral
Ireland	Helsinn Birex Pharm. Ltd. Damastown Mulhuddart Dublin 15 Ireland	Aulin	100 mg	Tablet	Oral
Ireland	Helsinn Birex Pharm. Ltd. Damastown Mulhuddart Dublin 15 Ireland	Aulin	100 mg	Granules	Oral
Ireland	Helsinn Birex Therapeutics Ltd. Damastown Mulhuddart Dublin 15 Ireland	Mesulid	100 mg	Tablet	Oral
Ireland	Helsinn Birex Therapeutics Ltd. Damastown Mulhuddart Dublin 15 Ireland	Mesulid	100 mg	Granules	Oral
Ireland	Pinewood Laboratories Ltd Ballymacarbry Clonmel Co. Tipperary Ireland	Mesine	100 mg	Tablet	Oral
Ireland	PCO Manufacturing Ltd. Unit 222 Western Industrial Estate, Naas Road, Dublin 12 Ireland	Aulin	100 mg	Tablet	Oral
Ireland	B + S Healthcare Unit 4 Bradfield Road, Ruislip, Middlesex HA4, United Kingdom	Aulin	100 mg	Granules	Oral

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Ireland	B + S Healthcare Unit 4 Bradfield Road, Ruislip, Middlesex HA4, United Kingdom	Aulin	100 mg	Tablet	Oral
Italy	FRANCIA FARMAC.IND.FAR.BIO.SRL VIA DEI PESTAGALLI, 7 20138 MILANO	ALGIMESIL	100 mg	Granules	oral use
Italy	FRANCIA FARMAC.IND.FAR.BIO.SRL VIA DEI PESTAGALLI, 7 20138 MILANO	ALGIMESIL	100 mg	Tablet	oral use
Italy	SIAR PHARMA Srl, VIA VERDI 33, 20060 BUSSERO	ALGOLIDER	100 mg	Granules	oral use
Italy	SIAR PHARMA Srl, VIA VERDI 33, 20060 BUSSERO	ALGOLIDER	100 mg	Tablet	oral use
Italy	SELVI LABORAT.BIOTERAPICO SpA, VIA PROCOIO, 28, 00065 FIANO ROMANO	ANTALGO	100 mg	Granules	oral use
Italy	ECOBI FARMACEUTICI Sas, VIA E.BAZZANO, 26, 16019 RONCO SCRIVIA	AREUMA	200 mg	Suppository	rectal use
Italy	ECOBI FARMACEUTICI Sas, VIA E.BAZZANO, 26, 16019 RONCO SCRIVIA	AREUMA	100 mg	Granules	oral use
Italy	ECOBI FARMACEUTICI Sas, VIA E.BAZZANO, 26, 16019 RONCO SCRIVIA	AREUMA	100 mg	Tablet	oral use
Italy	ROCHE SpA, P.ZZA DURANTE, 11, 20131 MILANO	AULIN	200 mg	Suppository	rectal use
Italy	ROCHE SpA, P.ZZA DURANTE, 11, 20131 MILANO	AULIN	100 mg	Granules	oral use
Italy	ROCHE SpA, P.ZZA DURANTE, 11, 20131 MILANO	AULIN	100 mg	Tablet	oral use
Italy	ROCHE SpA, P.ZZA DURANTE, 11, 20131 MILANO	AULIN BETA	400 mg	Granules	oral use
Italy	ROCHE SpA, P.ZZA DURANTE, 11, 20131 MILANO	AULIN BETA	400 mg	Tablet	oral use
Italy	ROCHE SpA, P.ZZA DURANTE, 11, 20131 MILANO	AULIN MITE	50 mg	Granules	oral use
Italy	AGIPS FARMACEUTICI Srl, VIA AMENDOLA, 4, 16035 RAPALLO	DELFO	100 mg	Granules	oral use
Italy	AGIPS FARMACEUTICI Srl, VIA AMENDOLA, 4, 16035 RAPALLO	DELFO	100 mg	Tablet	oral use
Italy	SARDA PHARMACEUTICA Srl, VIA CASTIGLIONE 92/B 09100 CAGLIARI	DIMESUL	100 mg	Granules	oral use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Italy	SO.SE.PHARM Srl, VIA DEI CASTELLI ROMANI, 22, 00040 POMEZIA	DOMES	100 mg	Granules	oral use
Italy	SO.SE.PHARM Srl, VIA DEI CASTELLI ROMANI, 22, 00040 POMEZIA	DOMES	100 mg	Tablet	oral use
Italy	SO.SE.PHARM Srl, VIA DEI CASTELLI ROMANI, 22, 00040 POMEZIA	DOMES	100 mg	Orodispersible tablet	oral use
Italy	SIFI SpA, VIA ERCOLE PATTI 36, 95020 LAVINAIO - ACI S.ANTONIO	EDEMAX	100 mg	Granules	oral use
Italy	SIFI SpA, VIA ERCOLE PATTI 36, 95020 LAVINAIO - ACI S.ANTONIO	EDEMAX	100 mg	Tablet	oral use
Italy	AESCLAPIUS FARMACEUTICI Srl,VIA COZZAGLIO, 24, 25125 BRESCIA	EFRIDOL	100 mg	Granules	oral use
Italy	AESCLAPIUS FARMACEUTICI Srl,VIA COZZAGLIO, 24, 25125 BRESCIA	EFRIDOL	100 mg	Tablet	oral use
Italy	I.B.N. SAVIO Srl, VIA E.BAZZANO, 14, 16019 RONCO SCRIVIA	EUDOLENE	100 mg	Granules	oral use
Italy	NCSN FARMACEUTICI Srl, VIA SVETONIO, 6, 00136 ROMA	FANSIDOL	100 mg	Granules	oral use
Italy	NCSN FARMACEUTICI Srl, VIA SVETONIO, 6, 00136 ROMA	FANSIDOL	100 mg	Capsule	oral use
Italy	SOFAR SpA, VIA ISONZO, 8, 20100 MILANO	FANSULIDE	100 mg	Granules	oral use
Italy	SOFAR SpA, VIA ISONZO, 8, 20100 MILANO	FANSULIDE	100 mg	Tablet	oral use
Italy	PRODOTTI FORMENTI Srl, VIA CORREGGIO, 43, 20149 MILANO	FLAMINIDE	100 mg	Granules	oral use
Italy	PRODOTTI FORMENTI Srl, VIA CORREGGIO, 43, 20149 MILANO	FLAMINIDE	100 mg	Tablet	oral use
Italy	C.T. LAB.FARMACEUTICO Srl, VILLA SAYONARA; STR.SOLARO 75/77, 18038 SANREMO	FLOLID	100 mg	Suppository	rectal use
Italy	C.T. LAB.FARMACEUTICO Srl, VILLA SAYONARA; STR.SOLARO 75/77, 18038 SANREMO	FLOLID	100 mg	Granules	oral use
Italy	C.T. LAB.FARMACEUTICO Srl, VILLA SAYONARA; STR.SOLARO 75/77, 18038 SANREMO	FLOLID	100 mg	Tablet	oral use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Italy	ALMUS Srl, VIA CESAREA, 11/10, 16121 GENOVA	IDEALID	100 mg	Tablet	oral use
Italy	MAGIS FARMACEUTICI SpA, VIA CACCIAMALI, 34-36-38/B, 25125 BRESCIA	ISODOL	100 mg	Granules	oral use
Italy	MAGIS FARMACEUTICI SpA, VIA CACCIAMALI, 34-36-38/B, 25125 BRESCIA	ISODOL	100 mg	Tablet	oral use
Italy	BONISCONTRO & GAZZONE Srl, VIA PAVIA,6, 20136 MILANO	LEDOREN	100 mg	Granules	oral use
Italy	BONISCONTRO & GAZZONE Srl, VIA PAVIA,6, 20136 MILANO	LEDOREN	100 mg	Tablet	oral use
Italy	ALTA CARE LAB.ITALIA Srl, VIALE DELLE MILIZIE, 134, 00192 ROMA	LIDERSOLV	100 mg	Granules	oral use
Italy	ALTA CARE LAB.ITALIA Srl, VIALE DELLE MILIZIE, 134, 00192 ROMA	LIDERSOLV	100 mg	Tablet	oral use
Italy	HELSINN BIREX PHARMAC.LTD, LARGO UMBERTO BOCCIONI, 1, 21040 ORIGGIO	MESULID	200 mg	Suppository	rectal use
Italy	HELSINN BIREX PHARMAC.LTD, LARGO UMBERTO BOCCIONI, 1, 21040 ORIGGIO	MESULID	100 mg	Granules	oral use
Italy	HELSINN BIREX PHARMAC.LTD, LARGO UMBERTO BOCCIONI, 1, 21040 ORIGGIO	MESULID	100 mg	Tablet	oral use
Italy	HELSINN BIREX PHARMAC.LTD, LARGO UMBERTO BOCCIONI, 1, 21040 ORIGGIO	MESULID FAST	400 mg	Granules	oral use
Italy	HELSINN BIREX PHARMAC.LTD, LARGO UMBERTO BOCCIONI, 1, 21040 ORIGGIO	MESULID MITE	50 mg	Granules	oral use
Italy	NEW RESEARCH Srl, V.DELLA TENUTA DI TORRENOVA142, 00133 ROMA	NERELID	100 mg	Granules	oral use
Italy	NEW RESEARCH Srl, V.DELLA TENUTA DI TORRENOVA142, 00133 ROMA	NERELID	100 mg	Capsule	oral use
Italy	I.BIR.N Srl Ist.Biot.Nazionale, VIA VITTORIO GRASSI, 9/15, 00155 ROMA	NIDE	100 mg	Granules	oral use
Italy	I.BIR.N Srl Ist.Biot.Nazionale, VIA VITTORIO GRASSI, 9/15, 00155 ROMA	NIDE	100 mg	Capsule	oral use
Italy	MOLTENI & C. F.LLI ALITTI SpA, STR.STATALE 67, LOC.GRANATIERI, 50018 SCANDICCI	NIDEMOL	200 mg	Suppository	rectal use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Italy	MOLTENI & C. F.LLI ALITTI SpA, STR.STATALE 67, LOC.GRANATIERI, 50018 SCANDICCI	NIDEMOL	100 mg	Granules	oral use
Italy	ITALFARMACO SpA, V.LE FULVIO TESTI, 330, 20126 MILANO	NIMEDEX	400 mg	Granules	oral use
Italy	ITALFARMACO SpA, V.LE FULVIO TESTI, 330, 20126 MILANO	NIMEDEX	400 mg	Tablet	oral use
Italy	ITALFARMACO SpA, V.LE FULVIO TESTI, 330, 20126 MILANO	NIMEDEX	400 mg	Granules	oral use
Italy	KRUGHER PHARMA Srl, VIA VOLTURNO, 10/12, 50019 SESTO FIORENTINO	NIMENOL	100 mg	Granules	oral use
Italy	KRUGHER PHARMA Srl, VIA VOLTURNO, 10/12, 50019 SESTO FIORENTINO	NIMENOL	100 mg	Granules	oral use
Italy	LAB.GUIDOTTI SpA, VIA LIVORNESE, 89, 56010 LA VETTOLA - PISA	NIMESULENE	200 mg	Suppository	rectal use
Italy	LAB.GUIDOTTI SpA, VIA LIVORNESE, 89, 56010 LA VETTOLA - PISA	NIMESULENE	100 mg	Granules	oral use
Italy	LAB.GUIDOTTI SpA, VIA LIVORNESE, 89, 56010 LA VETTOLA - PISA	NIMESULENE	100 mg	Tablet	oral use
Italy	ANGENERICO SpA, VIA NOCERA UMBRA, 75, 00181 ROMA	NIMESULIDE	200 mg	Suppository	rectal use
Italy	DOROM Srl, VIA GIULIO RICHARD, 7, 20143 MILANO	NIMESULIDE	200 mg	Suppository	rectal use
Italy	TEVA PHARMA ITALIA Srl, VIA GIULIO RICHARD, 7, 20143 MILANO	NIMESULIDE	200 mg	Suppository	rectal use
Italy	MERCK GENERICS ITALIA SpA, VIA AQUILEIA, 35, CINISELLO BALSAMO	NIMESULIDE	200 mg	Suppository	rectal use
Italy	DOC GENERICI Srl, VIA MANUZIO, 7, 20124 MILANO	NIMESULIDE	200 mg	Suppository	rectal use
Italy	EG SpA, VIA DOMENICO SCARLATTI, 31, 20124 MILANO	NIMESULIDE	100 mg	Chewable tablet	oral use
Italy	BENEDETTI SpA, VICOLO DE'BAC- CHETTONI, 1, 51100 PISTOIA	NIMESULIDE	100 mg	Granules	oral use
Italy	BENEDETTI SpA, VICOLO DE'BAC- CHETTONI, 1, 51100 PISTOIA	NIMESULIDE	100 mg	Granules	oral use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Italy	MIPHARM SpA, VIA QUARANTA, 12, 20141 MILANO	NIMESULIDE	100 mg	Granules	oral use
Italy	FARMAC.FORMENTI SpA, VIA CORREGGIO, 43, 20149 MILANO	NIMESULIDE	100 mg	Granules	oral use
Italy	SANDOZ SpA, L.GO U.BOCCIONI, 1, 21040 ORIGGIO	NIMESULIDE	100 mg	Granules	oral use
Italy	LABORATORI ALTER Srl, VIA EGADI, 7, 20144 MILANO	NIMESULIDE	100 mg	Granules	oral use
