Official Journal of the European Union

C 32

English edition

Information and Notices

Volume 58

30 January 2015

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EUROPEAN COMMISSION

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 December 2014 to 31 December 2014

(Published pursuant to Article 13 or Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council ([1]))

(2015/C 032/01)

([1]) OJ L 136, 30.4.2004, p. 1.

— **Issuing of a marketing authorisation** (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorisation	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
5.12.2014	Paliperidone Janssen	Paliperidone	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/971	Prolonged release suspension for injection	N05AX13	9.12.2014
8.12.2014	Duloxetine Lilly	Duloxetine	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/14/972	Gastro-resistant capsule, hard	N06AX21	10.12.2014
8.12.2014	Moventig	Naloxegol	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/14/962	Film-coated tablet	A06AH03	10.12.2014
16.12.2014	DUAVIVE	Oestrogens conjugated/bazedoxifene	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/14/960	Modified-release tablet	G03CX	18.12.2014
16.12.2014	Lynparza	Olaparib	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/14/959	Capsule, hard	L01	18.12.2014
19.12.2014	Cyramza	Ramucirumab	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/14/957	Concentrate for solution for infusion	L01XC	23.12.2014
19.12.2014	Rixubis	Nonacog gamma	Baxter Innovations GmbH Industriestraße 67, A-1221 Wien, Österreich	EU/1/14/970	Powder and solvent for solution for injection	B02BD04	23.12.2014
22.12.2014	Scenesse	Afamelanotide	Clinuvel UK Limited c/o — Reed Smith, Broadgate Tower, Third Floor, 20 Primrose Street, London, EC2A 2RS, United Kingdom	EU/1/14/969	Implant	D02BB02	29.12.2014

— **Modification of a marketing authorisation** (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
1.12.2014	Desloratadine Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/11/732	3.12.2014
1.12.2014	Ibandronic Acid Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/10/642	3.12.2014
1.12.2014	Irbesartan Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/09/576	3.12.2014
1.12.2014	Optimark	Mallinckrodt Deutschland GmbH Josef-Dietzgen-Strasse 1, D-53773 Hennef, Deutschland	EU/1/07/398	3.12.2014
4.12.2014	Menveo	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/10/614	9.12.2014
4.12.2014	Ratiograstim	Ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/08/444	8.12.2014
4.12.2014	Tevagrastim	Teva GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/08/445	8.12.2014
5.12.2014	Cystagon	Orphan Europe S.A.R.L. Immeuble Le Wilson, 70 avenue du Général de Gaulle, F-92 800 Puteaux, France	EU/1/97/039	9.12.2014
5.12.2014	Erbitux	Merck KGaA 64271 Darmstadt, Deutschland	EU/1/04/281	9.12.2014
5.12.2014	Vectibix	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/07/423	9.12.2014
11.12.2014	Bronchitol	Pharmaxis Pharmaceuticals Limited The Priory, Stomp Road, Burnham, Buckinghamshire SL1 7LW, United Kingdom	EU/1/12/760	15.12.2014
11.12.2014	Efavirenz Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/742	15.12.2014

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
11.12.2014	Eviplera	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/11/737	15.12.2014
11.12.2014	Levetiracetam Ratiopharm	Ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/11/702	15.12.2014
11.12.2014	Removab	Neovii Biotech GmbH Am Haag 6-7, 82166 Graefelfing, Deutschland	EU/1/09/512	15.12.2014
15.12.2014	Lantus	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/134	18.12.2014
15.12.2014	Lemtrada	Genzyme Therapeutics Ltd 4620 Kingsgate, Cascade Way, Oxford Business Park South, Oxford OX4 2SU, United Kingdom	EU/1/13/869	17.12.2014
15.12.2014	Levetiracetam Actavis Group	Actavis Group PTC ehf. Reykjavíkurvegur 76-78, 220 Hafnarfjörður, Iceland	EU/1/11/738	18.12.2014
15.12.2014	Mircera	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/07/400	18.12.2014
15.12.2014	Naglazyme	BioMarin Europe Ltd 164 Shaftesbury Avenue, London WC2H 8HL, United Kingdom	EU/1/05/324	17.12.2014
15.12.2014	Optisulin	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/133	18.12.2014
15.12.2014	Revestive	NPS Pharma Holdings Limited Grand Canal House, 1 Grand Canal Street Upper, Dublin 4, Ireland	EU/1/12/787	17.12.2014
15.12.2014	Somatropin Biopartners	BioPartners GmbH Kaiserpassage 11, D-72764 Reutlingen, Deutschland	EU/1/13/849	17.12.2014
15.12.2014	Tasigna	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/07/422	18.12.2014
15.12.2014	Xeloda	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/00/163	18.12.2014
16.12.2014	Afinitor	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/538	18.12.2014

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
16.12.2014	Brintellix	H. Lundbeck A/S Ottiliavej 9, DK-2500 Valby, Danmark	EU/1/13/891	18.12.2014
16.12.2014	Cimzia	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/09/544	17.12.2014
16.12.2014	Fasturtec	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/00/170	18.12.2014
16.12.2014	Hizentra	CSL Behring GmbH Emil-von-Behring-Straße 76, D-35041 Marburg, Deutschland	EU/1/11/687	18.12.2014
16.12.2014	HyQvia	Baxter Innovations GmbH Industriestraße 67, A-1221 Wien, Österreich	EU/1/13/840	18.12.2014
16.12.2014	Incivo	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/11/720	18.12.2014
16.12.2014	Lamivudine Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/566	18.12.2014
16.12.2014	Levetiracetam Actavis	Actavis Group PTC ehf. Reykjavíkurvegur 76-78, 220 Hafnarfjörður, Iceland	EU/1/11/713	18.12.2014
16.12.2014	Methylthioninium chloride Proveblue	Provepharm S.A.S. 22 Rue Marc Donadille, 13013 Marseille, France	EU/1/11/682	18.12.2014
16.12.2014	NULOJIX	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/11/694	18.12.2014
16.12.2014	Orphacol	Laboratoires CTRS 63 rue de l'Est, F-92100 Boulogne-Billancourt, France	EU/1/13/870	18.12.2014
16.12.2014	Paglitaz	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/11/721	18.12.2014
16.12.2014	Pioglitazone Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/12/757	18.12.2014
16.12.2014	Pioglitazone Teva Pharma	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/12/758	18.12.2014
16.12.2014	Remsima	Celltrion Healthcare Hungary Kft. Árpád Fejedelem útja 26-28, H-1023 Budapest, Magyarország	EU/1/13/853	18.12.2014

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
16.12.2014	Ristaben	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/621	19.12.2014
16.12.2014	Ristfor	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/620	17.12.2014
16.12.2014	Stivarga	Bayer Pharma AG D-13342 Berlin, Deutschland	EU/1/13/858	18.12.2014
16.12.2014	Ultibro Breezhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/13/862	18.12.2014
16.12.2014	Ulunar Breezhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/14/917	19.12.2014
16.12.2014	Votubia	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/11/710	18.12.2014
16.12.2014	Xoterna Breezhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/13/863	18.12.2014
16.12.2014	Zelboraf	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/12/751	19.12.2014
19.12.2014	CellCept	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/96/005	23.12.2014
19.12.2014	InductOs	Medtronic BioPharma B.V. Earl Bakkenstraat 10, NL-6422 PJ Heerlen, Nederland	EU/1/02/226	23.12.2014
19.12.2014	Puregon	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/96/008	23.12.2014
19.12.2014	Rilutek	Aventis Pharma S.A. 20 avenue Raymond Aron, F-92165 Antony CEDEX, France	EU/1/96/010	23.12.2014
19.12.2014	Stayveer	Marklas Nederland B.V. Beneluxlaan 2b, NL-3446 GR Woerden, Nederland	EU/1/13/832	5.1.2015
19.12.2014	Telmisartan Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/09/610	24.12.2014
19.12.2014	Travatan	Alcon Laboratories (UK) Ltd Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, United Kingdom	EU/1/01/199	23.12.2014
19.12.2014	Victoza	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/09/529	23.12.2014
19.12.2014	Zoledronic acid Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/12/771	24.12.2014
19.12.2014	Zoledronic acid Teva Pharma	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/12/772	24.12.2014

