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EUROPEAN COMMISSION

**Summary of European Union decisions on marketing authorisations in respect of medicinal products
from 1 October 2020 to 31 October 2020***(Published pursuant to Article 13 or Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of
the Council⁽¹⁾)**(2020/C 409/01)*

⁽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
27.10.2020	ARIKAYCE liposomal	amikacin	Insmmed Netherlands B.V. Stadsplateau 7, 3521 AZ Utrecht, Nederland	EU/1/20/1469	Nebuliser dispersion	J01GB06	28.10.2020
28.10.2020	Adakveo	crizanlizumab	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1476	Concentrate for solution for infusion	B06AX01	29.10.2020

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

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
28.10.2020	Turalio	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	—	29.10.2020

— **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
9.10.2020	Briviact	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/15/1073	12.10.2020
9.10.2020	Celsentri	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/07/418	14.10.2020
9.10.2020	Cuprior	Orphalan 226 Boulevard Voltaire, 75011 Paris, France	EU/1/17/1199	12.10.2020
9.10.2020	Doptelet	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/19/1373	16.10.2020
9.10.2020	Elonva	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/09/609	12.10.2020
9.10.2020	Laventair Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/14/899	14.10.2020
9.10.2020	Moventig	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/14/962	14.10.2020
9.10.2020	Nexavar	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/06/342	12.10.2020
9.10.2020	Pemetrexed Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/15/1071	13.10.2020
9.10.2020	Ritemvia	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/17/1207	12.10.2020
9.10.2020	Rixathon	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1185	12.10.2020
9.10.2020	Riximyo	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1184	13.10.2020
9.10.2020	Sialanar	Proveca Pharma Limited Marine House, Clanwilliam Place, Dublin 2, Ireland	EU/1/16/1135	15.10.2020

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
9.10.2020	Skilarence	Almirall, S.A. Ronda General Mitre, 151, 08022 Barcelona, España	EU/1/17/1201	13.10.2020
9.10.2020	Spherox	CO.DON AG Warthestraße 21, 14513 Teltow, Deutschland	EU/1/17/1181	14.10.2020
9.10.2020	Viekirax	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/14/982	14.10.2020
9.10.2020	Zeposia	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1442	12.10.2020
15.10.2020	Forxiga	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/12/795	19.10.2020
15.10.2020	Glyxambi	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/16/1146	20.10.2020
15.10.2020	IntronA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/99/127	16.10.2020
15.10.2020	Iscover	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/98/070	16.10.2020
15.10.2020	NovoEight	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/13/888	19.10.2020
15.10.2020	Noxafil	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/05/320	16.10.2020
15.10.2020	Rebif	Merck Europe B.V. Gustav Mahlerplein 102, Ito Toren, 1082 MA Amsterdam, Nederland	EU/1/98/063	18.10.2020
15.10.2020	Truxima	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/16/1167	16.10.2020
15.10.2020	ZALTRAP	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/12/814	16.10.2020
15.10.2020	Zessly	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1280	19.10.2020
16.10.2020	NovoSeven	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/96/006	19.10.2020
16.10.2020	Prometax	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/98/092	19.10.2020
19.10.2020	ALPROLIX	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/16/1098	20.10.2020
19.10.2020	Caelyx pegylated liposomal	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/96/011	20.10.2020

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
19.10.2020	Empliciti	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/16/1088	20.10.2020
19.10.2020	Eucreas	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/425	20.10.2020
19.10.2020	Exelon	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/98/066	20.10.2020
19.10.2020	Ifirmasta	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/08/480	20.10.2020
19.10.2020	Invanz	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/02/216	21.10.2020
19.10.2020	Kisqali	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/17/1221	20.10.2020
19.10.2020	Myocet liposomal	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/00/141	20.10.2020
19.10.2020	Olumiant	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/16/1170	21.10.2020
19.10.2020	Poteligeo	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/18/1335	26.10.2020
19.10.2020	Tandemact	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/06/366	25.10.2020
19.10.2020	Temomedac	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstraße 6, 22880 Wedel, Deutschland	EU/1/09/605	20.10.2020
19.10.2020	Temozolomide Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/10/615	20.10.2020
22.10.2020	Flucelvax Tetra	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Netherlands	EU/1/18/1326	23.10.2020
22.10.2020	Lenalidomide Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/18/1316	26.10.2020
22.10.2020	Mircera	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/07/400	24.10.2020
22.10.2020	Orfadin	Swedish Orphan Biovitrum International AB 112 76 Stockholm, Sverige	EU/1/04/303	26.10.2020