Italy	ANGENERICO SpA, VIA NOCERA UMBRA, 75, 00181 ROMA	NIMESULIDE	100 mg	Granules	oral use
Italy	DOROM Srl, VIA GIULIO RICHARD, 7, 20143 MILANO	NIMESULIDE	100 mg	Granules	oral use
Italy	POLIFARMA SpA, VIALE DELL'ARTE, 69, 00144 ROMA	NIMESULIDE	100 mg	Granules	oral use
Italy	TEVA PHARMA ITALIA Srl, VIA GIULIO RICHARD, 7, 20143 MILANO	NIMESULIDE	100 mg	Granules	oral use
Italy	MERCK GENERICS ITALIA SpA, VIA AQUILEIA, 35, 20092 CINISELLO BALSAMO	NIMESULIDE	100 mg	Granules	oral use
Italy	GET Srl, VIA DANTE ALIGHIERI, 73, 18038 SANREMO	NIMESULIDE	100 mg	Granules	oral use
Italy	JET GENERICI Srl, VIA MARIO LALLI, 8, 56127 PISA	NIMESULIDE	100 mg	Granules	oral use
Italy	ROBIN Srl, P.LE DURANTE FRANCESCO, 11, MILANO	NIMESULIDE	100 mg	Granules	oral use
Italy	DOC GENERICI Srl, VIA MANUZIO, 7, 20124 MILANO	NIMESULIDE	100 mg	Granules	oral use
Italy	EG SpA, VIA DOMENICO SCARLATTI, 31, 20124 MILANO	NIMESULIDE	100 mg	Granules	oral use
Italy	RATIOPHARM GMBH, VIALE MONZA, 270, 20128 MILANO	NIMESULIDE	100 mg	Granules	oral use
Italy	RANBAXY ITALIA SpA, P.ZA FILIPPO MEDA 3, 20121 MILANO	NIMESULIDE	100 mg	Granules	oral use
Italy	PLIVA PHARMA SpA, VIA TRANQUILLO CREMONA, 10, 20092 CINISELLO BALSAMO	NIMESULIDE	100 mg	Granules	oral use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Italy	ALMUS Srl, VIA CESAREA, 11/10, 16121 GENOVA	NIMESULIDE	100 mg	Granules	oral use
Italy	HEXAL SpA, VIA PARACELSO, 16, 20041 AGRATE BRIANZA	NIMESULIDE	100 mg	Granules	oral use
Italy	UNION HEALTH Srl, VIA ROCCAM-ANDOLFI, 1, 00156 ROMA	NIMESULIDE	100 mg	Granules	oral use
Italy	BENEDETTI SpA, VICOLO DE'BAC-CHETTONI, 1, 51100 PISTOIA	NIMESULIDE	100 mg	Tablet	oral use
Italy	MIPHARM SpA, VIA QUARANTA, 12, 20141 MILANO	NIMESULIDE	100 mg	Tablet	oral use
Italy	FARMAC.FORMENTI SpA, VIA CORREGGIO, 43, 20149 MILANO	NIMESULIDE	100 mg	Tablet	oral use
Italy	LABORATORI ALTER Srl, VIA EGADI, 7, 20144 MILANO	NIMESULIDE	100 mg	Tablet	oral use
Italy	TEVA PHARMA ITALIA Srl, VIA GIULIO RICHARD, 7, 20143 MILANO	NIMESULIDE	100 mg	Tablet	oral use
Italy	MERCK GENERICS ITALIA SpA, VIA AQUILEIA, 35, 20092 CINISELLO BALSAMO	NIMESULIDE	100 mg	Tablet	oral use
Italy	GET Srl, VIA DANTE ALIGHIERI, 73, 18038 SANREMO	NIMESULIDE	100 mg	Tablet	oral use
Italy	ROBIN Srl, P.LE DURANTE FRANCESCO, 11, MILANO	NIMESULIDE	100 mg	Tablet	oral use
Italy	DOC GENERICI Srl, VIA MANUZIO, 7, 20124 MILANO	NIMESULIDE	100 mg	Tablet	oral use
Italy	EG SpA, VIA DOMENICO SCARLATTI, 31, 20124 MILANO	NIMESULIDE	100 mg	Tablet	oral use
Italy	RATIOPHARM GMBH, VIALE MONZA, 270, 20128 MILANO	NIMESULIDE	100 mg	Tablet	
Italy	RANBAXY ITALIA SpA, P.ZA FILIPPO MEDA 3, 20121 MILANO	NIMESULIDE	100 mg	Tablet	oral use
Italy	PLIVA PHARMA SpA, VIA TRANQUILLO CREMONA, 10, 20092 CINISELLO BALSAMO	NIMESULIDE	100 mg	Tablet	oral use
Italy	HEXAL SpA, VIA PARACELSO, 16, 20041 AGRATE BRIANZA	NIMESULIDE	100 mg	Tablet	oral use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Italy	UNION HEALTH Srl, VIA ROCCAM-ANDOLFI, 1, 00156 ROMA	NIMESULIDE	100 mg	Tablet	oral use
Italy	EG SpA, VIA DOMENICO SCARLATTI, 31, 20124 MILANO	NIMESULIDE	100 mg	Tablet	oral use
Italy	RATIOPHARM GMBH, VIALE MONZA, 270, 20128 MILANO	NIMESULIDE	100 mg	Tablet	oral use
Italy	SANDOZ SpA, L.GO U.BOCCIONI, 1, 21040 ORIGGIO	NIMESULIDE	100 mg	Capsule	oral use
Italy	FARMAC.CABER SpA, VIALE CITTA' D'EUROPA, 681, ROMA	NIMS	100 mg	Granules	oral use
Italy	LEVOFARMA Srl, VIA CONFORTI, 42, 84083 CASTEL SAN GIORGIO	NOALGOS	100 mg	Granules	oral use
Italy	LAMPUGNANI FARMACEUTICI SpA, VIA BIANCA MARIA VISCONTI, 20122 MILANO	NOXALIDE	100 mg	Granules	oral use
Italy	LAMPUGNANI FARMACEUTICI SpA, VIA BIANCA MARIA VISCONTI, 20122 MILANO	NOXALIDE	60 ml 5 %	Drops	oral use
Italy	TAD PHARMA ITALIA Srl, VIA FELICE CASATI, 16, 20124 MILANO	ORONIME	100 mg	Orodispersible tablet	oral use
Italy	PANTAFARM Srl, VIA PALESTRO, 14, 00185 ROMA	PANTAMES	100 mg	Orodispersible tablet	oral use
Italy	VECCHI & PIAM Sapa, VIA PADRE G.SEMERIA, 5, 16131 GENOVA	REMOV	100 mg	Granules	oral use
Italy	VECCHI & PIAM Sapa, VIA PADRE G.SEMERIA, 5, 16131 GENOVA	REMOV	100 mg	Tablet	oral use
Italy	IST.CHIM.INTERN RENDE Srl, VIA SALARIA, 1240, 00138 ROMA	RESULIN	200 mg	Suppository	rectal use
Italy	IST.CHIM.INTERN RENDE Srl, VIA SALARIA, 1240, 00138 ROMA	RESULIN	100 mg	Granules	oral use
Italy	IST.CHIM.INTERN RENDE Srl, VIA SALARIA, 1240, 00138 ROMA	RESULIN	100 mg	Tablet	oral use
Italy	NOVARTIS CONSUMER HEALTH SpA, LARGO UMBERTO BOCCIONI, 1, 21040 ORIGGIO	REUMALIDE	200 mg	Suppository	rectal use
Italy	NOVARTIS CONSUMER HEALTH SpA, LARGO UMBERTO BOCCIONI, 1, 21040 ORIGGIO	REUMALIDE	100 mg	Granules	oral use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Italy	MDM SpA, VIALE PAPINIANO, 22/B, 20100 MILANO	SOLVING	100 mg	Granules	oral use
Italy	MDM SpA, VIALE PAPINIANO, 22/B, 20100 MILANO	SOLVING	100 mg	Tablet	oral use
Italy	FARMAC.DAMOR SpA, VIA EMILIO SCAGLIONE, 27, 80145 NAPOLI	SULIDAMOR	100 mg	Granules	oral use
Italy	FARMAC.DAMOR SpA, VIA EMILIO SCAGLIONE, 27, 80145 NAPOLI	SULIDAMOR	100 mg	Tablet	oral use
Italy	FARMAC.DAMOR SpA, VIA EMILIO SCAGLIONE, 27, 80145 NAPOLI	SULIDAMOR	100 mg	Granules	oral use
Italy	FARMAC.DAMOR SpA, VIA EMILIO SCAGLIONE, 27, 80145 NAPOLI	SULIDAMOR	100 mg	Tablet	oral use
Italy	TAD PHARMA ITALIA Srl, VIA FELICE CASATI, 16, 20124 MILANO	SULIDE	100 mg	Granules	oral use
Italy	TAD PHARMA ITALIA Srl, VIA FELICE CASATI, 16, 20124 MILANO	SULIDE	100 mg	Tablet	oral use
Italy	ERREKAPPA EUROTHERAPICI SpA, VIA C.MENOTTI, 1/A, 20129 MILANO	SULMEDIL	200 mg	Suppository	rectal use
Italy	ERREKAPPA EUROTHERAPICI SpA, VIA C.MENOTTI, 1/A, 20129 MILANO	SULMEDIL	100 mg	Granules	oral use
Italy	ERREKAPPA EUROTHERAPICI SpA, VIA C.MENOTTI, 1/A, 20129 MILANO	SULMEDIL	100 mg	Tablet	oral use
Latvia	Helsinn Birex Pharmaceutical Ltd., Damastown, Mulhurddart, Dublin 15, Ireland	Mesulid	100 mg	Tablet	Oral
Latvia	Laboratori Guidotti S. P. A., Via Trieste 40, I-56126 Pisa, Italy	Nimesil	100 mg	granules for oral suspension	Oral
Latvia	Medochemie Ltd., P. O. Box 51409, CY-3505 Limassol, Cyprus	Aponil	100 mg	Tablet	Oral
Latvia	Zentiva a. S., Nitrianska 100, 92027 Hlohovec, Slovakia	Coxtral	100 mg	Tablet	Oral
Lithuania	Medochemie Ltd., P. O. Box 51409 CY-3505 Limassol, Cyprus	Aponil	100 mg	Tablet	oral use
Lithuania	Zentiva a. s., U kabelovny 130102 37 Praha 10 Dolni Mecholupy, Czech Republic	Coxtral	100 mg	Tablet	oral use
Lithuania	Helsinn Birex Pharmaceuticals Ltd., Damastown Mulhuddart Dublin 15, Ireland	Mesulid	100 mg	Tablet	oral use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Lithuania	Laboratori Guidotti S.p.A., Via Livornese, 897-56010 Pisa-La Viottola, Italy	Nimesil	100 mg	granules for oral suspension	oral use
Malta	Vecchi & C Piam S A, Via Padre G Semeria, 5, Genoa 16131, Italy	Remov	100 mg	Tablet	Oral
Poland	Zentiva a.s. U Kabelovny 130 Dolni Mecholupy 102 37 Praque 10	COXTRAL	100 mg	tablet	oral use
Poland	Medicom International s.r.o., Paterni 7, Brno, 63500 Czech Republik	AULIN	100 mg	Granules for oral use	oral use
Poland	LABORATORI GUIDOTTI S.p.A. Via Livornese 897 I - 56010 San Piero a Grado PISA, Italy	NIMESIL	100 mg	Tablet	oral use
Poland	Medicom International s.r.o., Paterni 7, Brno, 63500 Czech Republik	AULIN	100 mg	Granules for oral use	oral use
Portugal	Angelini Farmacêutica, Lda. Rua João Chagas, 53 - 3º 1495-764 Cruz Quebrada - Dafundo	Aulin	100 mg	Tablet	Oral
Portugal	Angelini Farmacêutica, Lda. Rua João Chagas, 53 - 3º 1495-764 Cruz Quebrada - Dafundo	Aulin	100 mg	Powder for oral suspension	Oral
Portugal	Angelini Farmacêutica, Lda. Rua João Chagas, 53 - 3º 1495-764 Cruz Quebrada - Dafundo	Aulin	200 mg	Suppository	Rectal
Portugal	Rega Farma - Promoção de Produtos Farmacêuticos, S.A. Rua João Chagas, 53 - 3º 1495-764 Cruz Quebrada	Donulide	100 mg	Tablet	Oral
Portugal	Rega Farma - Promoção de Produtos Farmacêuticos, S.A. Rua João Chagas, 53 - 3º 1495-764 Cruz Quebrada	Donulide	100 mg	Powder for oral suspension	Oral
Portugal	Labesfal - Laboratórios Almiro, S.A. 3465-051 Campo de Besteiros	Nimalge	200 mg	Suppository	Rectal
Portugal	Vida - Produtos Farmacêuticos, S.A. Vala do Carregado 2600-726 Castanheira do Ribatejo	Nimartin	100 mg	Coated tablet	Oral
Portugal	Sanofi-Aventis - Produtos Farmacêuticos, S.A. Empreendimento Lagoas Park - Edifício 7 - 3º 2740-244 Porto Salvo	Nimed	100 mg	Coated tablet	Oral