— **Issuing of a marketing authorisation** (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorisation	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
22.12.2014	Bovela	Modified live BVDV-1, non-cytopathic parent strain KE-9, Modified live BVDV-2, non-cytopathic parent strain NY-93	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/2/14/176	Lyophilisate and solvent for suspension for injection	QI02AD02	29.12.2014

— **Modification of a marketing authorisation** (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
4.12.2014	Gripovac 3	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/09/102	8.12.2014
4.12.2014	Porcilis AR-T DF	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/00/026	8.12.2014
4.12.2014	Respiporc Flu3	IDT Biologika GmbH Am Pharmapark, D-06861 Dessau-Rosslau, Deutschland	EU/2/09/103	8.12.2014
11.12.2014	Comfortis	Eli Lilly and Company Ltd, Elanco Animal Health Lilly House Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	EU/2/10/115	15.12.2014
11.12.2014	Trifexis	Eli Lilly and Company Ltd, Elanco Animal Health Lilly House Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	EU/2/13/155	15.12.2014
16.12.2014	Pexion	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/12/147	18.12.2014

Anyone wishing to consult the public assessment report on the medicinal products in question and the decisions relating thereto is invited to contact:

The European Medicines Agency
30, Churchill Place, Canary Wharf
UK — LONDON E14 5EU

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 December 2014 to 31 December 2014

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

(2015/C 032/02)

— Issuing, maintenance or modification of a national marketing authorisation

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorisation	Member State concerned	Date of notification
16.12.2014	Plendil	See Annex I	See Annex I	See Annex I	17.12.2014
11.12.2014	Suanovil 20 Captalin	See Annex II	See Annex II	See Annex II	12.12.2014
22.12.2014	Oxynal-Targin	See Annex III	See Annex III	See Annex III	23.12.2014
5.12.2014	Resflor	See Annex IV	See Annex IV	See Annex IV	9.12.2014
16.12.2014	Polymyxin	See Annex V	See Annex V	See Annex V	17.12.2014
22.12.2014	Docetaxel	Docetaxel and alcohol in their formulation	Not applicable	Not applicable	23.12.2014

