

Annex I

List of the names, strengths of the veterinary medicinal products, animal species, route of administration, recommended dose and applicants/marketing authorisation holders in the member states

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Austria	Bayer Austria GmbH Herbststraße 6-10 1160 Wien AUSTRIA	Baytril 100 mg/ml Injektionslösung für Rinder und Schweine	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular, intravenous
Austria	Bayer Austria GmbH Herbststraße 6-10 1160 Wien AUSTRIA	Baytril 100 mg/ml Lösung zum Eingeben für Hühner und Puten	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Austria	Bayer Austria GmbH Herbststraße 6-10 1160 Wien AUSTRIA	Baytril 25 mg/ml Injektionslösung für Tiere	Enrofloxacin	25 mg/ml	Solution for injection	Pigs Rabbits	Intramuscular, subcutaneous
Austria	Bayer Austria GmbH Herbststraße 6-10 1160 Wien AUSTRIA	Baytril 25 mg/ml Lösung zum Eingeben für Kälber	Enrofloxacin	25 mg/ml	Oral solution	Calves	Oral
Austria	Bayer Austria GmbH Herbststraße 6-10 1160 Wien AUSTRIA	Baytril 5 mg/ml - Lösung zum Eingeben für Schweine	Enrofloxacin	5 mg/ml	Oral solution	Pigs	Oral
Austria	Bayer Austria GmbH Herbststraße 6-10 1160 Wien AUSTRIA	Baytril 50 mg/ml - Injektionslösung für Tiere	Enrofloxacin	50 mg/ml	Solution for injection	Calves Pigs	Subcutaneous, intramuscular
Austria	Bayer Austria GmbH Herbststraße 6-10 1160 Wien AUSTRIA	Baytril One 100 mg/ml Injektionslösung für Rinder	Enrofloxacin	100 mg/ml	Solution for injection	Cattle	Subcutaneous, intravenous

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Austria	Bayer Austria GmbH Herbststraße 6-10 1160 Wien AUSTRIA	Baytril RSI 100 mg/ml - Injektionslösung für Rinder und Schweine	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous or intravenous or intramuscular
Austria	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	MARBOKEM 100 mg/ml solution for injection	Marbofloxacin	100 mg/ml	Solution for injection	Cattle	Intramuscular
Austria	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Fenoflox 10% solution for injection	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
Austria	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Fenoflox 5% solution for injection	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
Austria	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enrox 100 mg/ml Lösung zum Eingeben für Hühner und Puten	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Austria	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	ENROXIL Injektionslösung 100 mg/ml für Rinder und Schweine	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular

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Austria	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	ENROXIL Injektionslösung 50 mg/ml für Kälber, Schweine und Hunde	Enrofloxacin	50 mg/ml	Solution for injection	Calves Pigs Dogs	Subcutaneous, intramuscular
Austria	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil Max 100 mg/ml Injektionslösung für Rinder	Enrofloxacin	100 mg/ml	Solution for injection	Cattle	Subcutaneous
Austria	Pfizer Corporation Austria GmbH Floridsdorfer Hauptstaße 1 1210 Wien AUSTRIA	Advocid 180 - 180 mg/ml - Injektionslösung für Rinder	Danofloxacin mesilate	228.4 mg/ml (equivalent to 180 mg/ml Danofloxacin)	Solution for injection	Cattle	Subcutaneous, intravenous
Austria	Pfizer Corporation Austria GmbH Floridsdorfer Hauptstaße 1 1210 Wien AUSTRIA	Advocid 25 mg/ml Injektionslösung für Rinder und Schweine	Danofloxacin	31.73 mg/ml (equivalent to 25 mg/ml Danofloxacin)	Solution for injection	Cattle Pigs	Intravenous, intramuscular
Austria	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 10 % Injektionslösung für Rinder und Schweine	Marbofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Austria	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl - Tabletten für Kälber	Marbofloxacin	50 mg	Tablets	Calves	Oral

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Austria	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 2% - Injektionslösung für Tiere	Marbofloxacin	20 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Austria	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl S 10 % Injektionslösung für Rinder	Marbofloxacin	100 mg/ml	Solution for injection	Cattle	Intramuscular
Austria	Virbac S.A. 1ere Avenue 2065 M LID B.P. 27 06516 Carros Cedex FRANCE	Powerflox 100 mg/ml Injektionslösung für Rinder und Schweine	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intravenous, intramuscular
Austria	Virbac S.A. 1ere Avenue 2065 M LID B.P. 27 06516 Carros Cedex FRANCE	Powerflox 50 mg/ml Injektionslösung für Rinder, Schweine, Hunde und Katzen	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
Belgium	Bayer N.V. Louizalaan 143 1050 Brussels BELGIUM	BAYTRIL 0,5% Sol. Orale	Enrofloxacin	0.5 g/100 ml	Oral solution	Piglets	Oral
Belgium	Bayer N.V. Louizalaan 143 1050 Brussels BELGIUM	BAYTRIL 10% Sol. Orale	Enrofloxacin	10 g/100 ml	Oral solution	Chickens Turkeys	Oral

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Belgium	Bayer N.V. Louizalaan 143 1050 Brussels BELGIUM	BAYTRIL 100	Enrofloxacin	10 g/100ml	Solution for injection	Bovine (non milk producing)	Subcutaneous
Belgium	Bayer N.V. Louizalaan 143 1050 Brussels BELGIUM	BAYTRIL 2,5% Sol. Orale	Enrofloxacin	2.5 g/100 ml	Oral solution	Calves	Oral
Belgium	Bayer N.V. Louizalaan 143 1050 Brussels BELGIUM	BAYTRIL 5% Sol. inj.	Enrofloxacin	5 g/100 ml	Solution for injection	Bovine Porcine	Intravenous, subcutaneous
Belgium	Ceva Santé Animale N.V. Metrologielaan 6 1130 Brussels BELGIUM	FLUMIQUIL 50%	Flumequine	50 g	Powder	Broilers Pigs Cattle (non ruminating)	Oral
Belgium	Codifar N.V. Lt. Caluwaertstraat 1 2160 Wommelgem BELGIUM	FLUMAX 50%	Flumequine	500 mg/g	Powder	Chickens	Oral
Belgium	Dopharma Research BV Zalmweg 24 4941 VX Raamsdonksveer NETHERLANDS	ENTERFLUME 50%	Flumequine	500 mg/g	Powder	Cattle (non ruminating) Hens (non laying)	Oral
Belgium	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	ENROXIL Sol. Orale 100MG/ML	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral

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Belgium	Pfizer Animal Health Benelux Division Pleinlaan 17 1050 Brussels BELGIUM	ADVOCIN 180	Danofloxacin	180 mg/ml	Solution for injection	Cattle	Subcutaneous, intravenous
Belgium	Pfizer Animal Health Benelux Division Pleinlaan 17 1050 Brussels BELGIUM	ADVOCIN 2,5%	Danofloxacin	25 mg/ml	Solution for injection	Bovine Porcine	Intramuscular, subcutaneous, intravenous
Belgium	Vétoquinol N.V. Kontichsesteenweg 42 2630 Aartselaar BELGIUM	MARBOCYL 10%	Marbofloxacin	100 mg/ml	Solution for injection	Bovine Sows	Intravenous, intramuscular, subcutaneous
Belgium	Vétoquinol N.V. Kontichsesteenweg 42 2630 Aartselaar BELGIUM	MARBOCYL 2%	Marbofloxacin	20 mg/ml	Solution for injection	Bovine Fattening pigs	Intravenous, intramuscular, subcutaneous
Belgium	Vétoquinol N.V. Kontichsesteenweg 42 2630 Aartselaar BELGIUM	MARBOCYL BOLUS	Marbofloxacin	50 mg	Tablets	Bovine	Oral
Belgium	Vétoquinol N.V. Kontichsesteenweg 42 2630 Aartselaar BELGIUM	MARBOCYL S 10%	Marbofloxacin	100 mg/ml	Solution for injection	Bovine	Intramuscular