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Portugal	Sanofi-Aventis - Produtos Farmacêuticos, S.A. Empreendimento Lagoas Park - Edifício 7 - 3º 2740-244 Porto Salvo	Nimed	100 mg	Powder for oral solution	Oral
Portugal	Sanofi-Aventis - Produtos Farmacêuticos, S.A. Empreendimento Lagoas Park - Edifício 7 - 3º 2740-244 Porto Salvo	Nimed	200 mg	Suppository	Rectal
Portugal	Laboratori Guidotti, S.p.A. Via Trieste, 40 I-56126 Pisa	Nimesulene	100 mg	Powder for oral suspension	Oral
Portugal	Alter, S.A. Estrada Marco do Grilo - Zemouto 2830 Coina	Nimesulida Alter 100 mg Comprimidos	100 mg	Tablet	Oral
Portugal	Arrowblue Produtos Farmacêuticos S.A. Av. D. João II, 10 Esqº - Torre Fernão de Magalhães 1998-025 Lisboa	Nimesulida Arrowblue	100 mg	Tablet	Oral
Portugal	Farmoquímica Baldacci, S.A. Rua Duarte Galvão, 44 1549-005 Lisboa	Nimesulida Baldacci 100 mg Comprimidos	100 mg	Tablet	Oral
Portugal	Bluepharma - Indústria Farmacêutica, S.A. São Martinho do Bispo 3045-016 Coimbra	Nimesulida Bluepharma 100 mg Comprimidos	100 mg	Tablet	Oral
Portugal	Ciclum Farma Unipessoal, Lda. Rua Alfredo da Silva, 16 2610-016 Amadora	Nimesulida Ciclum 100 mg Comprimidos	100 mg	Tablet	Oral
Portugal	Edol Themaxis - Produtos Farmacêuticos S.A. Avenida 25 de Abril, nº 6 - 6A 2795-195 Linda-a-Velha	Nimesulida Edol	100 mg	Tablet	Oral
Portugal	Farmoz - Sociedade Técnico-Medicinal S.A. Rua Prof. Henrique de Barros - Edifício Sagres - 3º A 2685-338 Prior Velho	Nimesulida Farmoz 100 mg Comprimidos	100 mg	Coated tablet	Oral
Portugal	Generis Farmacêutica, S.A. Office Park da Beloura - Edifício 4 - Quinta da Beloura 2710-444 Sintra	Nimesulida Generis 100 mg Comprimidos	100 mg	Tablet	Oral
Portugal	Generis Farmacêutica, S.A. Office Park da Beloura - Edifício 4 - Quinta da Beloura 2710-444 Sintra	Nimesulida Generis 100 mg Granulado para Solução Oral	100 mg	Powder for oral solution	Oral
Portugal	Companhia Portuguesa Higiene Pharma - Produtos Farmacêuticos, S.A. Rua dos Bem Lembrados, 141 - Manique 2645-471 Alcabideche	Nimesulida Gerilide 100 mg Comprimidos	100 mg	Tablet	Oral
Portugal	Companhia Portuguesa Higiene Pharma - Produtos Farmacêuticos, S.A. Rua dos Bem Lembrados, 141 - Manique 2645-471 Alcabideche	Nimesulida Gerilide 100 mg Granulado para Solução Oral	100 mg	Powder for oral solution	Oral

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Portugal	Germed Farmacêutica, Lda. Rua Alto do Montijo, 13 - 1º Dto - Edifício Monsanto 2790-012 Portela de Carnaxide	Nimesulida Germed 100 mg Comprimidos	100 mg	Tablet	Oral
Portugal	Germed Farmacêutica, Lda. Rua Alto do Montijo, 13 - 1º Dto - Edifício Monsanto 2790-012 Portela de Carnaxide	Nimesulida Germed 100 mg Granulado para suspensão oral	100 mg	Powder for oral suspension	Oral
Portugal	gp - genéricos portugueses, Lda. Rua Henrique Paiva Couceiro, 29 - Venda Nova 2700-451 Amadora	Nimesulida gp 100 mg Comprimidos	100 mg	Tablet	Oral
Portugal	Laboratórios Inibsa, S.A. Zona Industrial da Abrunheira - Edifício 1 - 2º I - Sintra Business Park 2710-089 Sintra	Nimesulida Inibsa 100 mg comprimidos	100 mg	Tablet	Oral
Portugal	Laboratórios Inibsa, S.A. Zona Industrial da Abrunheira - Edifício 1 - 2º I - Sintra Business Park 2710-089 Sintra	Nimesulida Inibsa 100 mg granulado para suspensão oral	100 mg	Powder for oral suspension	Oral
Portugal	Tecnimede - Sociedade Técnico-Medicinal S.A. Rua Prof. Henrique de Barros - Edifício Sagres - 3º A 2685-338 Prior Velho	Nimesulida Isartrox 100 mg Comprimidos	100 mg	Coated tablet	Oral
Portugal	Jaba Farmacêutica, S.A. Zona Industrial da Abrunheira - Edifício Jaba - Rua da Tapada Grande, 2 2710-089 Sintra	Nimesulida Jabasulide 100 mg Comprimidos	100 mg	Tablet	Oral
Portugal	Jaba Farmacêutica, S.A. Zona Industrial da Abrunheira - Edifício Jaba - Rua da Tapada Grande, 2 2710-089 Sintra	Nimesulida Jabasulide 100 mg Granulado Para Solução Oral	100 mg	Powder for oral solution	Oral
Portugal	Labesfal - Laboratórios Almiro, S.A. 3465-051 Campo de Besteiros	Nimesulida Labesfal	200 mg	Suppository	Rectal
Portugal	Labesfal - Laboratórios Almiro, S.A. 3465-051 Campo de Besteiros	Nimesulida Labesfal 100 mg Comprimidos	100 mg	Tablet	Oral
Portugal	Labesfal - Laboratórios Almiro, S.A. 3465-051 Campo de Besteiros	Nimesulida Labesfal 100 mg Granulado para Suspensão Oral	100 mg	Powder for oral suspension	Oral
Portugal	Vetiquima - Produtos Químicos, Lda. Estrada Nacional 10, Km 140,260 2696-901 Bobadela	21994 83 00	100 mg	Tablet	Oral
Portugal	Vetiquima - Produtos Químicos, Lda. Estrada Nacional 10, Km 140,260 2696-901 Bobadela	21994 83 00	100 mg	Powder for oral suspension	Oral
Portugal	Medicamed - Produtos Médicos e Farmacêuticos, S.A. Av. D. Afonso Henriques, 1462 - Edifício Olympus 4450-013 Matosinhos	Nimesulida Medicamed 100 mg Comprimidos	100 mg	Coated tablet	Oral