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

ANNEX I

List of the names, pharmaceutical form, strength of the medicinal product, route 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	AstraZeneca Österreich GmbH Schwarzenbergplatz 7 1037 Wien Austria	Plendil retard 2,5 mg — Filmtabletten	2,5 mg	Prolonged-release tablet	Oral use
Austria	AstraZeneca Österreich GmbH Schwarzenbergplatz 7 1037 Wien Austria	Plendil retard 5 mg — Filmtabletten	5 mg	Prolonged-release tablet	Oral use
Belgium	NV AstraZeneca SA Rue Egide van Ophemstraat 110, B-1180 Brussel Belgium	Plendil 5 mg Retard	5 mg	Prolonged-release tablet	Oral use
Belgium	NV AstraZeneca SA Rue Egide van Ophemstraat 110, B-1180 Brussel Belgium	Plendil 10 mg Retard	10 mg	Prolonged-release tablet	Oral use
Bulgaria	AstraZeneca AB S-151 85 Södertälje Sweden	Плендил (Plendil)	5 mg	Prolonged-release tablet	Oral use
Croatia	AstraZeneca d.o.o. Radnička cesta 80 10 000 Zagreb Croatia	Plendil 5 mg tablete s produljenim oslobađanjem	5 mg	Prolonged-release tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Croatia	AstraZeneca d.o.o. Radnička cesta 80 10 000 Zagreb Croatia	Plendil 10 mg tablete s produljenim oslobađanjem	10 mg	Prolonged-release tablet	Oral use
Cyprus	AstraZeneca AB S-151 85 Södertälje Sweden	Plendil	2,5 mg	Prolonged-release tablets	Oral use
Cyprus	AstraZeneca AB S-151 85 Södertälje Sweden	Plendil	5 mg	Prolonged-release tablet	Oral use
Cyprus	AstraZeneca AB S-151 85 Södertälje Sweden	Plendil	10 mg	Prolonged-release tablet	Oral use
Czech Republic	AstraZeneca UK Limited 2 Kingdom Street London W2 6BD United Kingdom	PLENDIL ER 5 mg	5 mg	Prolonged-release tablet	Oral use
Czech Republic	AstraZeneca UK Limited 2 Kingdom Street London W2 6BD United Kingdom	PLENDIL ER 10 mg	10 mg	Prolonged-release tablet	Oral use
Denmark	AstraZeneca A/S Arne Jacobsens Allé 13 2300 København S. Denmark	Plendil	2,5 mg	Prolonged-release tablet	Oral use
Denmark	AstraZeneca A/S Arne Jacobsens Allé 13 2300 København S. Denmark	Plendil	5 mg	Prolonged-release tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Denmark	AstraZeneca A/S Arne Jacobsens Allé 13 2300 København S. Denmark	Plendil	10 mg	Prolonged-release tablet	Oral use
Estonia	AstraZeneca AB S-151 85 Södertälje Sweden	Plendil	2,5 mg	Prolonged-release tablet	Oral use
Estonia	AstraZeneca AB S-151 85 Södertälje Sweden	Plendil	5 mg	Prolonged-release tablet	Oral use
Estonia	AstraZeneca AB S-151 85 Södertälje Sweden	Plendil	10 mg	Prolonged-release tablet	Oral use
Finland	AstraZeneca Oy Itsehallintokuja 4 02600 Espoo Finland	Plendil	2,5 mg	Prolonged-release tablet	Oral use
Finland	AstraZeneca Oy Itsehallintokuja 4 02600 Espoo Finland	Plendil	5 mg	Prolonged-release tablet	Oral use
Finland	AstraZeneca Oy Itsehallintokuja 4 02600 Espoo Finland	Plendil	10 mg	Prolonged-release tablet	Oral use
France	AstraZeneca 1 place Renault 92844 Rueil-Malmaison Cedex France	FLODIL	5 mg	Prolonged-release tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Germany	AstraZeneca GmbH 22876 Wedel Germany	Modip 2,5 mg	2,5 mg	Prolonged-release tablet	Oral use
Germany	AstraZeneca GmbH 22876 Wedel Germany	Modip 5 mg	5 mg	Prolonged-release tablet	Oral use
Germany	AstraZeneca GmbH 22876 Wedel Germany	Modip 10 mg	10 mg	Prolonged-release tablet	Oral use
Greece	AstraZeneca S.A. Theotokopoulou & Astronafton str 151 25 Maroussi Greece	Plendil	2,5 mg	Prolonged-release tablet	Oral use
Greece	AstraZeneca S.A. Theotokopoulou & Astronafton str 151 25 Maroussi Greece	Plendil	5 mg	Prolonged-release tablet	Oral use
Greece	AstraZeneca S.A. Theotokopoulou & Astronafton str 151 25 Maroussi Greece	Plendil	10 mg	Prolonged-release tablet	Oral use
Hungary	AstraZeneca Kft. H-1113 Budapest Bocskai út 134-146 Hungary	Plendil 2,5 mg retard filmtabletta	2,5 mg	Prolonged-release tablet	Oral use
Hungary	AstraZeneca Kft. H-1113 Budapest Bocskai út 134-146 Hungary	Plendil 5 mg retard filmtabletta	5 mg	Prolonged-release tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Iceland	AstraZeneca A/S Arne Jacobsens Allé 13 2300 Köbenhavn S. Denmark	Plendil	2,5 mg	Prolonged-release tablet	Oral use
Iceland	AstraZeneca A/S Arne Jacobsens Allé 13 2300 Köbenhavn S. Denmark	Plendil	5 mg	Prolonged-release tablet	Oral use
Iceland	AstraZeneca A/S Arne Jacobsens Allé 13 2300 Köbenhavn S. Denmark	Plendil	10 mg	Prolonged-release tablet	Oral use
Ireland	AstraZeneca UK Ltd. 600 Capability Green Luton LU1 3LU United Kingdom	Plendil 2,5 mg Prolonged-release, Film-coated Tablets	2,5 mg	Prolonged-release tablet	Oral use
Ireland	AstraZeneca UK Ltd. 600 Capability Green Luton LU1 3LU United Kingdom	Plendil 5 mg Prolonged-release, Film-coated Tablets	5 mg	Prolonged-release tablet	Oral use
Ireland	AstraZeneca UK Ltd. 600 Capability Green Luton LU1 3LU United Kingdom	Plendil 10 mg Prolonged-release, Film-coated Tablets	10 mg	Prolonged-release tablet	Oral use
Italy	AstraZeneca S.p.A Palazzo Volta Via F. Sforza 20080 Basiglio (MI) Italy	Plendil 5 mg compresse a rilascio prolungato	5 mg	Prolonged-release tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Italy	AstraZeneca S.p.A Palazzo Volta Via F. Sforza 20080 Basiglio (MI) Italy	Plendil 10 mg compresse a rilascio prolungato	10 mg	Prolonged-release tablet	Oral use
Italy	AstraZeneca S.p.A Palazzo Volta Via F. Sforza 20080 Basiglio (MI) Italy	Feloday 5 mg compresse a rilascio prolungato	5 mg	Prolonged-release tablet	Oral use
Italy	AstraZeneca S.p.A Palazzo Volta Via F. Sforza 20080 Basiglio (MI) Italy	Feloday 10 mg compresse a rilascio prolungato	10 mg	Prolonged-release tablet	Oral use
Italy	SIMESA S.p.A Palazzo Galileo Via F. Sforza 20080 Basiglio (MI) Italy	Prevex 5 mg compresse a rilascio prolungato	5 mg	Prolonged-release tablet	Oral use
Italy	SIMESA S.p.A Palazzo Galileo Via F. Sforza 20080 Basiglio (MI) Italy	Prevex 10 mg compresse a rilascio prolungato	10 mg	Prolonged-release tablet	Oral use
Latvia	AstraZeneca AB S-151 85, Södertälje Sweden	Plendil 5 mg ilgstošās darbības tabletes	5 mg	Prolonged-release tablet	Oral use
Latvia	AstraZeneca AB S-151 85, Södertälje Sweden	Plendil 10 mg ilgstošās darbības tabletes	10 mg	Prolonged-release tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Lithuania	AstraZeneca AB S-151 85, Södertälje Sweden	Plendil	2,5 mg	Prolonged-release tablet	Oral use
Lithuania	AstraZeneca AB S-151 85, Södertälje Sweden	Plendil	5 mg	Prolonged-release tablet	Oral use
Lithuania	AstraZeneca AB S-151 85, Södertälje Sweden	Plendil	10 mg	Prolonged-release tablet	Oral use
Luxembourg	NV AstraZeneca SA Rue Egide van Ophemstraat B-1180 Brussel Belgium	PLENDIL 5 mg Retard	5 mg	Prolonged-release tablet	Oral use
Luxembourg	NV AstraZeneca SA Rue Egide van Ophemstraat B-1180 Brussel Belgium	PLENDIL 10 mg Retard	10 mg	Prolonged-release tablet	Oral use
Malta	Astra Zeneca AB Gartunavagen, S-151 85 Sodertalje, Sweden	Plendil 5 mg Prolonged-release, Film-coated Tablets	5 mg	Prolonged-release tablet	Oral use
Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Plendil 2,5	2,5 mg	Prolonged-release tablet	Oral use
Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Plendil 5	5 mg	Prolonged-release tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Netherlands	AstraZeneca BV Louis Pasteurlaan 5 2719 EE Zoetermeer The Netherlands	Plendil 10	10 mg	Prolonged-release tablet	Oral use
Norway	AstraZeneca AS Postboks 6050, Etterstad 0601 Oslo Norway	Plendil	2,5 mg	Prolonged-release tablet	Oral use
Norway	AstraZeneca AS Postboks 6050, Etterstad 0601 Oslo Norway	Plendil	5 mg	Prolonged-release tablet	Oral use
Norway	AstraZeneca AS Postboks 6050, Etterstad 0601 Oslo Norway	Plendil	10 mg	Prolonged-release tablet	Oral use
Poland	AstraZeneca AB S-151 85 Sodertalje Sweden	Plendil	5 mg	Prolonged-release tablet	Oral use
Poland	AstraZeneca AB S-151 85 Sodertalje Sweden	Plendil	10 mg	Prolonged-release tablet	Oral use
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, 7 Queluz de baixo 2730-097 Barcarena Portugal	Preslow	5 mg	Prolonged-release tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, 7 Queluz de baixo 2730-097 Barcarena Portugal	Preslow	10 mg	Prolonged-release tablet	Oral use
Romania	AstraZeneca AB S-151 85 Sodertalje Sweden	Plendil	2,5 mg	Prolonged-release tablet	Oral use
Romania	AstraZeneca AB S-151 85 Sodertalje Sweden	Plendil	5 mg	Prolonged-release tablet	Oral use
Romania	AstraZeneca AB S-151 85 Sodertalje Sweden	Plendil	10 mg	Prolonged-release tablet	Oral use
Slovak Republic	AstraZeneca AB S-151 85 Sodertalje Sweden	Plendil 2,5 mg	2,5 mg	Prolonged-release tablet	Oral use
Slovak Republic	AstraZeneca AB S-151 85 Sodertalje Sweden	Plendil 5 mg	5 mg	Prolonged-release tablet	Oral use
Slovak Republic	AstraZeneca AB S-151 85 Sodertalje Sweden	Plendil 10 mg	10 mg	Prolonged-release tablet	Oral use
Spain	AstraZeneca Farmacéutica Spain, S.A. C/Serrano Galvache 56 Edificio Roble 28033 Madrid Spain	Plendil 5 mg comprimidos de liberación prolongada	5 mg	Prolonged-release tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Sweden	AstraZeneca AB S-151 85 Sodertalje Sweden	Plendil	2,5 mg	Prolonged-release tablet	Oral use
Sweden	AstraZeneca AB S-151 85 Sodertalje Sweden	Plendil	5 mg	Prolonged-release tablet	Oral use
Sweden	AstraZeneca AB S-151 85 Sodertalje Sweden	Plendil	10 mg	Prolonged-release tablet	Oral use
Sweden	AstraZeneca AB S-151 85 Sodertalje Sweden	Felodipin AstraZeneca	2,5 mg	Prolonged-release tablet	Oral use
Sweden	AstraZeneca AB S-151 85 Sodertalje Sweden	Felodipin AstraZeneca	5 mg	Prolonged-release tablet	Oral use
Sweden	AstraZeneca AB S-151 85 Sodertalje Sweden	Felodipin AstraZeneca	10 mg	Prolonged-release tablet	Oral use
United Kingdom	AstraZeneca UK Ltd. 600 Capability Green Luton LU1 3LU United Kingdom	Plendil	2,5 mg	Prolonged-release tablet	Oral use
United Kingdom	AstraZeneca UK Ltd. 600 Capability Green Luton LU1 3LU United Kingdom	Plendil	5 mg	Prolonged-release tablet	Oral use
United Kingdom	AstraZeneca UK Ltd. 600 Capability Green Luton LU1 3LU United Kingdom	Plendil	10 mg	Prolonged-release tablet	Oral use