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Bulgaria	Bayer HealthCare AG Animal Health Division 51368 Leverkusen GERMANY	Baytril 10 % oral solution	Enrofloxacin	100 mg/ml	Oral solution	Poultry Turkeys	Oral
Bulgaria	Bayer HealthCare AG Animal Health Division 51368 Leverkusen GERMANY	Baytril 5 % injectable solution	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs	Intramuscular, subcutaneous
Bulgaria	Biovet AD 39 Petar Rakov Str. 4550 Peshtera BULGARIA	Biofloxavet 10% Oral Solution	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral
Bulgaria	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Flumiquil 50 %	Flumequine	500 mg/g	Oral powder	Calves Pigs Poultry Fish	Oral
Bulgaria	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Quinoex-10	Enrofloxacin	100 mg/ml	Oral solution	Broilers Turkeys	Oral
Bulgaria	Divasa-Farmavic S.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	Enrovvet 10%	Enrofloxacin	100 mg/ml	Oral solution	Poultry Turkeys	Oral

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Bulgaria	Farmavet OOD 40 Otec Paisij Str. 9700 Shumen BULGARIA	Enrofloxacin 10 %	Enrofloxacin	100 mg/ml	Oral solution	Broilers	Oral
Bulgaria	Industrial Veterinaria S.A. Esmeralda, 19 - 4º 08950 Esplugues de Llobregat SPAIN	Ganadexil Enrofloxacin 5%	Enrofloxacin	50 mg/ml	Solution for injection	Calves Pigs Dogs	Intramuscular
Bulgaria	Laboratorios Calier, S.A. Barcelonés, 26 08520 Les Franqueses del Valles SPAIN	Roxacin Injectable	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intramuscular
Bulgaria	Laboratorios Calier, S.A. Barcelonés, 26 08520 Les Franqueses del Valles SPAIN	Roxacin Oral solution	Enrofloxacin	100 mg/ml	Oral solution	Broilers	Oral
Bulgaria	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	Hipralona ENRO-S Oral. Sol.	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral
Bulgaria	Laboratorios Syva, S.A. Avda Parroco Pablo Diez 49- 57 24010 Trobajo del Camino SPAIN	Flumesiva liquid 20%	Flumequine	200 mg/ml	Oral solution	Cattle Pigs Poultry Lambs	Oral

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Bulgaria	Laboratorios Syva, S.A. Avda Parroco Pablo Diez 49-57 24010 Trobajo del Camino SPAIN	Flumesyva pulvis 10 %	Flumequine	100 mg/g	Oral powder	Cattle Pigs Poultry	Oral
Bulgaria	Laboratorios Syva, S.A. Avda Parroco Pablo Diez 49-57 24010 Trobajo del Camino SPAIN	Syvaquinol 10%	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral
Bulgaria	Laboratorios Syva, S.A. Avda Parroco Pablo Diez 49-57 24010 Trobajo del Camino SPAIN	Syvaquinol-100	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intramuscular
Bulgaria	Laboratorios Syva, S.A. Avda Parroco Pablo Diez 49-57 24010 Trobajo del Camino SPAIN	Syvaquinol-25	Enrofloxacin	250 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Intramuscular
Bulgaria	Pfizer Ltd Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM	Advocin 180, 180 Solution for Injection for Cattle	Danofloxacin	180 mg/ml	Solution for injection	Cattle	Intramuscular

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Bulgaria	S.P. Veterinaria S.A. Ctra. de Reus a Vignols km 4.1 43330 Riudoms (Tarragona) SPAIN	Colmic - E	Enrofloxacin	100 mg/ml	Oral solution	Broilers	Oral
Bulgaria	Vetpartners OOD Ivan Asen Str. 4270 Parvomaj BULGARIA	Polistar Enro	Enrofloxacin	100 mg/ml	Oral solution	Broilers	Oral
Cyprus	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril Injection 5%	Enrofloxacin	5 g/100 ml	Solution for injection	Cattle Pigs Dogs	Subcutaneous, intramuscular
Cyprus	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril Oral Solution 0.5%	Enrofloxacin	5 mg/ml	Oral solution	Chickens Turkeys	Oral
Cyprus	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril Oral Solution 10%	Enrofloxacin	10 g/100ml	Oral solution	Chickens Turkeys	Oral
Cyprus	N A Chance Trading Co 18A, Aristophanous Avenue Strovolos 2039 Nicosia CYPRUS	Flumexil 10 % (Water Soluble Granules 90 g)	Flumequine	100 mg/g	Granules for oral solution	Cattle Buffalos Calves Foals Lambs Kids Pigs Piglets Rabbits Fowl	Oral

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Cyprus	N A Chance Trading Co 18A, Aristophanous Avenue Strovolos 2039 Nicosia CYPRUS	Flumexil 5% Suspension For Injection	Flumequine	50 mg/ml	Suspension for injection	Cattle Buffalos Horses Sheep Goats Pigs Rabbits Dogs Cats Chickens	Intramuscular
Cyprus	Panchris Feeds (Veterinary) Ltd. Industrial Area Aradippou 7100 P.O. Box 40261 6302 Larnaca CYPRUS	Amoxicillin 22,5% KAI Flumequine 15%	Amoxicillin Flumequine	per 100 g: 25.82 g amoxicillin trihydrate 15 g flumequine	Soluble powder	Pigs Broilers Turkeys	Oral
Cyprus	Panchris Feeds (Veterinary) Ltd. Industrial Area Aradippou 7100; P.O. Box 40261 6302 Larnaca CYPRUS	Naquilene 500 MP	Flumequine	50 g/100 g	Medicated feed	Pigs Fish	Oral
Cyprus	Pfizer Hellas SA Mesogeion Av 243 15451 N.Psihiko Athens GREECE	Advocin solution for injection	Danofloxacin mesilate	per ml: danofloxacin mesylate 31,73 mg equivalent to danofloxacin 25 mg	Solution for injection	Cattle Pigs	Intramuscular, intravenous
Cyprus	Vetagrira Ltd 3 Othelou Str. Dali Industrial Estate; P.O. Box 17020 2540 Nicosia CYPRUS	Flumisol Drinkable Solution	Flumequine	100 mg/ml	Oral solution	Poultry	Oral

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Cyprus	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 10%	Marbofloxacin	per ml: marbofloxacin 100 mg	Solution for Injection	Cattle Breeding sows	Subcutaneous, intramuscular, intravenous
Cyprus	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 2%	Marbofloxacin	Marbofloxacin 2.0 % w/v	Solution for injection	Cattle : pre- ruminants up to 100 kg bw Pigs	Subcutaneous, intramuscular, intravenous
Czech Republic	Bayer s.r.o Litvínovská 609/3 190 21 Praha 9 CZECH REPUBLIC	BAYTRIL 5% (w/v) injekční roztok	Enrofloxacin	50 mg/ml	Solution for injection	Calves Pigs Dogs	Subcutaneous, intramuscular
Czech Republic	Bayer s.r.o Litvínovská 609/3 190 21 Praha 9 CZECH REPUBLIC	BAYTRIL MAX	Enrofloxacin	100 mg/ml	Solution for injection	Cattle	Subcutaneous
Czech Republic	Bayer s.r.o Litvínovská 609/3 190 21 Praha 9 CZECH REPUBLIC	BAYTRILâ ORALE 0,5% sol	Enrofloxacin	5 mg/ml	Oral solution	Piglets	Oral
Czech Republic	Ceva Animal Health Slovakia s.r.o. Račianska 77 831 02 Bratislava SLOVAK REPUBLIC	FLUMIQUIL 50% plv. sol.	Flumequine	500 mg/g	Powder for oral solution	Chickens Fish Pigs Calves Sheep Goats	Oral