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
22.10.2020	Ribavirin Mylan	Mylan S.A.S. 117 allée des Parcs, 69800 Saint Priest, France	EU/1/10/634	26.10.2020
22.10.2020	Stivarga	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/858	26.10.2020
22.10.2020	Sutent	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/06/347	26.10.2020
22.10.2020	Zelboraf	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/12/751	24.10.2020
22.10.2020	Zoledronic acid Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/12/800	23.10.2020
27.10.2020	ABILIFY MAINTENANCE	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Noord-Holland, Nederland	EU/1/13/882	28.10.2020
27.10.2020	Delyba	Otsuka Novel Products GmbH Erika-Mann-Straße 21, 80636 München, Deutschland	EU/1/13/875	28.10.2020
27.10.2020	Faslodex	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/03/269	29.10.2020
27.10.2020	Gliolan	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstraße 6, 22880 Wedel, Deutschland	EU/1/07/413	9.11.2020
27.10.2020	Kaletra	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/01/172	28.10.2020
27.10.2020	KANJINTI	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/18/1281	28.10.2020
27.10.2020	Tecentriq	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1220	30.10.2020
27.10.2020	Xofigo	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/873	28.10.2020
27.10.2020	Zeजूla	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/17/1235	28.10.2020
27.10.2020	Zirabev	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/18/1344	28.10.2020

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
28.10.2020	Biktarvy	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/18/1289	2.11.2020
28.10.2020	Ifirmacombi	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/11/673	5.11.2020
28.10.2020	Udenyca	ERA Consulting GmbH Lange Straße 70, 29664 Walsrode, Deutschland	EU/1/18/1303	29.10.2020

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

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
27.10.2020	Ribavirin Mylan	Mylan S.A.S. 117 allée des Parcs, 69800 Saint Priest, France	EU/1/10/634	28.10.2020

— **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
14.10.2020	EQUIOXX	Audevard 42-46 rue Médéric, 92110 Clichy, France	EU/2/08/083	15.10.2020
30.10.2020	Credelio	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/17/206	3.11.2020

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

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
29.10.2020	Zulvac 8 Bovis	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/09/105	2.11.2020

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

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
NETHERLANDS

**Summary of European Union decisions on marketing authorisations in respect of medicinal products
from 1 October 2020 to 31 October 2020***(Decisions taken pursuant to Article 34 of Directive 2001/83/EC⁽¹⁾ or Article 38 of Directive 2001/82/EC⁽²⁾)**(2020/C 409/02)***— Issuing, maintenance or modification of a national marketing authorization**

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorization	Member State concerned	Date of notification
15.10.2020	Ibuprofen Kabi 400 mg Infusionslösung and associated names	ibuprofen	See Annex I	See Annex I	16.10.2020
12.10.2020	Betamox LA 150 mg/ml suspension for injection and associated names, and generic products thereof	Amoxicillin trihydrate	See Annex II	See Annex II	12.10.2020
12.10.2020	Stresnil 40 mg/ml solution for injection for pigs and associated names, and generic products thereof	azaperone	See Annex III	See Annex III	12.10.2020

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.⁽²⁾ OJ L 311, 28.11.2001, p. 1.

List of medicinal products and presentations

Member State EU/EEA	Applicant	Invented Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Austria	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 Bad Homburg v.d.H. 61352 Germany	Ibuprofen Kabi 400 mg Infusionslösung	400 mg	Solution for infusion	Intravenous use	4 mg/ml
Belgium	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 Bad Homburg v.d.H. 61352 Germany	Ibuprofen Fresenius Kabi 400 mg oplossing voor infusie Ibuprofen Fresenius Kabi 400 mg solution pour perfusion Ibuprofen Fresenius Kabi 400 mg Infusionslösung	400 mg	Solution for infusion	Intravenous use	4 mg/ml
Czech Republic	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 Bad Homburg v.d.H. 61352 Germany	Ibuprofen Kabi	400 mg	Solution for infusion	Intravenous use	4 mg/ml
Germany	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 Bad Homburg v.d.H. 61352 Germany	Ibuprofen Kabi 400 mg Infusionslösung	400 mg	Solution for infusion	Intravenous use	4 mg/ml
Hungary	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 Bad Homburg v.d.H. 61352 Germany	Ibuprofen Kabi 400 mg oldatos infúzió	400 mg	Solution for infusion	Intravenous use	4 mg/ml
The Netherlands	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 Bad Homburg v.d.H. 61352 Germany	Ibuprofen Fresenius Kabi 400 mg oplossing voor infusie	400 mg	Solution for infusion	Intravenous use	4 mg/ml