ANNEX II

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

Member State EU/ EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Belgium	Merial Belgium SA Culliganlaan 1c 1831 Diegem Belgium	Captalin	Spiramycin	1 000 000 IU/ml	Solution for injection	Cattle
Bulgaria	Ceva Animal Health Bulgaria Ltd 26 Elemag Str., ent.B, app.1 Sofia 1113 Bulgaria	Spirovet 600 000 IU/ml инжекционен разрвор за говеда и свине/Spirovet 600 000 IU/ml solution for injection for cattle and pigs	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs
Czech Republic	Merial 29 avenue Tony Garnier 69007 Lyon France	SUANOVIL 20 injekční roztok	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs
Czech Republic	Ceva Sante Animale Z.I. La Ballastière Libourne France	SPIROVET 600 000 IU/ml solution for injection for cattle and pigs	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs
Estonia	Merial 29 avenue Tony Garnier 69007 Lyon France	Suanovil 20	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs
Estonia	Ceva Sante Animale 10 avenue de la Ballastière 33500 Libourne France	Spirovet	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs

Member State EU/ EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
France	Merial 29 avenue Tony Garnier 69007 Lyon France	Suanovil 20	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs
France	Merial 29 avenue Tony Garnier 69007 Lyon France	Captalin	Spiramycin	1 000 000 IU/ml	Solution for injection	Cattle
France	Ceva Sante Animale 10 avenue de la Ballastière 33500 Libourne France	Spirovet	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs
France	Ceva Sante Animale 10 avenue de la Ballastière 33500 Libourne France	Spiramycine CEVA 600 000 UI/ ML solution injectable pour bovins et porcins	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs
Greece	Merial 29 avenue Tony Garnier 69007 Lyon France	Suanovil 20	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs
Hungary	Merial 29 avenue Tony Garnier 69007 Lyon France	Suanovil 20 % injekció	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs
Hungary	Ceva-Phylaxia Zrt. Szállás u. 5 1107 Budapest Hungary	Spirovet 600 000 NE/ml, injekció szarvasmarha és sertés részére	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs

Member State EU/ EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Ireland	Ceva Sante Animale 10 avenue de la Ballastière 33500 Libourne France	SPIROVET 600 000 IU/ml solution for injection for cattle and pigs	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs
Italy	Merial Italia S.p.A. Via Vittor Pisani 16 20124 Milano Italy	Captalin	Spiramycin	1 000 000 IU/ml	Solution for injection	Cattle
Italy	Merial Italia S.p.A. Via Vittor Pisani 16 20124 Milano Italy	Spiramin	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs
Italy	Ceva Salute Animale S.p.A. Viale Colleoni, 15 20864 Agrate Brianza (MB) Italy	Spiravet 20	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs
Latvia	Merial 29 avenue Tony Garnier 69007 Lyon France	Suanovil 20	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs
Lithuania	Ceva Sante Animale Z.I. La Ballastière 33500 Libourne France	SPIROVET 600 000 TV/ml, injekcinis tirpalas galvijams ir kiaulėms	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs

Member State EU/ EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Portugal	Merial Portuguesa — Saúde Animal, LDA Av. Maria Lamas, lote 19 — BL. A Piso 2 Parque Industrial e Comercial Serra das Minas 2635-432 Rio de Mouro Portugal	Suanovil 20	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs
Portugal	Ceva Saúde Animal — Produtos Farmacêuticos e Imunológicos, Lda. Rua Doutor António Loureiro Borges, 9/9A, 9°A Miraflores 1495-131 Algés Portugal	SPIROVET 600 000 UI/ml solução injetável para bovinos e suínos	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs
Romania	Ceva Sante Animale Z.I. de la Ballastière, BP 126 33500 Libourne Cedex FRANCE	Spirovet	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs
Romania	Merial Rue de Bourgelat 17 69002 Lyon France	Suanovil 20	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs
Slovakia	Merial 29 avenue Tony Garnier 69007 Lyon France	Suanovil 20 injekčný roztok	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs
Slovenia	Ceva Sante Animale 10 avenue de la Ballastière 33500 Libourne France	SPIROVET 600 000 IU/ml raztopina za injiciranje za govedo in prašiče	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs

Member State EU/ EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Spain	Merial Laboratorios S.A. Tarragona, N° 161 — Locales D/E 08820 Barcelona Spain	Suanovil 20	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs
United Kingdom	Ceva Animal Health Ltd Unit 3 Anglo Office Park White Lion Road Amersham Buckinghamshire HP7 9FB United Kingdom	Spirovet	Spiramycin	600 000 IU/ml	Solution for injection	Cattle Pigs

ANNEX III

List of the names, pharmaceutical form(s), strength(s) of the medicinal product(s), route(s) of administration, marketing authorisation holder(s) in the Member States

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Austria	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	10 mg/5 mg	prolonged-release tablets	oral
Austria	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	20 mg/10 mg	prolonged-release tablets	oral
Austria	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	5 mg/2,5 mg	prolonged-release tablets	oral
Austria	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	40 mg/20 mg	prolonged-release tablets	oral
Belgium	Mundipharma Comm. VA Blarenberglaan 3C, Mechelen 2800 Belgium	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	10 mg/5 mg	prolonged-release tablets	oral

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Belgium	Mundipharma Comm. VA Blarenberglaan 3C, Mechelen 2800 Belgium	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	20 mg/10 mg	prolonged-release tablets	oral
Belgium	Mundipharma Comm. VA Blarenberglaan 3C, Mechelen 2800 Belgium	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	5 mg/2,5 mg	prolonged-release tablets	oral
Belgium	Mundipharma Comm. VA Blarenberglaan 3C, Mechelen 2800 Belgium	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	40 mg/20 mg	prolonged-release tablets	oral
Bulgaria	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	5 mg/2,5 mg	prolonged-release tablets	oral
Bulgaria	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	10 mg/5 mg	prolonged-release tablets	oral
Bulgaria	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	20 mg/10 mg	prolonged-release tablets	oral
Bulgaria	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	40 mg/20 mg	prolonged-release tablets	oral

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Cyprus	Mundipharma Pharmaceuticals Ltd. 13, Othellos Street, Dhali Industrial Zone, Nicosia Cyprus	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	5 mg/2,5 mg	prolonged-release tablets	oral
Cyprus	Mundipharma Pharmaceuticals Ltd. 13, Othellos Street, Dhali Industrial Zone, Nicosia Cyprus	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	10 mg/5 mg	prolonged-release tablets	oral
Cyprus	Mundipharma Pharmaceuticals Ltd. 13, Othellos Street, Dhali Industrial Zone, Nicosia Cyprus	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	20 mg/10 mg	prolonged-release tablets	oral
Cyprus	Mundipharma Pharmaceuticals Ltd. 13, Othellos Street, Dhali Industrial Zone, Nicosia Cyprus	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	40 mg/20 mg	prolonged-release tablets	oral
Czech Republic	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate (Naloxone hydrochloride)	Targin 5 mg/2,5 mg tablety s prodlouženým uvolňováním	5 mg/2,5 mg	prolonged-release tablets	oral
Czech Republic	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate (Naloxone hydrochloride)	Targin 10 mg/5 mg tablety s prodlouženým uvolňováním	10 mg/5 mg	prolonged-release tablets	oral

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Czech Republic	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate (Naloxone hydrochloride)	Targin 20 mg/10 mg tablety s prodlouženým uvolňováním	20 mg/10 mg	prolonged-release tablets	oral
Czech Republic	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate (Naloxone hydrochloride)	Targin 40 mg/20 mg tablety s prodlouženým uvolňováním	40 mg/20 mg	prolonged-release tablets	oral
Denmark	Norpharma A/S Slotsmarken 15, Horsholm 2970 Denmark	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	10 mg/5 mg	prolonged-release tablets	oral
Denmark	Norpharma A/S Slotsmarken 15, Horsholm 2970 Denmark	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	20 mg/10 mg	prolonged-release tablets	oral
Denmark	Norpharma A/S Slotsmarken 15, Horsholm 2970 Denmark	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	5 mg/2,5 mg	prolonged-release tablets	oral
Denmark	Norpharma A/S Slotsmarken 15, Horsholm 2970 Denmark	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	40 mg/20 mg	prolonged-release tablets	oral
Estonia	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	5 mg/2,5 mg	prolonged-release tablets	oral