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Portugal	Medineo - Comercialização de Produtos Farmacêuticos, Lda. Rua Teófilo Braga, 14 2775-290 Parede	Nimesulida Medineo 100 mg Comprimidos	100 mg	Tablet	Oral
Portugal	Mepha - Investigação, Desenvolvimento e Fabricação Farmacêutica, Lda. Rua Elias Garcia, 28 C - Edifício 4 - Venda Nova 2701-355 Amadora	Nimesulida Mepha 100 mg Comprimidos	100 mg	Tablet	Oral
Portugal	Mepha - Investigação, Desenvolvimento e Fabricação Farmacêutica, Lda. Rua Elias Garcia, 28 C - Edifício 4 - Venda Nova 2701-355 Amadora	Nimesulida Mepha 100 mg Granulado para Suspensão Oral	100 mg	Powder for oral suspension	Oral
Portugal	Merck Genéricos - Produtos Farmacêuticos, Lda. Rua Alfredo da Silva, 3 C - 4º 1300-040 Lisboa		100 mg	Tablet	Oral
Portugal	Merck Genéricos - Produtos Farmacêuticos, Lda. Rua Alfredo da Silva, 3 C - 4º 1300-040 Lisboa	Nimesulida Merck Genéricos 100 mg Granulado para solução oral	100 mg	Powder for oral solution	Oral
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua Prof. Henrique de Barros - Edifício Sagres - 3º A 2685-338 Prior Velho	Nimesulida Neuride 100 mg Comprimidos	100 mg	Coated tablet	Oral
Portugal	Labesfal - Laboratórios Almiro, S.A. 3465-051 Campo de Besteiros	Nimesulida Nilmide 100 mg Comprimidos	100 mg	Tablet	Oral
Portugal	Labesfal - Laboratórios Almiro, S.A. 3465-051 Campo de Besteiros	Nimesulida Nilmide 100 mg Granulado Para Suspensão Oral	100 mg	Powder for oral suspension	Oral
Portugal	Pharmakern Portugal - Produtos Farmacêuticos, Sociedade Unipessoal, Lda. Av. José Gomes Ferreira, 11 - 3º, Sala 31 - Edifício Atlas II 1495-139 Miraflares - Algés	Nimesulida Pharmakern 100 mg Comprimidos	100 mg	Tablet	Oral
Portugal	Ranbaxy Portugal - Comércio e Desenvol. de Produtos Farmacêuticos, Unip., Lda. Rua do Campo Alegre, 1306, 3º - Sala 301/302 - Edifício Botânico 4150-174 Porto	Nimesulida Ranbaxy	100 mg	Tablet	Oral
Portugal	Ranbaxy Portugal - Comércio e Desenvol. de Produtos Farmacêuticos, Unip., Lda. Rua do Campo Alegre, 1306, 3º - Sala 301/302 - Edifício Botânico 4150-174 Porto	Nimesulida Ranbaxy	100 mg	Powder for oral suspension	Oral

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Portugal	Ratiopharm - Comércio e Indústria de Produtos Farmacêuticos, Lda. Rua Quinta do Pinheiro - Edifício Tejo - 6º Piso 2790-143 Carnaxide	Nimesulida Ratiopharm 100 mg Comprimidos	100 mg	Tablet	Oral
Portugal	Quiraus - Comércio Produtos Químicos e Tecnologia Farmacêutica, Lda. Av. Salvador Allende, 12 - 1º 2780-163 Oeiras	Nimesulida Reumesul 100 mg Comprimidos	100 mg	Tablet	Oral
Portugal	Sandoz Farmacêutica, Lda. Rua do Centro Empresarial - Edifício 3 - Loja 1 - Quinta da Beloura 2710-693 Sintra	Nimesulida Sandoz 100 mg Comprimidos	100 mg	Tablet	Oral
Portugal	Decafarma - Comércio de Produtos Farmacêuticos, Lda Centro Empresarial Sintra Estoril, V, Armazém E 3 2710-144 Sintra	Nimesulida Sulimed 100 mg Comprimidos	100 mg	Tablet	Oral
Portugal	Laboratórios Atral, S.A Vala do Carregado 2600-726 Castanheira do Ribatejo	Ribantil	100 mg	Coated tablet	Oral
Portugal	Pharmout - Farmacêutica Internacional, Lda. Rua da Quinta das Romeiras, 104 - 7º 1495-236 Algés	Vitolide	100 mg	Tablet	Oral
Romania	Faran Laboratories SA/Imedica SA, Sos. Bucuresti – Ploiesti Nr. 141D Sector 1, Bucuresti	AFLOGEN	100 mg	Tablet	oral use
Romania	Medochemie LTD, Str. Prof. Dr. Ion Cantacuzino nr. 5, sector 1, Bucuresti	Aponil	100 mg	Tablet	oral use
Romania	C.S.C. PHARMACEUTICALS, Drumul Sariei nr. 108, sector 6 Bucuresti	Aulin	100 mg	granules for oral suspension	oral use
Romania	C.S.C. PHARMACEUTICALS, Drumul Sariei nr. 108, sector 6 Bucuresti	Aulin	100 mg	Tablet	oral use
Romania	Zentiva AS, B-dul Theodor Pallady nr. 50, 032266 Bucuresti	Coxtral	100 mg	Tablet	oral use
Romania	ANFARM HELLAS SA/Imedica, Sos. Bucuresti – Ploiesti Nr. 141D Sector 1, Bucuresti	Lemesil	100 mg	Tablet	oral use
Romania	LABORATORI GUIDOTTI S.p.A., Via Livornese 897, I - 56010 La Vettola, PISA, Italy	Nimesil	100 mg	granules for oral suspension	oral use
Romania	Terapia SA, Str. Fabricii Nr. 124, 3400 Cluj Napoca, Jud. Cluj	Nimesulid	100 mg	Tablet	oral use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Romania	LABORMED PHARMA SRL, Splaiul Independentei Nr. 319, Sector 6, Bucuresti	Nimesulid LPH 100 mg	100 mg	Tablet	oral use
Romania	MAGISTRA C & C, Str. Aviator Belghiru Nr. 9, 8700 Constanta, Jud. Constanta	Nimesulid 100 mg	100 mg	Tablet	oral use
Romania	ARENA GROUP SA, Str. Stefan Mihaileanu Nr.31, Sector 2, 73101 Bucuresti	Nimesulid Arena 100 mg	100 mg	Tablet	oral use
Romania	SLAVIA PHARM SRL, Str. Stirbei Voda Nr.53-55, Sector 1, Bucuresti	Nimesulid Slavia	100 mg	Tablet	oral use
Romania	FARMACEUTICI DAMUR SPA, Calea Dorobantilor Nr.113 Ap.35, Cluj, Jud. Cluj	Sulidamor	100 mg	Powder for oral suspension	powder for oral suspension
Slovak Republic	Medicom International s.r.o., Brno, Czech Republik	AULIN 100 mg granulát	100 mg	Granules for oral use	oral use
Slovak Republic	Medicom International s.r.o., Brno, Czech Republik	AULIN 100 mg tablety	100 mg	Tablet	oral use
Slovak Republic	Zentiva a.s. , Praha, Czech Republik	COXTRAL	100 mg	Tablet	oral use
Slovak Republic	CSC Pharmaceuticals Handels GmbH, Wien, Austria	MESULID	100 mg	Tablet	oral use
Slovak Republic	Medicom International s.r.o., Brno, Czech Republik	NIMED	100 mg	Tablet	oral use
Slovak Republic	Laboratori Guidotti S. P. A., Via Livornese 897, La Vettola, 56010 Pisa, Italy	Nimesil	100 mg	Granules for oral suspension	oral use
Slovenia	CSC Pharma d.o.o. JANA HUSA 1a, SI-1000 Ljubljana Slovenia	Aulin	100 mg	Tablet	oral
Slovenia	CSC Pharma d.o.o. JANA HUSA 1a, SI-1000 Ljubljana Slovenia	Aulin	100 mg	Powder for oral suspension	oral
Spain	HELSINN BIREX PHARMACEUTICALS LTD Damastown Mulhuddart, County Dublin, 15 Ireland	GUAXAN 100 mg comprimidos	100 mg	Tablet	oral use

**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	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Austria	GlaxoSmithKline Pharma GmbH, Albert Schweitzer-Gasse 6, A-1140 Wien	Augmentin intravenös 550 mg – Trockenstechampullen	500/50 mg	Powder for solution for injection or infusion	Intravenous use	500 mg: 50 mg/vial
		Augmentin intravenös 1,1 g - Trockensubstanz zur Infusionsbereitung	1 000/100 mg	Powder for solution for infusion	Intravenous use	1 000 mg: 100 mg/vial
		Augmentin intravenös 2,2 g - Trockensubstanz zur Infusions- bereitung	2 000/200 mg	Powder for solution for infusion	Intravenous use	2 000 mg: 200 mg/vial
		Augmentin 625 mg - lösliche Tabletten	500/125 mg	Dispersible tablet	Oral use	
		Augmentin 625 mg – Filmtabletten	500/125 mg	Film-coated Tablet	Oral use	
		Augmentin 1 g – Filmtabletten	875/125 mg	Film-coated Tablet	Oral use	
		Augmentin 457 mg/5 ml – Trockensaft	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
	Sandoz GmbH, Biochemiestr. 10, A - 6250 Kundl	Clavamox intravenös 550 mg – Trockenstechampullen	500/50 mg	Powder for solution for injection or infusion	Intravenous use	500 mg: 50mg/10,5 ml
		Clavamox intravenös 1,1 g - Trockensubstanz zur Infusionsbereitung	1 000/100 mg	Powder for solution for infusion	Intravenous use	1 000 mg: 100 mg/ 100 ml
		Clavamox intravenös 2,2 g - Trockensubstanz zur Infusions- bereitung	2 000/200 mg	Powder for solution for infusion	Intravenous use	2 000 mg: 200 mg/ 100 ml
		Clavamox 625 mg - lösliche Tabletten	500/125 mg	Dispersible tablet	Oral use	
		Clavamox 625 mg – Filmtabletten	500/125 mg	Film-coated Tablet	Oral use	
		Clavamox 1 g – Filmtabletten	875/125 mg	Film-coated Tablet	Oral use	
		Clavamox 156,25 mg/5 ml – Trockensaft	125/31,25 mg/5 ml	Powder for oral suspension	Oral use	125/31,25 mg/5 ml
		Clavamox 312,5 mg/5 ml – Trockensaft	250/62,5 mg/5 ml	Powder for oral suspension	Oral use	250/62,5 mg/5 ml