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Czech Republic	Ceva Animal Health Slovakia s.r.o. Račianska 77 831 02 Bratislava SLOVAK REPUBLIC	QUINOEX® 10 sol	Enrofloxacin	100 mg/ml	Oral solution	Broilers Turkeys	Oral
Czech Republic	Fatro S.p.A., Via Emilia 285 400064 Ozzano Emilia (BO) ITALY	FLUMEXIL 5%	Flumequine	50 mg/ml	Suspension for injection	Cattle Sheep Goats Pigs Horses Rabbits Chickens Dogs	Intramuscular
Czech Republic	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 100 mg/ml injekční roztok	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Czech Republic	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 10% perorální roztok	Enrofloxacin	100 mg/ml	Oral solution	Chickens	Oral
Czech Republic	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 50 mg/ml injekční roztok	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs	Subcutaneous, intramuscular
Czech Republic	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 5% premix pro medikaci krmiva	Enrofloxacin	5 g/100 g	Premix for medicated feedingstuffs	Chickens Pigs	Oral
Czech Republic	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil Max 100 mg/ml, injekční roztok pro skot	Enrofloxacin	100 mg/ml	Solution for injection	Cattle	Subcutaneous

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Czech Republic	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	FLUBACTIN sol	Flumequine	200 mg/ml	Oral solution	Chickens Pigs Calves Lambs Goatlings Rabbits Fur animals	Oral
Czech Republic	Laboratorios Calier, S.A. Barcelonés, 26 08520 Les Franqueses del Valles SPAIN	ROXACIN inj	Enrofloxacin	100 mg/ml	Solution for injection	Pigs Cattle	Intramuscular
Czech Republic	Laboratorios Calier, S.A. Barcelonés, 26 08520 Les Franqueses del Valles SPAIN	ROXACIN oral. sol.	Enrofloxacin	100 mg/ml	Oral solution	Chickens Broilers	Oral
Czech Republic	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	HIPRALONA ENRO-I inj	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs	Intramuscular
Czech Republic	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	HIPRALONA ENRO-S sol	Enrofloxacin	100 mg/ml	Oral solution	Chickens	Oral

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Czech Republic	Laboratorios Karizoo, S.A. Polg. Industrial La Borda Mas Pujades, 11-12 08140 Caldes de Montbui (Barcelona) SPAIN	ENRO-K 10% perorální roztok	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Czech Republic	Lavet Gyógyszergyártó Kft. Ottó u. 14 1161 Budapest HUNGARY	DIFLOCIN 10% oral sol	Difloxacin hydrochloride	100 mg/ml	Oral solution	Chickens (broilers) Turkeys	Oral
Czech Republic	Pfizer s.r.o. Stroupežnického 17 150 00 Praha CZECH REPUBLIC	Advocin 180 mg/ml injekční roztok	Danofloxacin	180 mg/ml	Solution for injection	Cattle	Subcutaneous, intravenous
Czech Republic	Pharmagal, s.r.o. Murgašova 5 949 01 Nitra SLOVAK REPUBLIC	ENROGAL 100mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Pigs Calves Chickens (broilers) Turkey	Oral
Czech Republic	Pharmagal, s.r.o. Murgašova 5 949 01 Nitra SLOVAK REPUBLIC	ENROGAL inj	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Sheep Goats Dogs Cats	Subcutaneous, intramuscular
Czech Republic	Vétoquinol Biowet Sp. z o.o. ul. Kosynierów Gdyńskich 13-14 66-400 Gorzów Wielkopolski POLAND	ENROBIOFLOX 10 % (w/v) perorální roztok	Enrofloxacin	100 mg/ml	Oral solution	Chickens Calves Pigs	Oral

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Czech Republic	Vétoquinol s.r.o. Zámečnická 411 288 02 Nymburk CZECH REPUBLIC	MARBOCYL 10% inj	Marbofloxacin	100 mg/ml	Solution for injection	Cattle Sows	Intramuscular, subcutaneous
Czech Republic	Vétoquinol s.r.o. Zámečnická 411 288 02 Nymburk CZECH REPUBLIC	MARBOCYL 2% inj	Marbofloxacin	20 mg/ml	Solution for injection	Calves Pigs	Intramuscular, subcutaneous
Czech Republic	Vétoquinol s.r.o. Zámečnická 411 288 02 Nymburk CZECH REPUBLIC	MARBOCYL bolus	Marbofloxacin	50 mg/tablet	Tablets	Cattle	Oral
Czech Republic	Vétoquinol s.r.o. Zámečnická 411 288 02 Nymburk CZECH REPUBLIC	MARBOCYL S 100 mg/ml injekční roztok	Marbofloxacin	100 mg/ml	Solution for injection	Cattle	Intramuscular
Denmark	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril Vet.	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Poultry	Intravenous, intramuscular
Denmark	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril Vet.	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs Poultry	Intravenous, intramuscular
Denmark	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril Vet.	Enrofloxacin	25 mg/ml	Oral solution	Cattle	Oral
Denmark	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril Vet.	Enrofloxacin	100 mg/ml	Oral solution	Poultry (excluding laying)	Oral

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Denmark	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Marbokem	Marbofloxacin	100 mg/ml	Solution for injection	Cattle	Intramuscular
Denmark	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Poultry	Intravenous, intramuscular
Denmark	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl Vet.	Marbofloxacin	20 mg/ml	Solution for injection	Cattle Pigs	Intravenous
Denmark	Vetrepharm A/S Øgelundvej 7 7323 Brande DENMARK	Branzil Vet.	Oxolinic acid	100%	Medicated premix	Fish	Oral
Denmark	Vetrepharm A/S Øgelundvej 7 7323 Brande DENMARK	Branzil Vet.	Oxolinic acid	1000 mg/g	Oral powder	Fish	Oral
Estonia	Industrial Veterinaria S.A. Esmeralda, 19 - 4º 08950 Esplugues de Llobregat SPAIN	Ganadexil Enrofloxacin	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral
Estonia	Industrial Veterinaria S.A. Esmeralda, 19 - 4º 08950 Esplugues de Llobregat SPAIN	Ganadexil Enrofloxacin Inj 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle (calves) Pigs Dogs	Subcutaneous, intramuscular

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Estonia	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	Hipralona Enro-I	Enrofloxacin	50 mg/ml	Solution for injection	Cattle (calves) Pigs	Intramuscular
Estonia	Pfizer Animal Health Ramsgate Road Sandwich, Kent CT13 9NJ UNITED KINGDOM	Advocin 180	Danofloxacin	180 mg/ml	Solution for injection	Cattle	Subcutaneous, intravenous
Estonia	Vétoquinol Biowet Sp. z o.o. ul. Kosynierów Gdyńskich 13-14 66-400 Gorzów Wielkopolski POLAND	Enrobioflox 10%	Enrofloxacin	100 mg/ml	Oral solution	Cattle (calves) Pigs Dog Cat Poultry	Oral
Estonia	Vétoquinol Biowet Sp. z o.o. ul. Kosynierów Gdyńskich 13-14 66-400 Gorzów Wielkopolski POLAND	Enrobioflox 5% injection	Enrofloxacin	50 mg/ml	Solution for injection	Cattle (calves) Pigs Dog	Intramuscular, subcutaneous
Estonia	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 10%	Marbofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intramuscular, subcutaneous
Estonia	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 2%	Marbofloxacin	20 mg/ml	Solution for injection	Cattle (calves) Pigs	Intramuscular, subcutaneous