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Estonia	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	10 mg/5 mg	prolonged-release tablets	oral
Estonia	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	20 mg/10 mg	prolonged-release tablets	oral
Estonia	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	40 mg/20 mg	prolonged-release tablets	oral
Finland	Mundipharma Oy Rajatorpantie 41 B 01640 Vantaa Finland	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targiniq	10 mg/5 mg	prolonged-release tablets	oral
Finland	Mundipharma Oy Rajatorpantie 41 B 01640 Vantaa Finland	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targiniq	20 mg/10 mg	prolonged-release tablets	oral
Finland	Mundipharma Oy Rajatorpantie 41 B 01640 Vantaa Finland	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targiniq	5 mg/2,5 mg	prolonged-release tablets	oral
Finland	Mundipharma Oy Rajatorpantie 41 B 01640 Vantaa Finland	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targiniq	40 mg/20 mg	prolonged-release tablets	oral

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
France	Mundipharma SAS 100, avenue de Suffren, Paris 75015 France	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	5 mg/2,5 mg	prolonged-release tablets	oral
France	Mundipharma SAS 100, avenue de Suffren Paris 75015 France	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	10 mg/5 mg	prolonged-release tablets	oral
France	Mundipharma SAS 100, avenue de Suffren Paris 75015 France	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	20 mg/10 mg	prolonged-release tablets	oral
France	Mundipharma SAS 100, avenue de Suffren Paris 75015 France	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	40 mg/20 mg	prolonged-release tablets	oral
Germany	Mundipharma GmbH Mundipharma Str. 2 Limburg 65549 Germany	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Oxynal	10 mg/5 mg	prolonged-release tablets	oral
Germany	Mundipharma GmbH Mundipharma Str. 2, Limburg 65549 Germany	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Oxynal	20 mg/10 mg	prolonged-release tablets	oral
Germany	Mundipharma GmbH Mundipharma Str. 2, Limburg 65549 Germany	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	5 mg/2,5 mg	prolonged-release tablets	oral

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Germany	Mundipharma GmbH Mundipharma Str. 2 Limburg 65549 Germany	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	10 mg/5 mg	prolonged-release tablets	oral
Germany	Mundipharma GmbH Mundipharma Str. 2 Limburg 65549 Germany	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	20 mg/10 mg	prolonged-release tablets	oral
Germany	Mundipharma GmbH Mundipharma Str. 2 Limburg 65549 Germany	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	40 mg/20 mg	prolonged-release tablets	oral
Hungary	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	5 mg/2,5 mg	prolonged-release tablets	oral
Hungary	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	10 mg/5 mg	prolonged-release tablets	oral
Hungary	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	20 mg/10 mg	prolonged-release tablets	oral
Hungary	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	40 mg/20 mg	prolonged-release tablets	oral

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Iceland	Norpharma A/S Slotsmarken 15, Horsholm 2970 Denmark	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	10 mg/5 mg	prolonged-release tablets	oral
Iceland	Norpharma A/S Slotsmarken 15, Horsholm 2970 Denmark	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	20 mg/10 mg	prolonged-release tablets	oral
Iceland	Norpharma A/S Slotsmarken 15, Horsholm 2970 Denmark	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	5 mg/2,5 mg	prolonged-release tablets	oral
Iceland	Norpharma A/S Slotsmarken 15, Horsholm 2970 Denmark	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	40 mg/20 mg	prolonged-release tablets	oral
Ireland	Mundipharma Pharmaceuticals Ltd. Millbank House, Arkle Road Sandyford, Dublin 18 Ireland	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	10 mg/5 mg	prolonged-release tablets	oral
Ireland	Mundipharma Pharmaceuticals Ltd. Millbank House, Arkle Road Sandyford, Dublin 18 Ireland	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	20 mg/10 mg	prolonged-release tablets	oral
Ireland	Mundipharma Pharmaceuticals Ltd. Millbank House, Arkle Road Sandyford, Dublin 18 Ireland	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	5 mg/2,5 mg	prolonged-release tablets	oral

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Ireland	Mundipharma Pharmaceuticals Ltd. Millbank House, Arkle Road Sandyford, Dublin 18 Ireland	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	40 mg/20 mg	prolonged-release tablets	oral
Italy	Mundipharma Pharmaceuticals Srl Via G. Serbelloni 4, Milano 20122 Italy	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	5 mg/2,5 mg	prolonged-release tablets	oral
Italy	Mundipharma Pharmaceuticals Srl Via G. Serbelloni 4, Milano 20122 Italy	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	10 mg/5 mg	prolonged-release tablets	oral
Italy	Mundipharma Pharmaceuticals Srl Via G. Serbelloni 4, Milano 20122 Italy	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	20 mg/10 mg	prolonged-release tablets	oral
Italy	Mundipharma Pharmaceuticals Srl Via G. Serbelloni 4, Milano 20122 Italy	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	40 mg/20 mg	prolonged-release tablets	oral
Latvia	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride	Targin	5 mg/2,5 mg	prolonged-release tablets	oral

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Latvia	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride	Targin	10 mg/5 mg	prolonged-release tablets	oral
Latvia	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride	Targin	20 mg/10 mg	prolonged-release tablets	oral
Latvia	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride	Targin	40 mg/20 mg	prolonged-release tablets	oral
Luxembourg	Mundipharma Comm. VA Blarenberglaan 3C, Mechelen 2800 Belgium	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	10 mg/5 mg	prolonged-release tablets	oral
Luxembourg	Mundipharma Comm. VA Blarenberglaan 3C Mechelen 2800 Belgium	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	20 mg/10 mg	prolonged-release tablets	oral
Luxembourg	Mundipharma Comm. VA Blarenberglaan 3C Mechelen 2800 Belgium	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	5 mg/2,5 mg	prolonged-release tablets	oral
Luxembourg	Mundipharma Comm. VA Blarenberglaan 3C Mechelen 2800 Belgium	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	40 mg/20 mg	prolonged-release tablets	oral

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Norway	Mundipharma AS Dicks vei 10B, 1366 Lysaker Norway	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targiniq	10 mg/5 mg	prolonged-release tablets	oral
Norway	Mundipharma AS Dicks vei 10B, 1366 Lysaker Norway	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targiniq	20 mg/10 mg	prolonged-release tablets	oral
Norway	Mundipharma AS Dicks vei 10B, 1366 Lysaker Norway	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targiniq	5 mg/2,5 mg	prolonged-release tablets	oral
Norway	Mundipharma AS Dicks vei 10B, 1366 Lysaker Norway	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targiniq	40 mg/20 mg	prolonged-release tablets	oral
Poland	Norpharma A/S Slotsmarken 15, Horsholm 2970 Denmark	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	5 mg/2,5 mg	prolonged-release tablets	oral
Poland	Norpharma A/S Slotsmarken 15, Horsholm 2970 Denmark	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	10 mg/5 mg	prolonged-release tablets	oral
Poland	Norpharma A/S Slotsmarken 15, Horsholm 2970 Denmark	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	20 mg/10 mg	prolonged-release tablets	oral

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Poland	Norpharma A/S Slotsmarken 15, Horsholm 2970 Denmark	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	40 mg/20 mg	prolonged-release tablets	oral
Portugal	Mundipharma Farmaceutica Lda Rua Duque de Palmela, no 23, Lisboa 1250-097 Portugal	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	5 mg/2,5 mg	prolonged-release tablets	oral
Portugal	Mundipharma Farmaceutica Lda Rua Duque de Palmela, no 23, Lisboa 1250-097 Portugal	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	10 mg/5 mg	prolonged-release tablets	oral
Portugal	Mundipharma Farmaceutica Lda Rua Duque de Palmela, no 23, Lisboa 1250-097 Portugal	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	20 mg/10 mg	prolonged-release tablets	oral
Portugal	Mundipharma Farmaceutica Lda Rua Duque de Palmela, no 23, Lisboa 1250-097 Portugal	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	40 mg/20 mg	prolonged-release tablets	oral
Romania	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	5 mg/2,5 mg	prolonged-release tablets	oral