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
		Clavamox Duo – Trockensaft	400/57 mg/5 ml	Powder for oral suspension	Oral use	400/57 mg/5 ml
Belgium	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 1332 Genval	Augmentin P	500/50 mg	Powder for injection or infusion	Intravenous use	500 mg: 50 mg/10,5 ml or 25 ml
		Augmentin P	1 000/100 mg	Powder for infusion	Intravenous use	1 000 mg:100 mg/50 ml
		Augmentin	1 000/200 mg	Powder for injection	Intravenous use	1 000 mg: 200 mg/20 ml
		Augmentin	2 000/200 mg	Powder for infusion	Intravenous use	2 000 mg: 200 mg/ 100 ml
		Augmentin	500/125 mg	Film-coated tablet	Oral use	
		Augmentin	875/125 mg	Film-coated tablet	Oral use	
		Augmentin	125/31,25 mg/5 ml	Powder for oral suspension	Oral use	125 mg: 31,25 mg/5 ml
		Augmentin	250/62,5 mg/5 ml	Powder for oral suspension	Oral use	250 mg: 62,5 mg/5 ml
		Augmentin	500/125 mg	Powder for oral suspension	Oral use	
		Augmentin Retard	1 000/62,5 mg	Modified release tablet	Oral use	
Bulgaria	GlaxoSmithKline EOOD Ivan Vasov Complex Dimitar Manov street, bl.10, 1408 Sofia, Bulgaria	Augmentin	250/125 mg	Film-coated tablet	Oral use	
		Augmentin	500/125 mg	Film-coated tablet	Oral use	
		Augmentin	875/125 mg	Film-coated tablet	Oral use	
		Augmentin	125/31,25 mg/5 ml	Powder for oral suspension	Oral use	125 mg: 31,25 mg/5 ml
		Augmentin	250/62,5 mg/5 ml	Powder for oral suspension	Oral use	250 mg: 62,5 mg/5 ml
		Augmentin	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
		Augmentin ES	600/42,9 mg/5 ml	Powder for oral suspension	Oral use	600 mg: 42,9 mg/5 ml
		Augmentin SR	1 000/62,5 mg	Prolonged release tablet	Oral use	
Cyprus	SmithKline Beecham plc 980 Great West Road Brentford Middlesex TW8 9GS UK	Augmentin	500/100 mg	Powder for injection or infusion	Intravenous use	500 mg: 100 mg/10,5 ml or 60 ml
		Augmentin	1 000/200 mg	Powder for injection or infusion	Intravenous use	1 000 mg: 200 mg/ 20,9 ml or 120 ml
		Augmentin	500/125 mg	Film-coated tablet	Oral use	
		Augmentin	875/125 mg	Film-coated tablet	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
		Augmentin	250/62,5 mg/5 ml	Powder for oral suspension	Oral use	250 mg: 62,5 mg/5 ml
		Augmentin	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
		Augmentin ES	600/42,9 mg/5 ml	Powder for oral suspension	Oral use	600 mg: 42,9 mg/5 ml
		Augmentin SR	1 000/62,5 mg	Film-coated tablet	Oral use	
	Laboratórios BIAL À Av. da Siderurgia Nacional – 4745-457 S. Mamede do Coronado Portugal	Noprilam	500/125 mg	Film-coated tablet	Oral use	
		Noprilam DT	875/125 mg	Film-coated tablet	Oral use	
		Noprilam	156,23 mg/5 ml	Powder for oral suspension	Oral use	125 mg: 31,23 mg/5 ml
		Noprilam	250/62,5 mg/5 ml	Powder for oral suspension	Oral use	250 mg: 62,5 mg/5 ml
		Noprilam DT	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
Czech Republic	SmithKline Beecham plc trading as SmithKline Beecham Pharmaceuticals 980 Great West Road, Brentford, Middlesex TW8 9GS United Kingdom	Augmentin 600 mg	500/100 mg	Powder for injection or infusion	Intravenous use	500 mg: 100 mg/10,5 ml or 60 ml
		Augmentin 1,2 g	1 000/200 mg	Powder for injection or infusion	Intravenous use	1 000 mg: 200 mg/ 20,9 ml or 120 ml
	SmithKline Beecham plc trading as SmithKline Beecham Pharmaceuticals 980 Great West Road, Brentford, Middlesex TW8 9GS United Kingdom	Augmentin 375 mg	250/125 mg	Film-coated tablet	Oral use	
		Augmentin 625 mg	500/125 mg	Film-coated tablet	Oral use	
		Augmentin 1 g	875/125 mg	Film-coated tablet	Oral use	
		Augmentin 156 mg/5 ml	125/31,25 mg/5 ml	Powder for oral suspension	Oral use	125 mg: 31,25 mg/5 ml
		Augmentin 312 mg/5 ml	250/62,5 mg/5 ml	Powder for oral suspension	Oral use	250 mg: 62,5 mg/5 ml
		Augmentin Duo	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
		Augmentin SR	1 000/62,5 mg	modified-release tablet	Oral use	
Denmark	Meda AS Solvang 8 DK-3450 Allerød Denmark	Spektramox	500/125 mg	Film-coated tablet	Oral use	
		Spektramox	125/31,25 mg/5 ml	Powder for oral suspension	Oral use	125 mg: 31,25 mg/5 ml
		Spektramox	250/62,5 mg/5 ml	Powder for oral suspension	Oral use	250 mg: 62,5 mg/5 ml
		Spektramox 2:1	250/125 mg	Film-coated tablet	Oral use	
		Spektraforte	875/125 mg	Film-coated tablet	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Estonia	SmithKline Beecham plc. 980 Great West Road, Brentford Middlesex TW8 9GS United Kingdom	Augmentin	1 000/200 mg	Powder for injection or infusion	Intravenous use	1 000 mg: 200 mg/ 20,9 ml or 120 ml
		Augmentin	500/125 mg	Film-coated tablet	Oral use	
		Augmentin	875/125 mg	Film-coated tablet	Oral use	
		Augmentin	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
Finland	SmithKline Beecham plc 980 Great West Road Brentford, Middlesex TW8 9GS UK	Augmentin	875/125 mg	Film-coated tablet	Oral use	
		Augmentin (80/11.97 mg/ml)	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
	Orion-yhtymä Oyj, Orionintie 1, 02200 Espoo	Clavurion	875/125 mg	Film-coated tablet	Oral use	
		Clavurion	200/28,5 mg/5 ml	Powder for oral suspension	Oral use	200 mg:28,5 mg/5 ml
		Clavurion	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
France	Laboratoire GlaxoSmithKline 100, route de Versailles – 78163 Marly-le-Roi Cedex	Augmentin IV ENFANTS NOURRISSONS	500/50 mg	Powder for solution for injection AND Powder and solvent for solution for injection	Intravenous use	500 mg: 50 mg
		Augmentin IV ADULTES	500/100 mg	Powder for solution for injection	Intravenous use	500 mg:100 mg
		Augmentin IV ENFANTS	1 000/100 mg	Powder for solution for injection	Intravenous use	1 000 mg: 100 mg
		Augmentin IV ADULTES	1 000/200 mg	Powder for solution for injection AND Powder and solvent for solution for injection	Intravenous use	1 000 mg: 200 mg
		Augmentin IV ADULTES	2 000/200 mg	Powder for solution for injection	Intravenous use	2 000 mg: 200 mg
		Augmentin ADULTES	500/62,5 mg	Film-coated tablet	Oral use	
		Augmentin ENFANTS	100/12,5 mg/ml	Powder for oral suspension	Oral use	100 mg: 12,5 mg/ml
		Augmentin NOURRISSONS	100/12,5 mg/ml	Powder for oral suspension	Oral use	100 mg/12,5 mg/ml
		Augmentin NOURRISSONS	250/31,25 mg	Powder for oral suspension	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
		Augmentin ENFANTS	500/62,5 mg	Powder for oral suspension	Oral use	
		Augmentin ADULTES	1 000/125 mg	Powder for oral suspension	Oral use	
		Duamentin ADULTES	1 000/62,5 mg	Film-coated tablet	Oral use	
Germany	GlaxoSmithKline GmbH & Co. KG Theresienhöhe 11 80339 München	Augmentan i.v. pro infantibus 275 mg	250/25 mg	Powder for solution for infusion	Intravenous use	250 mg: 25 mg
		Augmentan i.v. 600 mg	500/100 mg	Powder for solution for injection or infusion	Intravenous use	500 mg: 100 mg
		Augmentan i.v. 1,2 g	1 000/200 mg	Powder for solution for infusion or infusion	Intravenous use	1 000 mg: 200 mg
		Augmentan i.v. 2,2 g	2 000/200 mg	Powder for solution for infusion	Intravenous use	2 000 mg: 200 mg
		Augmentan Tabs Tabletten	500/125 mg	Dispersible tablet	Oral use	
		Augmentan Filmtabletten 875/ 125 mg	875/125 mg	Film-coated tablet	Oral use	
		Augmentan Tropfen 50 mg/ 12,5 mg pro ml für Säuglinge	50/12,5 mg/ml	Powder for oral suspension	Oral use	50 mg: 12,5 mg/ml
		Augmentan Trockensaft 25 mg/ 6,25 mg pro ml	125/31,25 mg/5 ml	Powder for oral suspension	Oral use	125 mg: 31,25 mg/5 ml
		Augmentan forte Trockensaft 50 mg/12,5 mg pro ml	250/62,5 mg/5 ml	Powder for oral suspension	Oral use	250 mg: 62,5 mg/5 ml
		Augmentan Kindersaft	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
Greece	GlaxoSmithKline a.e.b.e, Leof. Kifissias 266, 152 32 Halandri, Athens	Augmentin	500/100 mg	Powder for injection	Intravenous use	500 mg: 100 mg/10,5 ml
		Augmentin	1 000/200 mg	Powder for injection	Intravenous use	1 000 mg: 200 mg/ 20,9 ml
		Augmentin	500/125 mg	Film-coated tablet	Oral use	
		Augmentin	875/125 mg	Film-coated tablet	Oral use	
		Augmentin	500/125 mg	Dispersible tablet	Oral use	
		Augmentin	125/31,25 mg/5 ml	Powder for oral suspension	Oral use	125 mg: 31,25 mg/5 ml
		Augmentin	250/62,5 mg/5 ml	Powder for oral suspension	Oral use	250 mg: 62,5 mg/5 ml