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Finland	Bayer HealthCare AG Animal Health Division 51368 Leverkusen GERMANY	Baytril Vet	Enrofloxacin	50 mg/ml	Solution for injection	Cats Dogs Cattle Sheep Goats Pigs	Intramuscular, subcutaneous, intravenous
Finland	Bayer HealthCare AG Animal Health Division 51368 Leverkusen GERMANY	Baytril Vet	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Sheep Goats Pigs	Intramuscular, subcutaneous, intravenous
Finland	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Fenoflox 10% solution for injection	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
Finland	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Fenoflox 5% solution for injection	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
Finland	Pfizer Oy, Animal Health Tietokuja 4 00330 Helsinki FINLAND	Advocin Vet	Danofloxacin	25 mg/ml	Solution for injection	Cattle Pigs	Intramuscular, subcutaneous, intravenous

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
France	Animalcare Ltd Common Road Dunnington York YO19 5RU UNITED KINGDOM	Enrocare 10 % Solution Injectable Pour Bovins et Porcs	Enrofloxacin	100 mg	Solution for injection	Pigs Cattle	Subcutaneous, intravenous, intramuscular
France	Animalcare Ltd Common Road Dunnington York YO19 5RU UNITED KINGDOM	Enrocare 5 % Solution Injectable Pour Bovins, Porcs, Chiens et Chats	Enrofloxacin	50 mg	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
France	Bayer Santé 13 rue Jean Jaures 92807 Puteaux FRANCE	Baytril 10 % Solution Buvable	Enrofloxacin	100 mg	Oral solution	Poultry Turkey	Oral
France	Bayer Santé 13 rue Jean Jaures 92807 Puteaux FRANCE	Baytril 10 % Solution Injectable	Enrofloxacin	100 mg	Solution for injection	Cattle Pigs	Subcutaneous, intravenous, intramuscular
France	Bayer Santé 13 rue Jean Jaures 92807 Puteaux FRANCE	Baytril 2,5 % Solution Buvable	Enrofloxacin	25 mg	Oral solution	Calves	Oral
France	Bayer Santé 13 rue Jean Jaures 92807 Puteaux FRANCE	Baytril 2,5 % Solution Injectable	Enrofloxacin	25 mg	Solution for injection	Piglets	Intramuscular

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
France	Bayer Santé 13 rue Jean Jaures 92807 Puteaux FRANCE	Baytril 5 % Solution Injectable	Enrofloxacin	50 mg	Solution for injection	Cattle Dogs Pigs	Subcutaneous, intramuscular
France	Bayer Santé 13 rue Jean Jaures 92807 Puteaux FRANCE	Baytril Bolus	Enrofloxacin	500 mg	Bolus	Calves	Oral
France	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Flumiquil Comprimés De 1,010 g	Flumequine	150 mg	Tablet	Cattle Goats Horses Sheep	Oral
France	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Flumiquil Poudre A 10 %	Flumequine	100 mg	Powder for oral solution	Calves	Oral
France	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Flumiquil Poudre A 3 %	Flumequine	30 mg	Powder for oral solution	Cattle Goats Horses Rabbits Sheep Fish Pigs Poultry	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
France	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Flumiquil Suspension Injectable	Flumequine	30 mg	Suspension for injection	Cattle Goats Horses Sheep Pigs Poultry	Intramuscular
France	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Flumisol 10 %	Flumequine	100 mg	Oral solution	Calves Poultry	Oral
France	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Flumisol 36 %	Flumequine	360 mg	Oral solution	Calves Poultry	Oral
France	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Flumix Flumequine 160 Salmonides	Flumequine	160 mg	Premix for medicated feedingstuffs	Salmon Trout	Oral
France	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Flumix Flumequine 24 Lapin-Volaille	Flumequine	24 mg	Premix for medicated feedingstuffs	Rabbits Poultry	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
France	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Flumix Flumequine 48 Porc	Flumequine	48 mg	Premix for medicated feedingstuffs	Pigs	Oral
France	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Flumix Poudre A 3 %	Flumequine	30 mg	Powder for oral solution	Fish Pigs Calves Poultry	Oral
France	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Fluquick Poudre A 50 %	Flumequine	500 mg	Powder for oral solution	Cattle Goats Rabbits Sheep Fish Pigs Poultry	Oral
France	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Marbokem 100 mg/ml Solution Injectable Pour Bovins	Marbofloxacin	100 mg	Solution for injection	Cattle	Intramuscular
France	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Quinoflox 10% Solution Buvable	Enrofloxacin	100 mg	Oral solution	Turkeys Chickens	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
France	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Fenoflox 10 %	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
France	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Fenoflox 5 %	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
France	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Floxibac 10 % Solution Injectable	Enrofloxacin	100 mg	Solution for injection	Cattle Dogs Cats Pigs	Subcutaneous, intramuscular
France	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Floxibac 5 % Solution Injectable	Enrofloxacin	50 mg	Solution for injection	Cattle Dogs Cats Pigs	Subcutaneous, intravenous, intramuscular
France	Coophavet S.A.S Saint Herblion, B.P. 7 44153 Ancenis Cedex FRANCE	Cofamix Acide Oxolinique 40 Volaille	Oxolinic acid	0.04 g	Premix for medicated feedingstuffs	Broilers	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
France	Coophavet S.A.S Saint Herblion, B.P. 7 44153 Ancenis Cedex FRANCE	Cofamix Acide Oxolinique 80 Porc	Oxolinic acid	0.08 g	Premix for medicated feedingstuffs	Piglets	Oral
France	Coophavet S.A.S Saint Herblion, B.P. 7 44153 Ancenis Cedex FRANCE	Cofoxyl Liquide	Oxolinic acid	0.05 g	Oral solution	Broilers	Oral
France	Coophavet S.A.S Saint Herblion, B.P. 7 44153 Ancenis Cedex FRANCE	Cofoxyl P.O.	Oxolinic acid	100 mg	Powder for oral solution	Calves Poultry	Oral
France	DELTAVIT Zone d'activités Nord-Est du Bois de Teillay 35150 Janzé FRANCE	PM 35 Acide Oxolinique 80 Porc	Oxolinic acid	8 g/100ml	Premix for medicated feedingstuffs	Piglets	Oral
France	DELTAVIT Zone d'activités Nord-Est du Bois de Teillay 35150 Janzé FRANCE	Solution Acide Oxolinique 5% Volailles Deltavit	Oxolinic acid	50 mg	Oral solution	Broilers	Oral
France	Franvet Zone industrielle d'Etriche Route d'Avire, BP 103 49500 Segré Cedex FRANCE	Acide Oxolinique 30 Volaille Franvet	Oxolinic acid	30 mg	Premix for medicated feedingstuffs	Poultry	Oral
France	Franvet Zone industrielle d'Etriche Route d'Avire, BP 103 49500 Segré Cedex FRANCE	Acide Oxolinique 60 Porc Franvet	Oxolinic acid	60 mg	Premix for medicated feedingstuffs	Pigs	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
France	Laboratoires Biové 3 Rue de Lorraine, BP 45 62510 Arques FRANCE	Inoxyl Acide Oxolinique 240 Salmonides	Oxolinic acid	240 mg	Premix for medicated feedingstuffs	Trout	Oral
France	Laboratoires Biové 3 Rue de Lorraine, BP 45 62510 Arques FRANCE	Inoxyl Bolus	Oxolinic acid	274 mg	Tablet	Calves	Oral
France	Laboratoires Biové 3 Rue de Lorraine, BP 45 62510 Arques FRANCE	Inoxyl Pate Orale	Oxolinic acid	20 mg	Oral paste	Piglets	Oral
France	Laboratoires Biové 3 Rue de Lorraine, BP 45 62510 Arques FRANCE	Inoxyl Poudre Orale	Oxolinic acid	100 mg	Powder for oral solution	Calves Poultry	Oral
France	Laboratoires Biové 3 Rue de Lorraine, BP 45 62510 Arques FRANCE	Inoxyl Solution Buvable	Oxolinic acid	50 mg	Oral solution	Poultry	Oral
France	Laboratoires Biové 3 Rue de Lorraine, BP 45 62510 Arques FRANCE	Soloxol	Oxolinic acid	50 mg	Oral solution	Poultry	Oral
France	Laboratorios Karizoo, S.A. Polg. Industrial La Borda Mas Pujades, 11-12 08140 Caldes de Montbui (Barcelona) SPAIN	Kariflox 10 % Solution Buvable Pour Poules et Dindes	Enrofloxacin	100 mg	Oral solution	Turkeys Chickens	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
France	Laboratorios Karizoo, S.A. Polg. Industrial La Borda Mas Pujades, 11-12 08140 Caldes de Montbui (Barcelona) SPAIN	Kariflox 2,5 % Solution Buvable Pour Veaux	Enrofloxacin	25 mg	Oral solution	Calves	Oral
France	Noe S.A.S. 10 rue Clement Ader ZA le Patis 78120 Rambouillet FRANCE	Cafmix Acide Oxolinique 40 Volaille	Oxolinic acid	0.04 g	Premix for medicated feedingstuffs	Broilers	Oral
France	Noe S.A.S. 10 rue Clement Ader ZA le Patis 78120 Rambouillet FRANCE	Cafmix Acide Oxolinique 80 Porc	Oxolinic acid	0.08 g	Premix for medicated feedingstuffs	Piglets	Oral
France	Noe S.A.S. 10 rue Clement Ader ZA le Patis 78120 Rambouillet FRANCE	Oxavic 5	Oxolinic acid	0.05 g	Oral solution	Broilers	Oral
France	Pfizer 23/25 avenue du Docteur Lannelongue 75014 Paris FRANCE	Advocine 180, 180 mg/ml, Solution Injectable Pour Bovins	Danofloxacin	180 mg	Solution for injection	Cattle	Subcutaneous, intravenous
France	Pfizer 23/25 avenue du Docteur Lannelongue 75014 Paris FRANCE	Advocine 25	Danofloxacin	25 mg	Solution for injection	Cattle Pigs	Intramuscular