Member State EU/EEA	Applicant	Invented Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Poland	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 Bad Homburg v.d.H. 61352 Germany	Ibuprofen Kabi	400 mg	Solution for infusion	Intravenous use	4 mg/ml
Portugal	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 Bad Homburg v.d.H. 61352 Germany	Ibuprofeno Kabi	400 mg	Solution for infusion	Intravenous use	4 mg/ml
Romania	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 Bad Homburg v.d.H. 61352 Germany	Ibuprofen Kabi 400 mg soluție perfuzabilă	400 mg	Solution for infusion	Intravenous use	4 mg/ml
Slovak Republic	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 Bad Homburg v.d.H. 61352 Germany	Ibuprofen Kabi 400 mg	400 mg	Solution for infusion	Intravenous use	4 mg/ml
Slovenia	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 Bad Homburg v.d.H. 61352 Germany	Ibuprofen Kabi 400 mg raztopina za infundiranje	400 mg	Solution for infusion	Intravenous use	4 mg/ml
Spain	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 Bad Homburg v.d.H. 61352 Germany	Ibuprofeno Kabi 400 mg solución para perfusión	400 mg	Solution for infusion	Intravenous use	4 mg/ml
United Kingdom	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 Bad Homburg v.d.H. 61352 Germany	Ibuprofen Kabi 400 mg Solution for Infusion	400 mg	Solution for infusion	Intravenous use	4 mg/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 EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Austria	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate H18 W620 Monaghan Ireland	Betamox long acting-Injektionssuspension für Tiere	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Austria	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA 150 mg/ml Injektionssuspension für Rinder, Schafe, Schweine, Hunde, Katzen	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Belgium	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Bulgaria	Asklep-Farma OOD j.k. Lyulin 7, bl. 711A, shop 3 Sofia Bulgaria	Betamox LA Injection	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Bulgaria	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA 150 mg/ml suspension for injection for cattle, sheep, pigs, dogs and cats	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Croatia	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA, 150 mg/mL, suspenzija za injekciju, za goveda, ovce, svinje, pse i mačke	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Croatia	GENERA d.d. Svetonedeljska cesta 2 Kalinovica 10436 Rakov Potok Croatia	Simivet retard, 150 mg/mL, suspenzija za injekciju, za goveda, ovce, svinje, pse i mačke	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Cyprus	Stavrinides Spyros Chemicals Ltd 28A Stasinou Ave Nicosia Cyprus	Betamox LA Injection, 150 mg/ml Ενέσιμο Εναιώρημα	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Cyprus	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA 150 mg/ml Ενέσιμο εναιώρημα για βοοειδή, πρόβατα, χοίρους, σκύλους, γάτες	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Czech Republic	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate Monaghan Ireland	Betamox LA 150 mg/ml injekční suspenze	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Denmark	ScanVet Animal Health A/S Kongevejen 66 3480 Fredensborg Denmark	Betamox Vet.	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Denmark	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Estonia	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Finland	Norbrook Laboratories Limited Station Works Camlough Road Newry, Co. Down BT35 6JP Northern Ireland United Kingdom	Betamox vet	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Finland	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox vet	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
France	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA 150 mg/ml Suspension for Injection for Cattle, Sheep, Pigs, Dogs, Cats	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcuta- neous use
Germany	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA 150 mg/ml suspension for injection	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcuta- neous use
Greece	Hellafarm A.E Fleming 15 15123, Marousi Greece	Betamox L.A	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcuta- neous use
Greece	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox L.A	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcuta- neous use
Hungary	Norbrook Laboratories Limited Station Works Camlough Road Newry, Co. Down BT35 6JP Northern Ireland United Kingdom	Betamox LA 150 mg/ml szuszpenziós injekció A. U.V.	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs	Intramuscular and/or subcuta- neous use

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Hungary	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA 150 mg/ml suspension for injection	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Hungary	Bayer Hungária Kft. 1123 Budapest Alkotás u. 50. Hungary	Amoxysol LA 150 mg/ml szuszpenziós injekció szarvasmarhák, sertések és juhok részére A.U.V.	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs	Intramuscular and/or subcutaneous use
Ireland	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate Monaghan Ireland	Betamox LA 150 mg/ml Suspension for Injection	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Ireland	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA 150 mg/ml suspension for injection	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Italy	Norbrook Laboratories Limited Station Works Camlough Road Newry, Co. Down BT35 6JP Northern Ireland United Kingdom	Betamox LA, 150 mg/ml sospensione iniettabile per bovini, suini, cani e gatti	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, pigs, dogs, cats	Intramuscular and/or subcutaneous use