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
		Augmentin	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
		Augmentin SR	1 000/62,5 mg	Film-coated tablet	Oral use	
		Augmentin ES	600/42,9 mg/5 ml	Powder for oral suspension	Oral use	600 mg: 42,9 mg/5 ml
Hungary	GlaxoSmithKline Kft. 1124 Bp, Csörsz u. 43 Hungary	Augmentin	500/100 mg	Powder for injection	Intravenous use	500 mg: 100 mg/10,5 ml
		Augmentin	1 000/200 mg	Powder for injection	Intravenous use	1 000 mg: 200 mg/ 20,9 ml
		Augmentin	250/125 mg	Film-coated tablet	Oral use	
		Augmentin	500/125 mg	Film-coated tablet	Oral use	
		Augmentin	125/31,25 mg/5 ml	Powder for oral suspension	Oral use	125 mg: 31,25 mg/5 ml
		Augmentin	250/62,5 mg/5 ml	Powder for oral suspension	Oral use	250 mg: 62,5 mg/5 ml
	GlaxoSmithKline Kft. 1124 Bp, Csörsz u. 43.	Augmentin Duo	875/125 mg	Film-coated tablet	Oral use	
		Augmentin Duo	500/125 mg	Film-coated tablet	Oral use	
		Augmentin Duo	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
		Augmentin Extra	600/42,9 mg/5 ml	Powder for oral suspension	Oral use	600 mg: 42,9 mg/5 ml
		Augmentin Extra	1 000/62,5 mg	Film-coated tablet	Oral use	
Iceland	GlaxoSmithKline ehf. Þverholti 14 105 Reykjavík.	Augmentin IV	500/100 mg	Powder for injection	Intravenous use	500 mg: 100 mg/10,5 ml
		Augmentin IV	1 000/200 mg	Powder for injection	Intravenous use	1 000 mg: 200 mg/ 20,9 ml
		Augmentin	500/125 mg	tablet	Oral use	
		Augmentin	875/125 mg	tablet	Oral use	
		Augmentin	250/62,5 mg/5 ml	Powder for oral suspension	Oral use	250 mg: 62,5 mg/5 ml
		Augmentin	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Ireland	GlaxoSmithKline (Ireland) Limited Stonemasons Way, Rathfarnham, Dublin 16	Augmentin Intravenous 500 mg/100 mg Powder for Solution for Injection or Infusion	500/100 mg	Powder for solution for injection or infusion	Intravenous use	500 mg: 100 mg/10,5 ml
		Augmentin Intravenous 1 000 mg/200 mg Powder for Solution for Injection or Infusion	1 000/200 mg	Powder for solution for injection or infusion	Intravenous use	1 000 mg: 200 mg/ 20,9 ml
		Augmentin Tablets 250 mg/ 125 mg	250/125 mg	Film-coated tablet	Oral use	
		Augmentin Dispersible Tablets 250 mg/125 mg	250/125 mg	Dispersible Tablet	Oral use	
		Augmentin Duo Tablets 500/ 125 mg	500/125 mg	Film-coated tablet	Oral use	
		Augmentin 500/125 mg Film- Coated Tablets	500/125 mg	Film-coated tablet	Oral use	
		Augmentin 875 mg/125 mg Film Coated Tablets	875/125 mg	Film-coated tablet	Oral use	
		Augmentin Paediatric Suspension	125/31,25 mg/5 ml	Powder for oral suspension	Oral use	125 mg: 31,25 mg/5 ml
		Augmentin Junior Suspension	125/62,5 mg/5 ml	Powder for oral suspension	Oral use	125 mg: 62,5 mg/5 ml
		Augmentin Duo Suspension 400 mg/57 mg	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
	Clonmel Healthcare Limited Waterford Road Clonmel Tipperary Ireland	Clavamel 250 mg/125 mg Tablets	250/125 mg	Film-coated tablet	Oral use	
		Clavamel 125 mg/31.25 mg Paediatric Powder for Oral Suspension	125/31,25 mg/5 ml	Powder for oral suspension	Oral use	125 mg: 31,25 mg/5 ml
		Clavamel 125 mg/62,5 mg Junior Powder for Oral Suspension	125/62,5 mg/5 ml	Powder for oral suspension	Oral use	125 mg: 62,5 mg/5 ml
Italy	GlaxoSmithKline S.p.A. - Via A. Fleming, 2 – 37135 Verona	Augmentin	1 000/200 mg	Powder for injection	Intravenous use	1 000 mg: 200 mg/20 ml
		Augmentin	2 000/200 mg	Powder for infusion	Intravenous use	2 000 mg: 200 mg
		Augmentin	875/125 mg	Film-coated tablet	Oral use	
		Augmentin	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
		Augmentin	400/57 mg	Powder for oral suspension	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
	Valeas S.p.A. via Vallisneri 10 20133 Milano	Augmentin	875/125 mg	Powder for oral suspension	Oral use	
		Neoduplamox	875/125 mg	Film-coated tablet	Oral use	
		Neoduplamox	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
		Neoduplamox	400/57 mg	Powder for oral suspension	Oral use	
		Neoduplamox	875/125 mg	Powder for oral suspension	Oral use	
	Solvay Pharma S.p.A. Via della Libertà, 30 10095 Grugliasco (TO)	Clavulin	875/125 mg	Film-coated tablet	Oral use	
		Clavulin	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
		Clavulin	400/57 mg	Powder for oral suspension	Oral use	
		Clavulin	875/125 mg	Powder for oral suspension	Oral use	
Latvia	GlaxoSmithKline Latvia SIA Bruninieku 5, Riga, LV-1001, Latvia	Augmentin	1 000/200 mg	Powder for solution for injection	Intravenous use	1 000 mg: 200 mg/20,9 ml
		Augmentin	500/125 mg	Film-coated tablet	Oral use	
		Augmentin	875/125 mg	Film-coated tablet	Oral use	
		Augmentin	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
		Augmentin ES	600/42,9 mg/5 ml	Powder for oral suspension	Oral use	600 mg: 42,9 mg/5 ml
		Augmentin SR	1 000/62,5 mg	Film-coated tablet	Oral use	
Lithuania	Beecham Group plc. 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom	Augmentin	500/125 mg	Film-coated tablet	Oral use	
		Augmentin	875/125 mg	Film-coated tablet	Oral use	
		Augmentin	200/28,5 mg/5 ml	Powder for oral suspension	Oral use	200 mg/28,5 mg/5 ml
		Augmentin	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg/57 mg/5 ml
	UAB „GlaxoSmithKline Lietuva“ A. Goštauto g. 40A LT-01112 Vilnius, Lithuania	Augmentin ES	600/42,9 mg/5 ml	Powder for oral suspension	Oral use	600 mg/42,9 mg/5 ml
Luxembourg	GlaxoSmithKline s.a. / n.v. Rue du Tilleul 13 1332 Genval	Augmentin P	500/50 mg	Powder for injection or infusion	Intravenous use	500 mg/50 mg/10,5 ml or 25 ml
		Augmentin P	1 000/100 mg	Powder for infusion	Intravenous use	1 000 mg/100 mg/50 ml

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
		Augmentin	1 000/200 mg	Powder for injection	Intravenous use	1 000 mg/200 mg/20 ml
		Augmentin	2 000/200 mg	Powder for infusion	Intravenous use	2 000 mg/200 mg/ 100 ml
		Augmentin	500/125 mg	Film-coated tablet	Oral use	
		Augmentin	875/125 mg	Film-coated tablet	Oral use	
		Augmentin	125/31,25 mg/5 ml	Powder for oral suspension	Oral use	125 mg: 31,25 mg/5 ml
		Augmentin	250/62,5 mg/5 ml	Powder for oral suspension	Oral use	250 mg: 62,5 mg/5 ml
		Augmentin	500/125 mg	Powder for oral suspension	Oral use	
		Augmentin Retard,	1 000/62,5 mg	Modified release tablet	Oral use	
Malta	Beecham Group plc 980 Great West Road, Brentford, Middlesex TW8 9GS United Kingdom	Augmentin Intravenous 600 mg	500/100 mg	Powder for solution for injection or infusion	Intravenous use	500 mg: 100 mg/10,5 ml
		Augmentin Intravenous 1,2 g	1 000/200 mg	Powder for solution for injection or infusion	Intravenous use	1 000 mg: 200 mg/ 20,9 ml
	GlaxoSmithKline (Ireland) Limited Stonemasons Way, Rathfarnham Dublin 16 Ireland	Augmentin 250/125 mg	250/125 mg	Film-coated tablet	Oral use	
		Augmentin Duo 500/125 tablets	500/125 mg	Film-coated tablet	Oral use	
		Augmentin 875/125 mg tablets	875/125 mg	Film-coated tablet	Oral use	
	SmithKline Beecham plc 980 Great West Road Brentford Middlesex TW8 9GS	Augmentin Duo 400/57	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
	Laboratórios BIAL Portela & C ^a , S.A. À Av. da Siderurgia Nacional – 4745- 457 S. Mamede do Coronado Portugal	Noprilam	500/125 mg	Coated tablet	Oral use	
		Noprilam DT	875/125 mg	Coated tablet	Oral use	
		Noprilam DT	400/57 mg/5 ml	Powder for oral suspension	Oral use	400/57 mg/5 ml
Netherlands	Glaxo Smith Kline B.V. Huis ter Heideweg 62 3705 LZ ZEIST THE NETHERLANDS	Augmentin	250/25 mg	Powder for injection	Intravenous use	250 mg: 25 mg/5,2 ml
		Augmentin	500/50 mg	Powder for injection	Intravenous use	500 mg: 50 mg/10,5 ml
		Augmentin	500/100 mg	Powder for injection	Intravenous use	500 mg: 100 mg/10,5 ml