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
France	Pfizer 23/25 avenue du Docteur Lannelongue 75014 Paris FRANCE	Advocine Poudre Orale	Danofloxacin	0.1667 g	Oral powder	Chickens Broilers	Oral
France	Pfizer 23/25 avenue du Docteur Lannelongue 75014 Paris FRANCE	Danocin 180	Danofloxacin	180 mg	Solution for injection	Cattle	Subcutaneous
France	Sogeval Zone Industrielle des Touches 200, avenue de Mayenne B.P. 2227 53022 Laval Cedex 9 FRANCE	Concentrat Vo69 Acide Oxolinique 40 Volaille	Oxolinic acid	0.04 g	Premix for medicated feedingstuffs	Broilers	Oral
France	Sogeval Zone Industrielle des Touches 200, avenue de Mayenne B.P. 2227 53022 Laval Cedex 9 FRANCE	Concentrat Vo69 Acide Oxolinique 80 Porc	Oxolinic acid	0.08 g	Premix for medicated feedingstuffs	Piglets	Oral
France	Sogeval Zone Industrielle des Touches 200, avenue de Mayenne B.P. 2227 53022 Laval Cedex 9 FRANCE	Enroval 10 % Solution Buvable	Enrofloxacin	0.10 g	Oral solution	Poultry	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
France	Sogeval Zone Industrielle des Touches 200, avenue de Mayenne B.P. 2227 53022 Laval Cedex 9 FRANCE	Flumival 10% Solution Orale Pour Volailles et Veaux	Flumequine	100 mg	Oral solution	Calves Poultry	Oral
France	Sogeval Zone Industrielle des Touches 200, avenue de Mayenne B.P. 2227 53022 Laval Cedex 9 FRANCE	Oxolin 5 %	Oxolinic acid	0.05 g	Oral solution	Broilers	Oral
France	Universal Farma, S.L Gran Via Carlos III 98-7a 08028 Barcelona SPAIN	Lanflox 10 % Solution Buvable Pour Poulets et Dindes	Enrofloxacin	100 mg	Oral solution	Turkeys Chickens	Oral
France	Universal Farma, S.L Gran Via Carlos III 98-7a 08028 Barcelona SPAIN	Lanflox 2,5 % Solution Buvable Pour Veaux	Enrofloxacin	25 mg	Oral solution	Calves	Oral
France	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 10%	Marbofloxacin	100 mg	Solution for injection	Cattle Sows	Subcutaneous, intramuscular, intravenous
France	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 2 %	Marbofloxacin	20 mg	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular, intravenous

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
France	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl Bolus	Marbofloxacin	50 mg	Tablet	Calves	Oral
France	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl S	Marbofloxacin	100 mg	Solution for injection	Cattle	Intramuscular
France	Virbac S.A. 1ere Avenue 2065 M LID B.P. 27 06516 Carros Cedex FRANCE	Oxomid	Oxolinic acid	50 mg	Powder for oral solution	Pigs Calves	Oral
France	Virbac S.A. 1ere Avenue 2065 M LID B.P. 27 06516 Carros Cedex FRANCE	Oxomid 20	Oxolinic acid	200 mg	Powder for oral solution	Poultry	Oral
France	Virbac S.A. 1ere Avenue 2065 M LID B.P. 27 06516 Carros Cedex FRANCE	Oxomid Acide Oxolinique 240 Salmonides	Oxolinic acid	240 mg	Premix for medicated feeding stuff	Trout	Oral
France	Virbac S.A. 1ere Avenue 2065 M LID B.P. 27 06516 Carros Cedex FRANCE	Revofloxx 10 % Solution Injectable	Enrofloxacin	100 mg	Solution for injection	Cattle Pigs	Subcutaneous, intravenous

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
France	Virbac S.A. 1ere Avenue 2065 M LID B.P. 27 06516 Carros Cedex FRANCE	Revoflox 5 % Solution Injectable	Enrofloxacin	50 mg	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
France	Virbac S.A. 1ere Avenue 2065 M LID B.P. 27 06516 Carros Cedex FRANCE	Tenotryl 10 % Solution Buvable	Enrofloxacin	100 mg	Oral solution	Turkeys Chickens	Oral
Germany	Albrecht GmbH Hauptstr. 6 - 8 88326 Aulendorf GERMANY	Enro-Sleecol 100 mg/ml	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intravenous, intramuscular, subcutaneous
Germany	Albrecht GmbH Hauptstr. 6 - 8 88326 Aulendorf GERMANY	Enro-Sleecol 50 mg/ml	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs	Intravenous, intramuscular, subcutaneous
Germany	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril - Das Original - 10% Injektionslösung	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intravenous, intramuscular, subcutaneous
Germany	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril - Das Original - 5% Injektionslösung	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs	Intravenous, intramuscular, subcutaneous
Germany	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril 0.5%	Enrofloxacin	5 mg/ml	Gastroenteral solution	Cattle	Gastroenteral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Germany	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril 10%	Enrofloxacin	100 mg/ml	Gastroenteral solution	Chickens Turkeys Hens	Gastroenteral
Germany	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril 100mg/ml Injektionslösung	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intravenous, intramuscular, subcutaneous
Germany	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril 2.5%	Enrofloxacin	25 mg/ml	Gastroenteral solution	Cattle	Gastroenteral
Germany	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril Uterusstab	Enrofloxacin	200 mg	Intrauterine tablet	Cattle	Intrauterine
Germany	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril - Das Original - 2,5 % Injektionslösung	Enrofloxacin	25 mg/ml	Solution for injection	Pigs Dogs Cats Rabbit	Intravenous, intramuscular, subcutaneous
Germany	Calluna Pharma bvba Lindendreef 16 box 4 2320 Hoogstraten BELGIUM	Enrofloxacin 10% WDT, Solution for injection	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intravenous, intramuscular, subcutaneous
Germany	Calluna Pharma bvba Lindendreef 16 box 4 2320 Hoogstraten BELGIUM	Enrofloxacin 5% WDT, Solution for injection	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs	Intramuscular, subcutaneous