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trimox LA 150 mg/ml, sospensione iniettabile per bovini, ovini, suini, cani e gatti	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcuta- neous use
Latvia	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA 150 mg/ml suspensija injekcijām liel- lopiem, aitām, cūkām, suņiem, kaķiem	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcuta- neous use
Latvia	Norbrook Laboratories Limited Station Works Camlough Road Newry, Co. Down BT35 6JP Northern Ireland United Kingdom	Betamox LA 150 mg/ml suspensija injekcijām liel- lopiem, aitām, cūkām, suņiem, kaķiem	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcuta- neous use
Lithuania	Norbrook Laboratories Limited Station Works Camlough Road Newry, Co. Down BT35 6JP Northern Ireland United Kingdom	Betamox LA, 150 mg/ml, injekcinė suspensija gal- vijams, kiaulėms, avims, šunims ir katėms	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcuta- neous use
Lithuania	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA 150 mg/ml Suspension for Injection for Cattle, Sheep, Pigs, Dogs, Cats	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcuta- neous use

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Norway	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox Vet	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
The Netherlands	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA 150 mg/ml suspensie voor injectie voor runderen, schapen, varkens, honden, katten	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Poland	Scanvet Poland Sp. z o.o. ul. Kiszowska 9 Gniezno 62-200 Poland	Betamox L.A.	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Poland	Nordpharm Poland Sp. z o.o. Al. Jerozolimskie 99 lok. 39 02-001 Warszawa Poland	Amoxyvet LA	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Poland	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Portugal	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate Monaghan Ireland	Betamox LA 150 mg/ml Suspension for Injection	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Portugal	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA 150 mg/ml suspension for injection	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Romania	Norbrook Laboratories Limited Station Works Camlough Road Newry, Co. Down BT35 6JP Northern Ireland United Kingdom	Betamox LA, 150 mg/ml	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Romania	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA 150 mg/ml	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Slovak Republic	Norbrook Laboratories Limited Station Works Camlough Road Newry, Co. Down BT35 6JP Northern Ireland United Kingdom	Betamox LA 150 mg/ml injekčná suspenzia	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
Slovak Republic	Zoetis Česká republika, s.r.o náměstí 14. října 642/17 150 00 Prague 5 Czech Republic	Duphamox LA 150 mg/ml injekčná suspenzia	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Slovak Republic	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA 150 mg/ml Suspension for Injection for Cattle, Sheep, Pigs, Dogs, Cats	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcuta- neous use
Slovenia	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA 150 mg/ml suspension for injection for cattle, sheep, pigs, dogs and cats	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcuta- neous use
Slovenia	GENERA SI d.o.o. Parmova ulica 53 1000 Ljubljana Slovenia	Simivet retard 150 mg/ml suspenzija za injiciranje	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcuta- neous use
Spain	Norbrook Laboratories Limited Station Works Camlough Road Newry, Co. Down BT35 6JP Northern Ireland United Kingdom	Betamox LA	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs	Intramuscular and/or subcuta- neous use
Sweden	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox vet	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcuta- neous use

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
United Kingdom	Norbrook Laboratories Limited Station Works Camlough Road Newry, Co. Down BT35 6JP Northern Ireland United Kingdom	Betamox LA 150 mg/ml Suspension for Injection	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs	Intramuscular and/or subcutaneous use
United Kingdom	Norbrook Laboratories Limited Station Works Camlough Road Newry, Co. Down BT35 6JP Northern Ireland United Kingdom	Amoxycare LA Suspension for Injection 15 % w/v	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use
United Kingdom	Univet Ltd Tullyvin Cootehill Co. Cavan Ireland	Trymox LA 150 mg/ml Suspension for Injection for Cattle, Sheep, Pigs, Dogs, Cats	Amoxicillin trihydrate	150 mg/ml	Suspension for injection	Cattle, sheep, pigs, dogs, cats	Intramuscular and/or subcutaneous use