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
		Augmentin	1 000/100 mg	Powder for injection	Intravenous use	1 000 mg: 100 mg/ 20,9 ml
		Augmentin	1 000/200 mg	Powder for injection	Intravenous use	1 000 mg: 200 mg/ 20,9 ml
		Augmentin	2 000/200 mg	Powder for infusion	Intravenous use	2 000 mg: 200 mg/ 120 ml
		Augmentin	500/125 mg	Film-coated tablet	Oral use	
		Augmentin	875/125 mg	Film-coated tablet	Oral use	
		Augmentin	100/12,5 mg/ml	Powder for oral suspension	Oral use	100 mg: 12,5 mg/ml
		Augmentin	125/31,25 mg/5 ml	Powder for oral suspension	Oral use	125 mg: 31,25 mg/5 ml
		Augmentin	250/62,5 mg/5 ml	Powder for oral suspension	Oral use	250 mg: 62,5 mg/5 ml
	Glaxo Smith Kline B.V. Huis ter Heideweg 62 3705 LZ ZEIST THE NETHERLANDS	amoxicilline/clavulaanzuur	250/62,5 mg	Powder for oral suspension	Oral use	
Poland	GlaxoSmithKline Export Ltd 980 Great West Road Brentford, Middlesex, TW8 9GS UK	Augmentin	500/100 mg	Powder for injection	Intravenous use	500 mg: 100 mg/10,5 ml
		Augmentin	1 000/200 mg	Powder for injection	Intravenous use	1 000 mg: 200 mg/ 20,9 ml
		Augmentin	2 000/200 mg	Powder for infusion	Intravenous use	2 000 mg: 200 mg/ 120 ml
		Augmentin	250/125 mg	Film-coated tablet	Oral use	
		Augmentin	500/125 mg	Film-coated tablet	Oral use	
		Augmentin	875/125 mg	Film-coated tablet	Oral use	
		Augmentin	125/31,25 mg/5 ml	Powder for oral suspension	Oral use	125 mg:31,25 mg/5 ml
		Augmentin	250/62,5 mg/5 ml	Powder for oral suspension	Oral use	250 mg:62,5 mg/5 ml
		Augmentin	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
		Augmentin ES	600/42,9 mg/5 ml	Powder for oral suspension	Oral use	600 mg: 42,9 mg/5 ml
		Augmentin SR	1 000/62,5 mg	Prolonged release tablet	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Portugal	GlaxoSmithKline – Produtos Farmacêuticos Lda Rua Dr. António Loureiro Borges, 3 Aquiparque – Miraflores 1495 – 131 Algés	Augmentin	500/125 mg	Film-coated tablet	Oral use	
		Augmentin Duo	875/125 mg	Film-coated tablet	Oral use	
		Augmentin	125/31,25 mg/5 ml	Powder for oral suspension	Oral use	125 mg: 31,25 mg/5 ml
		Augmentin Forte	250/62,5 mg/5 ml	Powder for oral suspension	Oral use	250 mg:62,5 mg/5 ml
		Augmentin Duo	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
		Augmentin ES	600/42,9 mg/5 ml	Powder for oral suspension	Oral use	600 mg: 42,9 mg/5 ml
	Bial - Portela & C ^a , S.A À Av. da Siderurgia Nacional – 4745- 457 S. Mamede do Coronado Portugal	Clavamox 125	125/31,25 mg/5 ml	Powder for oral suspension	Oral use	125 mg: 31,25 mg/5 ml
		Clavamox 250	250/62,5 mg/5 ml	Powder for oral suspension	Oral use	250 mg: 62,5 mg/5 ml
		Clavamox 500	500/125 mg	Film-coated tablet	Oral use	
		Clavamox DT	875/125 mg	Film-coated tablet	Oral use	
		Clavamox DT 400	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
		Clavamox ES	600/42,9 mg/5 ml	Powder for oral suspension	Oral use	600 mg: 42,9 mg/5 ml
		Noprilam	500/125 mg	Film-coated tablet	Oral use	
		Noprilam	125/31,25 mg/5 ml	Powder for oral suspension	Oral use	125 mg: 31,25 mg/5 ml
		Noprilam	250/62,5 mg/5 ml	Powder for oral suspension	Oral use	250 mg: 62,5 mg/5 ml
		Noprilam DT	875/125 mg	Film-coated tablet	Oral use	
	Laboratórios Vitória, S.A. Rua Elias Garcia, 28 – Venda Nova 2700-327 Amadora (Sob licença GlaxoSmithKline – Produtos Farmacêuticos, Lda.)	Penilan	500/125 mg	Film-coated tablet	Oral use	
		Penilan	125/31,25 mg/5 ml	Powder for oral suspension	Oral use	125 mg: 31,25 mg/5 ml
		Penilan DT	875/125 mg	Film-coated tablet	Oral use	
		Penilan Forte	250/62,5 mg/5 ml	Powder for oral suspension	Oral use	250 mg: 62,5 mg/5 ml
Romania	Beecham Group PLC 980 Great West Road, Brentford, Middlesex TW8 9GS United Kingdom	Augmentin intravenos 1,2 g	1 000/200 mg	Powder for injection/infusion	Intravenous use	1 000 mg: 200 mg/ 20,9 ml
		Augmentin Intravenos 2,2 g	2 000/200 mg	Powder for infusion	Intravenous use	2 000 mg: 200 mg/ 120 ml
		Augmentin 625 mg	500/125 mg	Film-coated tablet	Oral use	
		Augmentin 1 g	875/125 mg	Film-coated tablet	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
		Augmentin BIS	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
		Augmentin ES	600/42,9 mg/5 ml	Powder for oral suspension	Oral use	600 mg: 42,9 mg/5 ml
		Augmentin SR	1 000/62,5 mg	Prolonged release film-coated tablet	Oral use	
Slovak Republic	GlaxoSmithKline Slovakia sro., Galvaniho7/A, 82104 Bratislava, Slovakia	Augmentin 375 mg	250/125 mg	Film-coated tablet	Oral use	
		Augmentin 625 mg	500/125 mg	Film-coated tablet	Oral use	
		Augmentin 1 g	875/125 mg	Film-coated tablet	Oral use	
		Augmentin DUO	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
		Augmentin ES	600/42,9 mg/5 ml	Powder for oral suspension	Oral use	600 mg: 42,9 mg/5 ml
		Augmentin SR	1 000/62,5 mg	Prolonged-release tablet	Oral use	
Slovenia	GSK d.o.o., Ljubljana Knezov štrdon 90 SI-1000 Ljubljana Slovenija	Augmentin Augmentin 0,6 g prašek za raztopino za injiciranje ali infundiranje	500/100 mg	Powder for injection	Intravenous use	500 mg: 100 mg/10,5 ml
		Augmentin 1,2 g prašek za raztopino za injiciranje ali infundiranje	1 000/200 mg	Powder for injection	Intravenous use	1 000 mg: 200 mg/ 20,9 ml
		Augmentin 625 mg filmsko obložene tablete	500/125 mg	Film-coated tablet	Oral use	
		Augmentin 1 000 mg filmsko obložene tablete	875/125 mg	Film-coated tablet	Oral use	
		Augmentin 457 mg/5 ml prašek za peroralno suspenzijo	400/57 mg/5 ml	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
		Augmentin SR 1 000 mg/62,5 mg filmsko obložene tablete s podaljšanim sproščanjem	1 000/62,5 mg	Film-coated tablet	Oral use	
Spain	GlaxoSmithKline, S.A. P.T.M.- C/Severo Ochoa, 2 28760 Tres Cantos (Madrid).	Augmentine Intravenoso	500/50 mg	Powder for injection	Intravenous use	500 mg: 50 mg/10,5 ml
		Augmentine Intravenoso	1 000/200 mg	Powder for injection	Intravenous use	1 000 mg: 200 mg/ 20,9 ml
		Augmentine Intravenoso	2 000/200 mg	Powder for infusion	Intravenous use	2 000 mg: 200 mg/ 120 ml
		Augmentine	500/125 mg	Film-coated tablet	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
		Augmentine	875/125 mg	Film-coated tablet	Oral use	
		Augmentine	100/12,5 mg/ml	Powder for oral suspension	Oral use	100 mg: 12,5 mg/ml
		Augmentine	500/125 mg	Powder for oral suspension	Oral use	
		Augmentine	875/125 mg	Powder for oral suspension	Oral use	
		Augmentine Plus	1 000/62,5 mg	Film-coated tablet	Oral use	
	Laboratorios Beecham, S.A. P.T.M.- C/Severo Ochoa, 2 28760 Tres Cantos (Madrid).	Pangamox	250/62,5 mg	Powder for oral suspension	Oral use	
		Pangamox	500/125 mg	Powder for oral suspension	Oral use	
		Pangamox	875/125 mg	Powder for oral suspension	Oral use	
	Allen Farmacéutica, S.A.P.T.M.- C/Severo Ochoa, 2 28760 Tres Cantos (Madrid).	Clavepen	500/125 mg	Film-coated tablet	Oral use	
		Clavumox	500/125 mg	Film-coated tablet	Oral use	
		Clavumox	875/125 mg	Film-coated tablet	Oral use	
		Clavumox	125/31,25 mg/5 ml	Oral suspension	Oral use	125 mg: 31,25 mg/5 ml
		Clavumox	250/62,5 mg	Powder for oral suspension	Oral use	
		Clavepen	500/125 mg	Powder for oral suspension	Oral use	
		Clavumox	500/125 mg	Powder for oral suspension	Oral use	
		Clavumox	875/125 mg	Powder for oral suspension	Oral use	
		Amoxicilina/Ác. Clavulanico ALLEN	875/125 mg	Powder for oral suspension	Oral use	
Sweden	Meda AB Box 906 170 09 Sverige (SWE) Sweden	Spektramox	250/125 mg (Amoxicillin: 250 mg)	Film-coated tablet	Oral use	
		Spektramox	500/125 mg (Amoxicillin: 500 mg)	Film-coated tablet	Oral use	
		Spektramox	875/125 mg (Amoxicillin 875 mg)	Film-coated tablet	Oral use	
		Spektramox	125/31,25 mg/5 ml (Amoxicillin 25 mg/ml)	Powder for oral suspension	Oral use	125 mg: 31,25 mg/5 ml
		Spektramox	125/31,25 mg (Amoxicillin: 125 mg)	Powder for oral suspension	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
United Kingdom	Beecham Group PLC SB House Great West Road Brentford Middlesex TW8 9GS United Kingdom	Spektramox	250/62,5 mg/5 ml (Amoxicillin: 50 mg/ml)	Powder for oral suspension	Oral use	250 mg: 62,5 mg/5 ml
		Spektramox	400/57 mg/5 ml (Amoxicillin: 80 mg/ml)	Powder for oral suspension	Oral use	400 mg: 57 mg/5 ml
		Augmentin Intravenous 600 mg & 1,2 gm	500/100 mg	Powder for injection	Intravenous use	500 mg: 100 mg/10,5 ml
		Augmentin Intravenous 600 mg & 1,2 gm	1 000/200 mg	Powder for injection	Intravenous use	1 000 mg: 200 mg/ 20,9 ml
		Augmentin 375 mg Tablets	250/125 mg	Film-coated tablet	Oral use	
		Augmentin 375 mg dispersible tablets	250/125 mg	Dispersible tablets	Oral use	
		Augmentin 1 g Tablets	875/125 mg	Film-coated tablet	Oral use	
		Augmentin 625 mg Tablets	500/125 mg	Film-coated tablet	Oral use	
		Augmentin 250/62 SF Suspension	250/62,5 mg/5 ml	Powder for oral suspension	Oral use	250 mg: 62,5 mg/5 ml
		Augmentin 125/31 SF Sachet	125/31,25 mg	Powder for oral suspension	Oral use	
		Augmentin 125/31 SF Suspension	125/31,25 mg/5 ml	Powder for oral suspension	Oral use	125 mg: 31,25 mg/5 ml
		Augmentin Duo	200/28,5 mg/5 ml	Powder for oral suspension	Oral use	200 mg: 28,5 mg/5 ml