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Romania	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	10 mg/5 mg	prolonged-release tablets	oral
Romania	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	20 mg/10 mg	prolonged-release tablets	oral
Romania	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	40 mg/20 mg	prolonged-release tablets	oral
Slovak Republic	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	5 mg/2,5 mg	prolonged-release tablets	oral
Slovak Republic	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	10 mg/5 mg	prolonged-release tablets	oral
Slovak Republic	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	20 mg/10 mg	prolonged-release tablets	oral

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Slovak Republic	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	40 mg/20 mg	prolonged-release tablets	oral
Slovenia	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	5 mg/2,5 mg	prolonged-release tablets	oral
Slovenia	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	10 mg/5 mg	prolonged-release tablets	oral
Slovenia	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	20 mg/10 mg	prolonged-release tablets	oral
Slovenia	Mundipharma Gesellschaft m.b.H Apollogasse 16-18, Wien 1070 Austria	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	40 mg/20 mg	prolonged-release tablets	oral
Spain	Mundipharma Pharmaceuticals, S.L. C/Bahía de Pollensa, 11 Madrid 28042 Spain	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	5 mg/2,5 mg	prolonged-release tablets	oral

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Spain	Mundipharma Pharmaceuticals, S.L. C/Bahía de Pollensa, 11 Madrid 28042 Spain	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	10 mg/5 mg	prolonged-release tablets	oral
Spain	Mundipharma Pharmaceuticals, S.L. C/Bahía de Pollensa, 11, Madrid 28042 Spain	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	20 mg/10 mg	prolonged-release tablets	oral
Spain	Mundipharma Pharmaceuticals, S.L. C/Bahía de Pollensa, 11 Madrid 28042 Spain	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targin	40 mg/20 mg	prolonged-release tablets	oral
Sweden	Mundipharma AB Mölndalsvägen 30B Göteborg 412 63 Sweden	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targiniq	10 mg/5 mg	prolonged-release tablets	oral
Sweden	Mundipharma AB Mölndalsvägen 30B Göteborg 412 63 Sweden	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targiniq	20 mg/10 mg	prolonged-release tablets	oral
Sweden	Mundipharma AB Mölndalsvägen 30B Göteborg 412 63 Sweden	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targiniq	5 mg/2,5 mg	prolonged-release tablets	oral

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Sweden	Mundipharma AB Mölndalsvägen 30B Göteborg 412 63 Sweden	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targiniq	40 mg/20 mg	prolonged-release tablets	oral
The Netherlands	Mundipharma Pharmaceuticals B.V. De Wel 20, MV Hoevelaken 3871 The Netherlands	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	10 mg/5 mg	prolonged-release tablets	oral
The Netherlands	Mundipharma Pharmaceuticals B.V. De Wel 20, MV Hoevelaken 3871 The Netherlands	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	20 mg/10 mg	prolonged-release tablets	oral
The Netherlands	Mundipharma Pharmaceuticals B.V. De Wel 20, MV Hoevelaken 3871 The Netherlands	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	5 mg/2,5 mg	prolonged-release tablets	oral
The Netherlands	Mundipharma Pharmaceuticals B.V. De Wel 20, MV Hoevelaken 3871 The Netherlands	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	40 mg/20 mg	prolonged-release tablets	oral
United Kingdom	Napp Pharmaceuticals Ltd. Cambridge Science Park Milton Road CB4 0GW United Kingdom	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	10 mg/5 mg	prolonged-release tablets	oral

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
United Kingdom	Napp Pharmaceuticals Ltd. Cambridge Science Park Milton Road CB4 0GW United Kingdom	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	20 mg/10 mg	prolonged-release tablets	oral
United Kingdom	Napp Pharmaceuticals Ltd. Cambridge Science Park Milton Road CB4 0GW United Kingdom	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	5 mg/2,5 mg	prolonged-release tablets	oral
United Kingdom	Napp Pharmaceuticals Ltd. Cambridge Science Park Milton Road CB4 0GW United Kingdom	Oxycodone hydrochloride/Naloxone hydrochloride dihydrate	Targinact	40 mg/20 mg	prolonged-release tablets	oral

ANNEX IV

List of the name, pharmaceutical form, strength of the veterinary medicinal product, animal species, route of administration, marketing authorisation holder in the Member States

Member State EU/ EEA	Marketing authorisation holder	Name	INN	Pharmaceutical form	Strength	Animal species	Route of administration
Austria	Intervet GesmbH Siemensstrasse 107 1210 Wien Austria	RESFLOR 300/16,5 mg/mL Lösung zur Injektion für Rinder	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
Belgium	Intervet International B.V. Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Resflor 300, 16,5 mg/mL solution injectable pour bovines	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
Bulgaria	Intervet International B.V. Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	РЕСФЛОР 300/16,5 мг/мл Разтвор за инжективно приложение при едри преживни животни	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
Cyprus	Schering-Plough S.A. 63, Agiou Dimitriou street 17456 Alimos Greece	RESFLOR 300/16,5 mg/mL Ενέσιμο Διάλυμα για βοοειδή	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
Czech Republic	Intervet International B.V. Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Resflor injekční roztok pro skot	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
Denmark	Intervet International B.V. Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Resflor vet. injection, solution for Injection for Cattle	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous

Member State EU/ EEA	Marketing authorisation holder	Name	INN	Pharmaceutical form	Strength	Animal species	Route of administration
Estonia	Intervet International B.V. Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Resflor vet. injection, solution for Injection for Cattle	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
Finland	Intervet International B.V. Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Resflor vet. injection, solution for Injection for Cattle	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
France	Intervet MSD Santé Animale 7 Rue Olivier de Serres Angers Technopole CS 17144 49071 Beaucouzé France	RESFLOR SOLUTION INJECTABLE	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
Germany	Intervet Deutschland GmbH Feldstraße 1a D-85716 Unterschleißheim Germany	RESFLOR 300/16,5 mg/mL Lösung zur Injektion für Rinder	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
Greece	Intervet Hellas S.A. 63, Agiou Dimitriou street 17456 Alimos Greece	RESFLOR 300/16,5 mg/mL Ενέσιμο Διάλυμα για βοοειδή	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
Hungary	Intervet International B.V. Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	RESFLOR INJEKCIÓS OLDAT	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous

Member State EU/ EEA	Marketing authorisation holder	Name	INN	Pharmaceutical form	Strength	Animal species	Route of administration
Ireland	Intervet Ireland Ltd. Magna Drive Magna Business Park Citywest Rd. Dublin 24 Ireland	RESFLOR 300/16,5 mg/mL Solution for Injection for Cattle	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
Italy	Intervet MSD Santé Animale 7 Rue Olivier de Serres Angers Technopole CS 17144 49071 Beaucouzé France	RESFLOR 300/16,5 mg/mL SOLUZIONE INIETTABILE per bovini	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
Latvia	Intervet International B.V. Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Resflor vet. injection, solution for Injection for Cattle	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
Lithuania	Intervet International B.V. Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Resflor vet. injection, solution for Injection for Cattle	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
Luxembourg	Intervet International B.V. Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Resflor 300, 16,5 mg/mL solution injectable pour bovines	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
The Netherlands	Intervet Nederland B.V. Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Resflor 300, 16,5 mg/mL oplossing voor injectie voor runderen	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous

Member State EU/ EEA	Marketing authorisation holder	Name	INN	Pharmaceutical form	Strength	Animal species	Route of administration
Norway	Intervet International B.V. Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Resflor vet. injection, solution for Injection for Cattle	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
Poland	Intervet International B.V. Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Resflor 300/16,5 mg/mL roztwór do wstrzykiwań dla bydła	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
Portugal	MSD Animal Health, Lda. Quinta da Fonte Edifício Vasco da Gama 19 2770-192 Paço de Arcos Portugal	RESFLOR 300/16,5 mg/mL Solução Injectável para Bovinos	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
Romania	Intervet Romania s.r.l. Soseua de Centura no. 13A Comuna Chiajna Judet Ilfov Romania	RESFLOR 300/16,5 mg/mL solutie injectabila pentru bovine	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
Slovakia	Intervet International B.V. Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Resflor injekčný roztok pre hovädzí dobytok	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
Slovenia	Intervet International B.V. Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Resflor 300/16,5 mg/mL raztopina za injiciranje za govedo	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous