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 EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Austria	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Separon 40 mg/ml Injektionslösung für Schweine	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Austria	Serumwerk Bernburg AG Hallesche Landstrasse 105 b 06406 Bernburg/Saale Germany	Azaporc 40 mg/ml Injektionslösung für Schweine	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Austria	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Stresnil 40 mg/ml Injektionslösung für Schweine	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Belgium	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Duitsland	Stresnil 40 mg/ml	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Bulgaria	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Stresnil 40 mg/ml injectable solution	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Bulgaria	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Sedanol 40 mg/ml solution for injection for pigs	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Croatia	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Sedanol 40 mg/ml solution for injection for pigs	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Cyprus	Elanco GmbH Heinz-Lohmann-Str. 4 27472 Cuxhaven Germany	Stresnil, 40 mg/mL ενέσιμο διάλυμα για χοίρους	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Czech Republic	Elanco GmbH Heinz Lohmann Str. 4 27472 Cuxhaven Germany	Stresnil 40 mg/ml injekční roztok pro prasata	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Czech Republic	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Sedanol 40 mg/ml injekční roztok pro prasata	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Denmark	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Separon vet.	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Estonia	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Sedanol 40 mg/ml solution for injection for pigs	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Finland	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Separon vet.	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
France	Elanco GmbH Heinz-Lohmann-Strasse 4 27472 Cuxhaven Germany	Stresnil	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Germany	Serumwerk Bernburg AG Hallesche Landstr. 105b 06406 Bernburg Germany	Azaporc 40 mg/ml Injektionslösung für Schweine	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Germany	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Sedanol 40 mg/ml	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Germany	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Stresnil	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Greece	Elanco GmbH Heinz-Lohmann-Str.4 27472 Cuxhaven Germany	Stresnil ενέσιμο διάλυμα 40 mg/ml	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Greece	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Separon 40 mg/ml solution for injection for pigs	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Hungary	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Stresnil 40 mg/ml oldatos injekció sertéseknek A.U.V.	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Hungary	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Sedanol 40 mg/ml solution for injection for pigs	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Iceland	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Separon vet.	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Ireland	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Stresnil 40 mg/ml solution for injection for pigs	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Ireland	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Sedanol 40 mg/ml solution for injection for pigs	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Italy	Eli Lilly Italia S.P.A. Via Gramsci, 731-733 50019 Sesto Fiorentino (FI) Italy	Stresnil 40 mg/ml soluzione iniettabile per suini	Azaperone	40 mg/ml	Solution for injections	Pigs	Intramuscular use
Italy	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Sedanol 40 mg/ml solution for injection for pigs	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Latvia	Elanco GmbH Heinz-Lohmann Str. 4 27472 Cuxhaven Germany	Stresnil	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Latvia	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Sedanol	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Lithuania	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Sedanol 40 mg/ml solution for injection for pigs	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Lithuania	Elanco GmbH Heinz-Lohmann Str. 4 27472 Cuxhaven Germany	Stresnil 40 mg/ml injekcinis tirpalas kiaulėms	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
The Netherlands	Elanco GmbH Heinz-Lohmann-Strasse 4 27472 Cuxhaven Germany	Stresnil 40 mg/ml oplossing voor injectie voor varkens	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
The Netherlands	Kernfarm B.V. De Corridor 14D 3621 ZB Breukelen The Netherlands	Stresnil 40 mg/ml oplossing voor injectie voor varkens	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Norway	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Separon vet. 40 mg/ml solution for injection for pigs	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Poland	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Sedanol 40 mg/ml solution for injection for pigs	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Poland	Elanco GmbH Heinz-Lohmann-Strasse 4 27472 Cuxhaven Germany	Stresnil	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Portugal	Ecuphar Veterinaria S.L.U Avenida Río de Janeiro, 60-66, planta 13 08016 Barcelona Spain	Stresnil 40 mg/ml solução injetável para suínos	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Portugal	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Sedanol 40 mg/ml solução injetável para suínos	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Romania	Elanco GmbH Heinz-Lohmann-Strasse 4 27472 Cuxhaven Germany	Stresnil 40 mg/ml	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Romania	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Sedanol 40 mg/ml solution for injection for pigs	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Slovakia	Elanco GmbH Heinz-Lohmann-Str. 4 27472 Cuxhaven Germany	Stresnil 40 mg/ml injekčný roztok pre ošípané	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Slovakia	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Sedanol 40 mg/ml injekčný roztok pre ošípané	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Slovenia	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Sedanol 40 mg/ml solution for injection for pigs	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Spain	Ecuphar Veterinaria S.L.U. Avda. Rio de Janeiro, 60-66 planta 13 08016 Barcelona Spain	Stresnil 40 mg/ml solución inyectable para porcino	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
Sweden	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Separon vet.	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
United Kingdom	Eli Lilly and Company Limited Elanco Animal Health Lilly House Priestley Road Basingstoke RG24 9NL United Kingdom	Stresnil 40 mg/ml solution for injection for pigs	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use
United Kingdom	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Sedanol 40 mg/ml solution for injection for pigs	Azaperone	40 mg/ml	Solution for injection	Pigs	Intramuscular use

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