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Germany	Krka, d.d, Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 100 mg/ml	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intramuscular, subcutaneous
Germany	Krka, d.d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 50 mg/ml	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs	Intramuscular, subcutaneous
Germany	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil	Enrofloxacin	100 mg/ml	Gastroenteral solution	Chickens Turkeys Hens	Gastroenteral
Germany	Medistar Arzneimittel-Vertrieb GmbH Schäferkampstr. 20 59439 Holzwickede GERMANY	Enrostar 10%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intravenous, intramuscular, subcutaneous
Germany	Medistar Arzneimittel-Vertrieb GmbH Schäferkampstr. 20 59439 Holzwickede GERMANY	Enrostar 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs	Intramuscular, subcutaneous
Germany	Pfizer GmbH Linkstr. 10 10785 Berlin GERMANY	Advocid 180mg/ml	Danofloxacin	180 mg/ml	Solution for injection	Cattle	Subcutaneous, intravenous

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Germany	Pfizer GmbH Linkstr. 10 10785 Berlin GERMANY	Advocid 2,5 %	Danofloxacin	25 mg/ml	Solution for injection	Cattle Pigs	Intramuscular, intravenous
Germany	Serumwerk Bernburg AG Hallesche Landstr. 105b 06406 Bernburg GERMANY	Ursofloxacin 10%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intravenous, intramuscular, subcutaneous
Germany	Serumwerk Bernburg AG Hallesche Landstr. 105b 06406 Bernburg GERMANY	Ursofloxacin 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs	Intravenous, intramuscular, subcutaneous
Germany	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 10%	Marbofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intravenous, intramuscular, subcutaneous
Germany	Vétoquinol Verwaltungs GmbH Parkstr. 10 88212 Ravensburg GERMANY	Marbocyl 2%	Marbofloxacin	20 mg/ml	Solution for injection	Cattle Pigs	Intravenous, intramuscular, subcutaneous
Germany	Vétoquinol Verwaltungs GmbH Parkstr. 10 88212 Ravensburg GERMANY	Marbocyl Bolus	Marbofloxacin	50 mg	Intraruminal device	Cattle	Gastroenteral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Germany	Vétoquinol Verwaltungs GmbH Parkstr. 10 88212 Ravensburg GERMANY	Marbocyl S, 10%	Marbofloxacin	100 mg/ml	Solution for injection	Cattle	Intramuscular
Germany	Virbac S.A. 1ere Avenue 2065 M LID B.P. 27 06516 Carros Cedex FRANCE	Powerflox 100 mg/ml Solution for injection	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intravenous, intramuscular, subcutaneous
Germany	Virbac S.A. 1ere Avenue 2065 M LID B.P. 27 06516 Carros Cedex FRANCE	Powerflox 50 mg/ml Solution for injection	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Intramuscular, subcutaneous
Greece	Agroseed-Candilidis Parapleuros Attikis Road Exodos 1, Thesi Xiro Pigadi 19600 Mandra Attikis GREECE	Flumequine Agroseed 10%	Flumequine	10%	Oral powder	Calves Lambs Poultry Fish	Oral
Greece	Agroseed-Candilidis Parapleuros Attikis Road Exodos 1, Thesi Xiro Pigadi 19600 Mandra Attikis GREECE	Flumequine Agroseed 20%	Flumequine	20%	Oral powder	Calves Lambs Poultry	Oral
Greece	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril	Enrofloxacin	5%	Solution for injection	Calves Pigs	Subcutaneous, intramuscular

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Greece	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril	Enrofloxacin	0.5%	Oral solution	Chickens Turkeys	Oral
Greece	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril	Enrofloxacin	2.5%	Oral solution	Calves	Oral
Greece	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril	Enrofloxacin	10%	Oral solution	Chickens Turkeys	Oral
Greece	Ceva Hellas S.A. Ag. Nikolaou 15 17455 Alimos Attikis GREECE	Flumix	Flumequine	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Greece	Dopharma Research BV Zalmweg 24 4941 VX Raamsdonksveer NETHERLANDS	Flumequine 50%	Flumequine	50%	Oral powder	Broilers	Oral
Greece	Laboratoires Biové 3 Rue de Lorraine, BP 45 62510 Arques FRANCE	Inoxyl	Oxolinic acid, sodium salt	300 mg/tablet	Tablets	Calves	Oral
Greece	Laboratoires Biové 3 Rue de Lorraine, BP 45 62510 Arques FRANCE	Inoxyl	Oxolinic acid	50 mg/ml	Oral solution	Chickens	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Greece	Laboratoires Biové 3 Rue de Lorraine, BP 45 62510 Arques FRANCE	Inoxyl	Oxolinic acid	240 mg/g	Premix for medicated feedingstuffs	Broilers Pigs	Oral
Greece	Laboratoires Biové 3 Rue de Lorraine, BP 45 62510 Arques FRANCE	Inoxyl	Oxolinic acid	20 mg/ml	Oral suspension	Pigs	Oral
Greece	Laboratoires Biové 3 Rue de Lorraine, BP 45 62510 Arques FRANCE	Inoxyl	Oxolinic acid, sodium salt	115 mg/g	Oral powder	Calves Chickens	Oral
Greece	Laboratorio Maymo, S.A. Via Augusta, 302 08017 Barcelona SPAIN	Quimiocoli	Enrofloxacin	100 mg/ml	Oral solution	Broilers	Oral
Greece	New Vet Hellas AE Fleming 15 15123 Marousi Attikis GREECE	Flexin	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Greece	Pfizer Hellas SA Mesogeion Av 243 15451 N.Psihiko Athens GREECE	Advocin	Danofloxacin	25 mg/ml	Solution for injection	Cattle Pigs	Intramuscular, intravenous
Greece	Pharmaqua-D. Kokkoris and Bros D. Solomou 28 14451 Metamorfosi Attikis GREECE	Vitaquin 500	Flumequine	50%	Oral powder	Broilers	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Greece	S.P. Veterinaria S.A. Ctra. de Reus a Vignols km 4.1 43330 Riudoms (Tarragona) SPAIN	Enrofloxacin 10%	Enrofloxacin	10%	Oral solution	Chickens Turkeys	Oral
Greece	Tetoros Bros ABE 10 Km National road Athens-Lamia 14451 Metamorfofi Attikis GREECE	Flumequine Durden	Flumequine	50%	Oral powder	Broilers	Oral
Greece	VETHELLAS 31 Augoustou 51 41221 Larissa GREECE	Oxolinic Acid	Oxolinic acid	50%	Premix for medicated feedingstuffs	Fish	Oral
Greece	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl	Marbofloxacin	2%	Solution for injection	Calves Pigs	Subcutaneous, intramuscular
Greece	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl	Marbofloxacin	10%	Solution for injection	Cattle Sows	Subcutaneous, intramuscular
Greece	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl S	Marbofloxacin	10%	Solution for injection	Cattle	Intramuscular