Member State EU/ EEA	Marketing authorisation holder	Name	INN	Pharmaceutical form	Strength	Animal species	Route of administration
Spain	Merck Sharp & Dohme Animal Health S.L. Polígono Industrial El Montalvo I c/Zeppelín nº 6, parcela 38 37008 Carbajosa de la Sagrada — Salamanca Spain	RESFLOR SOLUCIÓN INYECTABLE	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous
United Kingdom	Intervet UK Ltd. Walton Manor, Walton Milton Keynes MK7 7AJ United Kingdom	RESFLOR 300/16,5 mg/mL Solution for Injection for Cattle	Florfenicol, flunixin	Solution for injection	300 mg/ml 16,5 mg/ml	Cattle	Subcutaneous

ANNEX V

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration and marketing authorisation holders in the Member States

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Austria	Forest Pharma B.V. Newtonlaan 115 3584 BH Utrecht The Netherlands	Colistin Forest — Trockenstechampullen mit Lösungsmittel	1 000 000 I.U.	powder and solvent for suspension for injection, nebuliser solution	intramuscular use, intravenous use, inhalation use
Austria	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Tadim 1 Million I.E. Pulver zur Herstellung einer Infusionslösung	1 000 000 I.U.	powder for solution for infusion	intravenous use
Austria	Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S Denmark	Colistin Xellia 1 Million I.E. Pulver zur Herstellung einer Injektions-/Infusionslösung	1 000 000 I.U.	powder for solution for injection/infusion	intravenous use
Austria	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Tadim 1 Million I.E. Pulver zur Herstellung einer Lösung für einen Vernebler	1 000 000 I.U.	powder for nebuliser solution	inhalation use
Austria	PARI Pharma GmbH Moosstrasse 3 82319 Starnberg Germany	ColiFin 1 Mio. I.E. Pulver zur Herstellung einer Lösung für einen Vernebler	1 000 000 I.U.	powder for nebuliser solution	inhalation use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Austria	PARI Pharma GmbH Moosstrasse 3 82319 Starnberg Germany	ColiFin 2 Mio. I.E. Pulver zur Herstellung einer Lösung für einen Vernebler	2 000 000 I.U.	powder for nebuliser solution	inhalation use
Belgium	Forest Laboratories UK Ltd. Riverbridge House Anchor Boulevard Crossways Business Park Dartford Kent DA2 6SL United Kingdom	Colistineb 1 000 000 IE	1 000 000 I.U.	powder for solution for injection/infusion	intravenous use, inhalation use
Belgium	Forest Laboratories UK Ltd. Riverbridge House Anchor Boulevard Crossways Business Park Dartford Kent DA2 6SL United Kingdom	Colistineb 2 000 000 IE	2 000 000 I.U.	powder for solution for injection/infusion	intravenous use, inhalation use
Bulgaria	Alvogen IPCo.S.ar. I. 5 Rue Heienhaff Senningerberg L-1736 Luxembourg	Colistin Alvogen	1 000 000 I.U.	powder for solution for injection/infusion	intravenous use
Bulgaria	Alvogen IPCo.S.ar. I. 5 Rue Heienhaff Senningerberg L-1736 Luxembourg	Colistin Alvogen	2 000 000 I.U.	powder for solution for injection/infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Croatia	Altamedics d.o.o. Karlovačka cesta 24a, Zagreb 10020 Croatia	Colixin 1 milijun IU prašak za otopinu za injekciju	1 000 000 I.U.	powder for solution for injection	intravenous use
Czech Republic	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford Kent DA2 6SL United Kingdom	Colomycin injekce 1 000 000 IU	1 000 000 I.U.	powder for solution for injection/infusion or nebuliser solution	intravenous use, inhalation use
Denmark	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin	1 000 000 I.U.	nebuliser solution	inhalation use
Denmark	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin	10 000 000I.U.	powder for solution for infusion	intravenous use
Denmark	Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S Denmark	Colistimethatnatrium 'Xellia'	1 000 000 I.U.	powder for solution for injection/infusion	intravenous use
France	Sanofi-Aventis France 1-13 boulevard R. Rolland 75014 Paris France	COLIMYCINE 1 MUI, poudre et solvant pour inhalation par nébuliseur	1 000 000 I.U.	powder and solvent for nebuliser solution	inhalation use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
France	Sanofi-Aventis France 1-13 boulevard R. Rolland 75014 Paris France	COLIMYCINE 1 000 000 U.I., poudre et solvant pour solution injectable	1 000 000 I.U.	powder and solvent for solution for injection	intravenous use
France	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	TADIM 1 million d'unités internationales (UI) poudre pour solution pour inhalation par nébuliseur	1 000 000 I.U.	powder for nebuliser solution	inhalation use
Germany	Forest Laboratories Nederland B.V. Newtonlaan 115 3584 BH Utrecht The Netherlands	Colistin CF	1 000 000 I.U.	powder and solvent for nebuliser solution	inhalation use
Germany	InfectoPharm Arzneimittel und Consilium GmbH Von-Humboldt-Straße 1 64646 Heppenheim Germany	Colistimethat-Natrium Infectopharm I.E. Pulver zur Herstellung einer Injektions- oder Infusionslösung	1 000 000 I.U.	powder for solution for injection/infusion	intravenous use
Germany	InfectoPharm Arzneimittel und Consilium GmbH Von-Humboldt-Straße 1 64646 Heppenheim Germany	Colistimethat-Natrium Infectopharm I.E. Pulver zur Herstellung einer Injektions- oder Infusionslösung	1 000 000 I.U.	powder for solution for injection/infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	Profile Pharma Limited Bicentennial Building Southern Gate Chichester PO19 8EZ United Kingdom	Promixin 1 MI.E. Pulver zur Herstellung einer Lösung für einen Vernebler	1 000 000 I.U.	powder for nebuliser solution	inhalation use
Germany	Profile Pharma Limited Bicentennial Building Southern Gate Chichester PO19 8EZ United Kingdom	Promixin 1 MI.E. Pulver zur Herstellung einer Lösung für einer Infusionslösung	1 000 000 I.U.	powder for solution for infusion	intravenous use
Greece	NORMA HELLAS AE 54 Menandrou str 10431 Athens Greece	COLISTIN/NORMA	1 000 000 I.U.	powder for solution for injection	intramuscular use
Greece	NORMA HELLAS AE 54 Menandrou str 10431 Athens Greece	COLISTIN/NORMA	1 000 000 I.U.	powder and solvent for nebuliser solution	inhalation use
Greece	NORMA HELLAS AE 54 Menandrou str 10431 Athens Greece	COLISTIN/NORMA	1 000 000 I.U.	powder for solution for infusion	intravenous use
Greece	NORMA HELLAS AE 54 Menandrou str 10431 Athens Greece	COLISTIN/NORMA	2 000 000 I.U.	powder for solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Greece	ALLERTEC HELLAS AE 74 Karamanli str. 55134, Kalamaria, Thessaloniki Greece	TADIM	1 000 000 I.U.	powder and solvent for nebuliser solution	inhalation use
Hungary	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford, Kent DA2 6SL United Kingdom	COLOMYCIN	1 000 000 I.U.	powder for solution for injection/infusion, powder for nebuliser solution	intravenous use, inhalation use
Hungary	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford, Kent DA2 6SL United Kingdom	COLOMYCIN	2 000 000 I.U.	powder for solution for injection/infusion, powder for nebuliser solution	intravenous use, inhalation use
Iceland	Alvogen IPCo S.à.r.l., 5 Rue Heienhaff, L-1736 Senningerberg Luxembourg	Colistimethate Alvogen	1 000 000 I.U.	powder for solution for injection or infusion	intravenous use
Iceland	Alvogen IPCo S.à.r.l., 5 Rue Heienhaff, L-1736 Senningerberg Luxembourg	Colistimethate Alvogen	2 000 000 I.U.	powder for solution for injection or infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Ireland	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford, Kent DA2 6SL United Kingdom	Colomycin Injection 1 million International Units. Powder for solution for injection, infusion or inhalation	1 000 000 I.U.	powder for solution for injection, infusion or inhalation	intravenous use, inhalation use