ANNEX XI

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANT AND MARKETING AUTHORISATION HOLDER IN THE MEMBER STATES

Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Denmark	STADA Arzneimittel AG Stadastrasse 2-18 61118 Bad Vilbel, Germany		Fentrans Depotplaster	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Germany		STADA Arzneimittel AG Stadastrasse 2-18, 61118 Bad Vilbel, Germany	Fentanyl-GRY	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		

ANNEX XII

**LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE
OF ADMINISTRATION, APPLICANT AND MARKETING AUTHORISATION HOLDER IN THE MEMBER
STATES**

Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Denmark	STADA Arzneimittel AG Stadastrasse 2-18 61118 Bad Vilbel Germany		Matripain Depotplaster	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Germany		STADA Arzneimittel AG Stadastrasse 2-18 61118 Bad Vilbel Germany	Fentanyl AL	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANTS AND MARKETING AUTHORISATION HOLDER IN THE MEMBER STATES

Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Austria		Teva Pharma B.V. 3640 AE Mijdrecht, Industrieweg 23, P.O. Box 217 The Netherlands	Fentanyl TEVA transdermales Pflaster	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Belgium		TEVA Pharma Belgium N.V B-2610 Wilrijk; Laarstraat 16, Belgium	Fentanyl TEVA Pleister voor transdermaal gebruik	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Czech Republic		Teva Pharmaceuticals CR, s.r.o. Radlická 3185/1C Praha 5 Czech Republic	Fentanyl - TEVA 25 µg/h	25 µg/h	Transdermal patch	Transdermal use
			Fentanyl - TEVA 50 µg/h	50 µg/h		
			Fentanyl - TEVA 75 µg/h	75 µg/h		
			Fentanyl - TEVA 100 µg/h	100 µg/h		
Denmark	STADA Arzneimittel AG Stadastrasse 2-18, 61118 Bad Vilbel Germany		Matrigesic Depotplaster	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Estonia		Teva Pharmaceuticals Europe B.V. 3641 RK Mijdrecht, Industrieweg 23 The Netherlands	Fentanyl - TEVA transdermalpatch	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		

Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Finland		TEVA Sweden AB PO Box 1070; 251 10 Helsingborg, Sweden	Fentanyl TEVA	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
France		Société TEVA CLASSICS Immeuble Le Palatin 1; 1, Cours du Triangle; 92936 Paris La Défense Cedex, France	Fentanyl TEVA dispositif transdermique	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Hungary		TEVA Magyarország Rt. Rákóczi út. 70- 72, H-1074 Budapest Hungary	Fentanyl – Teva tapasz	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Italy		TEVA Pharma Italia S.r.l. Via Giulio Richard, 7 20143 Milan Italy	Fentanil Teva cerotti transdermici	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Latvia		Teva Pharmaceuticals Europe B.V. 3641 RK Mijdrecht, Indrustrieweg 23 The Netherlands	Fentanyl - TEVA transdermālie plāksteri	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Lithuania		Teva Pharmaceuticals Europe B.V. Industrieweg 23, 3641 RK Mijdrecht The Netherlands	Fentanyl - TEVA	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		

Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Luxembourg		TEVA Pharma Belgium N.V B-2610 Wilrijk; Laarstraat 16, Belgium	Fentanyl TEVA Dispositif transdermique	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
The Netherlands		STADA Arzneimittel AG Stadastrasse 2-18 61118 Bad Vilbel Germany	Fentanyl 25 microgram/uur PCH, pleister voor transdermaal gebruik	25 µg/h	Transdermal patch	Transdermal use
			Fentanyl 50 microgram/uur PCH, pleister voor transdermaal gebruik	50 µg/h		
			Fentanyl 75 microgram/uur PCH, pleister voor transdermaal gebruik	75 µg/h		
			Fentanyl 100 microgram/uur PCH, pleister voor transdermaal gebruik	100 µg/h		
Norway		TEVA Sweden AB PO Box 1070; 251 10 Helsingborg Sweden	Fentanyl TEVA	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Poland		TEVA PHARMACEUTICALS Polska Sp. Z.o.o. Emilii Plater 53, 00-113 Warsaw Poland	Fentanyl TEVA system transdermalny	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Portugal		Teva Pharma - Produtos Farma- ceuticos, Lda Lagoas Park, Edifício 1, Piso 3, 2740 - 264 Porto Salvo Portugal	Fentanilo Teva	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		

Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Slovak Republic		Teva Pharmaceuticals CR, s.r.o Dražní 7; 627 00 Brno Czech Republic	Fentanyl – TEVA	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Slovenia		Teva Pharmaceuticals Europe B.V. 3641 RK Mijdrecht, Indrustrieweg 23 The Netherlands	Fentanil TEVA transdermalni obliž	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Spain		TEVA GENERICOS ESPAÑOLA, S.L. Guzman el Bueno; 133. Edif. Britannia 28003 Madrid Spain	Fentanilo TEVA parches transdermicos EFG	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Sweden		TEVA Sweden AB PO Box 1070; 251 10 Helsingborg, Sweden	Matrigesic transdermal patch	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
United Kingdom		TEVA UK Limited Brampton Road; Hampden Park; Eastbourne; East Sussex BN22 9AG United Kingdom	Fentanyl Transdermal Patch	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		

ANNEX XIV

**LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE
OF ADMINISTRATION, APPLICANT AND MARKETING AUTHORISATION HOLDER IN THE MEMBER
STATES**

Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Denmark	STADA Arzneimittel AG Stadastrasse 2-18 61118 Bad Vilbel Germany		Fentador Depotplaster	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Germany		STADA Arzneimittel AG Stadastrasse 2-18, 61118 Bad Vilbel, Germany	Fentador	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANTS AND MARKETING AUTHORISATION HOLDER IN THE MEMBER STATES

Member State	Marketing Authorisation Holder	Applicant/MAH	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Austria		STADA Arzneimittel GmbH Muthgasse 36/2 1190 Wien Austria	Fentanyl STADA Depotpflaster	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Belgium		Eurogenerics N.V., Heizel Esplanade Heysel b22 1020 Brussels Belgium	Fentanyl EG Pleister voor transdermaal gebruik	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Czech Republic		STADA Arzneimittel AG Stadastrasse 2-18 61118 Bad Vilbel Germany	Fentanyl STADA 25 µg/h	25 µg/h	Transdermal patch	Transdermal use
			Fentanyl STADA 50 µg/h	50 µg/h		
			Fentanyl STADA 75 µg/h	75 µg/h		
			Fentanyl STADA 100 µg/h	100 µg/h		
Denmark	STADA Arzneimittel AG Stadastrasse 2-18 61118 Bad Vilbel Germany		Fentastad depotplaster	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Estonia		STADA Arzneimittel AG Stadastrasse 2-18 61118 Bad Vilbel Germany	Fentaderm transdermal patch	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		

Member State	Marketing Authorisation Holder	Applicant/MAH	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Finland		STADA Arzneimittel AG Stadastrasse 2-18, 61118 Bad Vilbel Germany	Fentanyl STADA	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
France		EGLABO Le Quintet-Bat A 12 rue Danjou 92517 Boulogne Billancourt Cedex France	Fentanyl EG LABO, dispositif transdermique	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Hungary		STADA Arzneimittel AG Stadastrasse 2-18 61118 Bad Vilbel Germany	Fentanyl STADA tapasz	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Italy		EG S.p.A. Via D. Scarlatti, 31 20124 Milano Italy	Nilafen cerotti transdermici	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Latvia		STADA Arzneimittel AG Stadastrasse 2-18 61118 Bad Vilbel Germany	Fentastad transdermālie plāksteri	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Lithuania		STADA Arzneimittel AG Stadastrasse 2-18 61118 Bad Vilbel Germany	Fentaderm	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		

Member State	Marketing Authorisation Holder	Applicant/MAH	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Luxembourg		Eurogenerics N.V., Heizel Esplanade Heysel b22, 1020 Brussels Belgium	Fentanyl EG pleister voor transdermal gebruik	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
The Netherlands		STADA Arzneimittel AG Stadastrasse 2-18 61118 Bad Vilbel Germany	Fentanyl CF 25 microgram/uur, pleister voor transdermaal gebruik	25 µg/h	Transdermal patch	Transdermal use
			Fentanyl CF50 microgram/uur, pleister voor transdermaal gebruik	50 µg/h		
			Fentanyl CF 75 microgram/uur, pleister voor transdermaal gebruik	75 µg/h		
			Fentanyl CF 100 microgram/uur, pleister voor transdermaal gebruik	100 µg/h		
Poland		STADA Arzneimittel AG Stadastrasse 2-18 61118 Bad Vilbel Germany	Fentanyl STADA	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Portugal		Ciclum Farma Unipessoal, Lda. Quinta da Fonte, Rua Vitor Câmara, nº 2, Edifício D. Amélia - Piso 1, Ala B, 2770-229 Paço de Arcos Portugal	Fentanilo Ciclum	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Slovak Republic		STADA Arzneimittel AG Stadastrasse 2-18 61118 Bad Vilbel Germany	Fentanyl STADA transdermálna náplast'	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		

Member State	Marketing Authorisation Holder	Applicant/MAH	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Spain		Lab. STADA Frederic Mompou,5 08960 Sant Just Desvern, Barcelona Spain	Fentanilo STADA parches transdermicos EFG	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
Sweden		STADA Arzneimittel AG Stadastrasse 2-18 61118 Bad Vilbel Germany	Fentanyl STADA transdermal patch	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		
United Kingdom		Genus Pharmaceuticals Ltd. (trading as Genus Pharmaceuticals) Benham, Valence, Newbury Berkshire, RG20 8LU United Kingdom	Fentanyl Transdermal Patch	25 µg/h	Transdermal patch	Transdermal use
				50 µg/h		
				75 µg/h		
				100 µg/h		