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Greece	Virbac S.A. 1ere Avenue 2065 M LID B.P. 27 06516 Carros Cedex FRANCE	Floxatril	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Hungary	Abo-Mix Co. Ltd. Simai u. 6 4400 Nyíregyháza HUNGARY	Euro-Quin 10 % Powder for Oral Solution	Flumequine	50 g/500 g	Powder	Chickens	Oral
Hungary	Ascor Chimici S.r.l. Via Piana 265 47032 Capocolle di Bertinoro (FC) ITALY	Naquilene 500 MP Premix For Medicated Feeding Stuff	Flumequine	50mg/100g	Premix for medicated feedingstuffs	Pigs	Oral
Hungary	Bayer Hungária Kft. Alkotás u. 50. 1123 Budapest HUNGARY	Baytril 0,5 % Oral Solution	Enrofloxacin	5 mg/ml	Oral solution	Pigs	Oral
Hungary	Bayer Hungária Kft. Alkotás u. 50. 1123 Budapest HUNGARY	Baytril 10 % injection	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Hungary	Bayer Hungária Kft. Alkotás u. 50. 1123 Budapest HUNGARY	Baytril 10 % Oral Solution	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Hungary	Bayer Hungária Kft. Alkotás u. 50. 1123 Budapest HUNGARY	Baytril 2,5 % Injection	Enrofloxacin	25 mg/ml	Solution for injection	Pigs Rabbits Dogs Cats Exotic pet animals	Intramuscular, subcutaneous
Hungary	Bayer Hungária Kft. Alkotás u. 50. 1123 Budapest HUNGARY	Baytril 2,5 % Oral Solution	Enrofloxacin	25 mg/ml	Oral solution	Calves Exotic pet animals	Oral
Hungary	Bayer Hungária Kft. Alkotás u. 50. 1123 Budapest HUNGARY	Baytril 5 % injection	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs	Subcutaneous, intramuscular
Hungary	Ceva-Phylaxia Co. Ltd. Szállás u. 5. 1107 Budapest HUNGARY	Flumiquil 50 % powder	Flumequine	50 g/100 g	Powder	Calves Pigs Chickens Turkeys Fish	Oral
Hungary	Ceva-Phylaxia Co. Ltd. Szállás u. 5. 1107 Budapest HUNGARY	Marbochem 10 % solution for injection	Marbofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intramuscular, subcutaneous
Hungary	Ceva-Phylaxia Co. Ltd. Szállás u. 5. 1107 Budapest HUNGARY	Quinoex 10 oral solution	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Hungary	Ceva-Phylaxia Co. Ltd. Szállás u. 5. 1107 Budapest HUNGARY	Quinoflox 100 mg/ml oral solution	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Hungary	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Fenoflox 10 %	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
Hungary	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Fenoflox 5 %	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
Hungary	Divasa-Farmavic S.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	Enrovet 10 % solution	Enrofloxacin	100 mg/ml	Oral solution	Chickens	Oral
Hungary	Dunavet-B Zrt. Dolgos u. 2. 1126 Budapest HUNGARY	Ganadexil enrofloxacina 0,5 % oral pump	Enrofloxacin	5 mg/ml	Oral solution	Pigs	Oral
Hungary	Dunavet-B Zrt. Dolgos u. 2. 1126 Budapest HUNGARY	Ganadexil enrofloxacina oral solution	Enrofloxacin	100 mg/ml	Oral solution	Chickens	Oral

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Hungary	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 10 % injection	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Hungary	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 10 % oral solution	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Hungary	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 5 % injection	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Sheep Goats Pigs Dogs	Subcutaneous, intramuscular
Hungary	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 5 % premix for medicated feeding stuff	Enrofloxacin	5 g/100 g	Medicated premix	Pigs Chickens	Oral
Hungary	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil Max 100 mg/ml injection	Enrofloxacin	100 mg/ml	Solution for injection	Cattle	Subcutaneous
Hungary	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	Hipralona Enro-I Injection	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs	Intramuscular
Hungary	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	Hipralona Enro-S Oral Solution	Enrofloxacin	100 mg/ml	Oral solution	Chickens	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Hungary	Laboratorios Karizoo, S.A. Polg. Industrial La Borda Mas Pujades, 11-12 08140 Caldes de Montbui (Barcelona) SPAIN	Kariflox 10 % oral solution	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Hungary	Laboratorios Syva, S.A. Avda Parroco Pablo Diez 49-57 24010 Trobajo del Camino SPAIN	Syvaquinol 10 % oral solution	Enrofloxacin	100 mg/ml	Oral solution	Chickens	Oral
Hungary	Laboratorios Syva, S.A. Avda Parroco Pablo Diez 49-57 24010 Trobajo del Camino SPAIN	Syvaquinol 100 injection	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Hungary	Lavet Gyógyszergyártó Kft. Ottó u. 14 1161 Budapest HUNGARY	Diflocin 10 % oral solution	Difloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Hungary	Lavet Gyógyszergyártó Kft. Ottó u. 14 1161 Budapest HUNGARY	Enro-Quinol Plus 10 % oral solution	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Hungary	Lavet Gyógyszergyártó Kft. Ottó u. 14 1161 Budapest HUNGARY	Quinocol oral solution	Enrofloxacin Colistin sulphate	100 mg/ml enrofloxacin 109 IU colistin sulphate	Oral solution	Chickens Turkeys	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Hungary	Orion Corporation Orionintie 1A 02200 Espoo FINLAND	Efrion 100 mg/ml oral solution	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Hungary	S.P. Veterinaria S.A. Ctra. de Reus a Vignols km 4.1 43330 Riudoms (Tarragona) SPAIN	Enrocoli oral solution	Enrofloxacin Colistin sulphate	50 mg/ml enrofloxacin 500 000 IU/ml colistin sulphate	Oral solution	Chickens	Oral
Hungary	Swifts Pharma Kft. Kossuth u. 25. 2821 Gyermely HUNGARY	Quinovet F 10 % oral solution	Enrofloxacin	10 g/100 ml	Oral solution	Cattle (suckling calves) Pigs Chickens Turkeys	Oral
Hungary	Vétoquinol Biowet Sp. z o.o. ul. Kosynierów Gdyńskich 13-14 66-400 Gorzów Wielkopolski POLAND	Enrobioflox 10 % oral solution	Enrofloxacin	100 mg/ml	Oral solution	Cattle Pigs Chickens Dogs Cats	Oral
Hungary	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 10 % injection	Marbofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Hungary	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 2 % injection	Marbofloxacin	20 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Hungary	VMD Állatgyógyászati Kft. Közraktár u. 22/b. 1093 Budapest HUNGARY	Enroveto-20 oral solution	Enrofloxacin	200 g/1000 ml	Oral solution	Pigs Chickens Turkeys	Oral
Iceland	Bayer A/S Nørgaardsvej 32 Postboks 2090 2800 KGS Lyngby DENMARK	Baytril vet	Enrofloxacin	25 mg/ml	Oral solution	Calves	Oral
Iceland	Bayer A/S Nørgaardsvej 32 Postboks 2090 2800 KGS Lyngby DENMARK	Baytril vet	Enrofloxacin	50 mg/ml	Solution for injection	Calves Steer Pigs Poultry Dogs Cats	Intravenous, intramuscular
Iceland	Bayer A/S Nørgaardsvej 32 Postboks 2090 2800 KGS Lyngby DENMARK	Baytril vet	Enrofloxacin	100 mg/ml	Solution for injection	Calves Steer Pigs Poultry Dogs Cats	Intravenous, intramuscular
Ireland	Bayer plc Animal Health Division Bayer House Strawberry Hill Newbury Berkshire RG14 1JA UNITED KINGDOM	Baytril 2.5% Oral Solution	Enrofloxacin	25 mg/ml	Oral solution	Calves Exotic Animals (small mammals, reptiles, avian species)	Oral