Ireland	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford, Kent DA2 6SL United Kingdom	Colomycin Injection 2 million International Units. Powder for solution for injection, infusion or inhalation	2 000 000 I.U.	powder for solution for injection, infusion or inhalation	intravenous use, inhalation use
Ireland	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin, 1 million International Units (IU), Powder for Nebuliser Solution	1 000 000 I.U.	powder for nebuliser solution	inhalation use
Italy	UCB Pharma S.p.A. Via Gadames 5720151 — Milano (MI) Italy	COLIMICINA	1 000 000 I.U.	powder and solvent for solution for injection	intramuscular use
Italy	PARI Pharma GmbH Moosstrasse 3 82319 Starnberg Germany	COLFINAIR	1 000 0000 I.U.	powder for nebuliser solution	inhalation use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Italy	PARI Pharma GmbH Moosstrasse 3 82319 Starnberg Germany	COLFINAIR	2 000 000 I.U.	powder for nebuliser solution	Inhalation use
Italy	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	PROMIXIN	10 000 000 I.U.	powder for nebuliser solution	Inhalation use
Luxembourg	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Tadim	1 000 000 I.U.	powder for nebuliser solution	inhalation use
Malta	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford, Kent DA2 6SL United Kingdom	Colomycin Injection 1million International Units powder for solution for injection, infusion or inhalation	1 000 000 I.U.	powder for solution for injection/infusion/inhalation	intravenous use, inhalation use
Norway	Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S Denmark	Colistimethate Xellia	1 000 000 I.U.	powder for solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Norway	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin	1 000 000 I.U.	powder for nebuliser solution	nasal use
Norway	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin	1 000 000 I.U.	powder for solution for infusion	intravenous use
Poland	Tarchomińskie Zakłady Farmaceutyczne 'Polfa' S.A. 2, A. Fleminga Str. 03-176 Warsaw Poland	Colistin TZF	1 000 000 I.U.	powder for solution for injection, injection or inhalation	intramuscular use, intravenous use, inhalation use
Poland	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin	1 000 000 I.U.	powder for nebuliser solution	inhalation use
Portugal	Generis Farmacêutica, S.A. Rua João de Deus 19 2700-487 Amadora Portugal	Colistina Generis	1 000 000 I.U.	powder for solution for injection or for nebuliser solution	intravenous use, inhalation use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Portugal	Pharmis Biofarmacêutica, Lda. Praceta do Farol, lote 101 Cascais 2750-341 Portugal	Colixin	2 000 000 I.U.	powder for solution for injection or for nebuliser solution	intravenous use, inhalation use
Portugal	Pharmis Biofarmacêutica, Lda. Praceta do Farol, lote 101 Cascais 2750-341 Portugal	Colixin	1 000 000 I.U.	powder for solution for injection or for nebuliser solution	intravenous use, inhalation use
Portugal	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin	1 000 000 I.U.	powder for nebuliser solution	inhalation use
Romania	S.C. ANTIBIOTICE S.A., Str. Valea Lupului nr. 1 707410 Iaşi România	COLISTINĂ ANTIBIOTICE 1 000 000 UI,	1 000 000 I.U.	powder for solution for injection/infusion	intravenous use
Romania	Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S Denmark	Colistimetat sodic Xellia 1 milion unități internaționale (U.I.)	1 000 000 I.U.	powder for solution for injection/infusion	intravenous use
Slovak Republic	Sanofi-Aventis Slovakia s.r.o. Einsteinova 24 851 01 Bratislava Slovak Republic	Colimycine	1 000 000 I.U.	powder for solution for injection	intravenous use, intramuscular use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Slovak Republic	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford, Kent DA2 6SL United Kingdom	KOLOMYCÍN INJEKCIA 1 milión IU	1 000 000 I.U.	powder for solution for injection/infusion/ inhalation	intravenous use, inhalation use
Slovak Republic	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford, Kent DA2 6SL United Kingdom	KOLOMYCÍN INJEKCIA 2 milión IU	2 000 000 I.U.	powder for solution for injection/infusion/ inhalation	intravenous use, inhalation use
Spain	GES GENÉRICOS ESPAÑOLES LABORATORIO, S.A. Cólquide, 6 — Portal 2, 1º-Oficina F 28230 Las Rozas (Madrid) Spain	Colistimetato de sodio GES 1 MUI polvo para solución inyectable/para inhalación por nebulizador	1 000 000 I.U.	powder for solution for injection, powder for nebuliser solution	intravenous use, inhalation use
Spain	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin 1 millón de Unidades Internacionales (UI) polvo para solución para inhalación por nebulizador	1 000 000 I.U.	powder for nebuliser solution	inhalation use
Spain	Pharmis Biofarmacêutica, Lda. Praceta do Farol, lote 101 Cascais 2750-341 Portugal	Colixin 1 MUI polvo para solución inyectable o para solución para inhalación por nebulizador	1 000 000 I.U.	powder for solution for injection, powder for nebuliser solution	intravenous use, inhalation use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Sweden	Profile Pharma Limited Bicentennial Building Southern Gate Chichester West Sussex PO19 8EZ United Kingdom	Tadim	1 000 000 I.U.	powder for nebuliser solution	inhalation use
Sweden	Profile Pharma Limited Bicentennial Building Southern Gate Chichester West Sussex PO19 8EZ United Kingdom	Tadim	1 000 000 I.U.	powder for solution for infusion	intravenous use
Sweden	Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S Denmark	Colistin Xellia	1 000 000 I.U.	powder for solution for injection/infusion	intravenous use
The Netherlands	Forest Pharma B.V. Newtonlaan 115 3584 BH Utrecht The Netherlands	Colistin, poeder voor vernevelоplossing met oplosmiddel 1.000.000 IE	1 000 000 I.U.	powder for nebuliser solution	inhalation use
United Kingdom	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford, Kent DA2 6SL United Kingdom	Colomycin Injection 2 million international units powder for solution for injection, infusion or inhalation	2 000 000 I.U.	powder for solution for injection	intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
United Kingdom	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford, Kent DA2 6SL United Kingdom	Colomycin Injection 1 million international units powder for solution for injection, infusion or inhalation	1 000 000 I.U.	powder for solution for injection, infusion or inhalation	intramuscular use, intravenous use, inhalation use
United Kingdom	Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S Denmark	Colistimethate sodium 1 million international units powder for solution for injection or infusion	1 000 000 I.U.	powder for solution for injection/infusion	intravenous use
United Kingdom	Beacon Pharmaceuticals Limited, Tunbridge Wells, Kent TN1 1YG United Kingdom	Colistimethate sodium 1 million I.U. powder for solution for injection	1 000 000 I.U.	powder for solution for injection	intravenous use, inhalation use
United Kingdom	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin 1 million international units (IU) powder for nebuliser solution	1 000 000 I.U.	powder for nebuliser solution	inhalation use
United Kingdom	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin 1 million international units (IU) powder for solution for infusion	1 000 000 I.U.	powder for solution for injection	intramuscular use, intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
United Kingdom	PARI Pharma GmbH Moosstrasse 3 82319 Starnberg Germany	Colifin 1 MIU powder for nebuliser solutions	1 000 000 I.U.	powder for nebuliser solution	inhalation use
United Kingdom	PARI Pharma GmbH Moosstrasse 3 82319 Starnberg Germany	Colifin 2 MIU powder for nebuliser solutions	2 000 000 I.U.	powder for nebuliser solution	inhalation use

ISSN 1977-091X (electronic edition)
ISSN 1725-2423 (paper edition)

Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

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