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Ireland	Bayer plc Animal Health Division Bayer House Strawberry Hill Newbury Berkshire RG14 1JA UNITED KINGDOM	Baytril 5% Solution for Injection	Enrofloxacin	5%	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
Ireland	Bayer plc Animal Health Division Bayer House Strawberry Hill Newbury Berkshire RG14 1JA UNITED KINGDOM	Baytril 10% Oral Solution.	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Ireland	Bayer plc Animal Health Division Bayer House Strawberry Hill Newbury Berkshire RG14 1JA UNITED KINGDOM	Baytril 10% Solution for Injection	Enrofloxacin	10%	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Ireland	Bayer plc Animal Health Division Bayer House Strawberry Hill Newbury Berkshire RG14 1JA UNITED KINGDOM	Baytril Max 10% Solution for Injection	Enrofloxacin	100 mg/ml	Solution for injection	Cattle	Subcutaneous

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Ireland	Bayer plc Animal Health Division Bayer House Strawberry Hill Newbury Berkshire RG14 1JA UNITED KINGDOM	Baytril Piglet Doser 0.5% Oral Solution	Enrofloxacin	5 mg/ml	Oral solution	Piglets	Oral
Ireland	Ceva Animal Health Ltd 90 The Broadway Chesham Buckinghamshire HP5 1EG UNITED KINGDOM	Flumisol Oral Solution 100mg/ml	Flumequine	100 mg/ml	Oral solution	Poultry	Oral
Ireland	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Marbokem 100 mg/ml solution for injection	Marbofloxacin	100 mg/ml	Solution for injection	Cattle	Intramuscular
Ireland	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Fenoflox 10%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Ireland	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Fenoflox 5%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
Ireland	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Floxibac 10% solution for injection	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intravenous, intramuscular
Ireland	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Floxibac 5% solution for injection	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
Ireland	Animalcare Ltd Common Road Dunnington York YO19 5RU UNITED KINGDOM	Enrocare 10% Solution for Injection for Cattle, Pigs	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Ireland	Animalcare Ltd Common Road Dunnington York YO19 5RU UNITED KINGDOM	Enrocare 5% Solution for Injection for Cattle, Pigs, Dogs and Cats	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
Ireland	Krka, d.d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil solution for injection 100mg/ml for cattle and pigs	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous intramuscular
Ireland	Krka d.d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil solution for injection 50 mg/ml for calves, pigs and dogs	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs	Subcutaneous, intramuscular
Ireland	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil Max 100 mg/ml solution for injection for cattle	Enrofloxacin	100 mg/ml	Solution for injection	Cattle	Subcutaneous
Ireland	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil oral solution 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Ireland	Laboratorios Karizoo, S.A. Polg. Industrial La Borda Mas Pujades, 11-12 08140 Caldes de Montbui (Barcelona) SPAIN	ENRO-K 10% Oral Solution	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral

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Ireland	Laboratorios Karizoo, S.A. Polg. Industrial La Borda Mas Pujades, 11-12 08140 Caldes de Montbui (Barcelona) SPAIN	KARIFLOX 10% Oral Solution for Chickens and Turkeys	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Ireland	Laboratorios Karizoo, S.A. Polg. Industrial La Borda Mas Pujades, 11-12 08140 Caldes de Montbui (Barcelona) SPAIN	KARIFLOX 25 mg/ml oral solution for calves	Enrofloxacin	25 mg/ml	Oral solution	Calves	Oral
Ireland	Laboratorios Karizoo, S.A. Polg. Industrial La Borda Mas Pujades, 11-12 08140 Caldes de Montbui (Barcelona) SPAIN	KARIFLOX 5 mg/ml oral solution for piglets	Enrofloxacin	5 mg/ml	Oral solution	Piglets	Oral
Ireland	Orion Corporation Orionintie 1A 02200 Espoo FINLAND	EFRION 100 mg/ml Oral Solution for Chickens and Turkeys	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Ireland	Pfizer Animal Health Walton Oaks Dorking Road Tadworth, Surrey FT20 7NS UNITED KINGDOM	ADVOCIN 180, 180 mg/ml, Solution for Injection for Cattle	Danofloxacin	180 mg/ml	Solution for injection	Cattle	Subcutaneous, intravenous

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Ireland	Pfizer Animal Health Walton Oaks Dorking Road Tadworth, Surrey FT20 7NS UNITED KINGDOM	Advocin Injectable Solution	Danofloxacin	25 mg/ml	Solution for injection	Cattle Pigs	Intramuscular, intravenous, intramuscular
Ireland	S.P. Veterinaria S.A. Ctra. de Reus a Vignols km 4.1 43330 Riudoms (Tarragona) SPAIN	FLOXAMAX Enrofloxacin 10 % concentrate for oral solution. Chickens and turkeys	Enrofloxacin	10%	Concentrate for oral solution	Chickens Turkeys	Oral
Ireland	Universal Farma, S.L Gran Via Carlos III 98-7a 08028 Barcelona SPAIN	Lanflox 10% Oral Solution for Chickens and Turkeys	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Ireland	Universal Farma, S.L Gran Via Carlos III 98-7a 08028 Barcelona SPAIN	Unisol (Aviflox 10% Oral Solution)	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Ireland	Universal Farma, S.L Gran Via Carlos III 98-7a 08028 Barcelona SPAIN	UNISOL 0.5% oral solution for piglets	Enrofloxacin	5 mg/ml	Oral solution	Piglets	Oral
Ireland	Universal Farma, S.L Gran Via Carlos III 98-7a 08028 Barcelona SPAIN	UNISOL 2.5% oral solution for calves	Enrofloxacin	25 mg/ml	Oral solution	Calves	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Ireland	Vetoquinol UK Ltd Great Slade, Buckingham Industrial Estate Buckingham Buckinghamshire MK18 1PA UNITED KINGDOM	Marbocyl 10% Solution for Injection	Marbofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intramuscular, subcutaneous, intravenous
Ireland	Vetoquinol UK Ltd Great Slade, Buckingham Industrial Estate Buckingham Buckinghamshire MK18 1PA UNITED KINGDOM	Marbocyl 2% w/v Solution for Injection	Marbofloxacin	2%	Solution for injection	Pre-ruminating calves Ruminating calves Pigs	Intramuscular, subcutaneous, intravenous
Ireland	Vetoquinol UK Ltd Great Slade, Buckingham Industrial Estate Buckingham Buckinghamshire MK18 1PA UNITED KINGDOM	Marbocyl Bolus	Marbofloxacin	50 mg	Bolus	Cattle (neonatal calves)	Oral
Ireland	Vetoquinol UK Ltd Great Slade, Buckingham Industrial Estate Buckingham Buckinghamshire MK18 1PA UNITED KINGDOM	Marbocyl Solo 10% Solution for Injection for cattle	Marbofloxacin	100 mg/ml	Solution for injection	Cattle	Intramuscular

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Italy	Andreotti Farmaceutical Srl Via Eridania Ovest 65 45030 Guarda Veneta (RO) ITALY	Flumequine 50% Liquid (Andreotti)	Flumequine	No information available	No information available	No information available	No information available
Italy	Ascor Chimici S.r.l. Via Piana 265 47032 Capocolle di Bertinoro (FC) ITALY	Amoxicillina 22,5% + Flumechina 15%	Amoxicillin Flumequine	amoxicillin 22,5g/100g flumequine15g/100g	Powder for oral solution	Pigs Broilers Turkeys	Oral
Italy	Ascor Chimici S.r.l. Via Piana 265 47032 Capocolle di Bertinoro (FC) ITALY	Flumechina 10% (Ascor Chimici)	Flumequine	10g/100g	Powder for oral solution	Broiler	Oral
Italy	Ascor Chimici S.r.l. Via Piana 265 47032 Capocolle di Bertinoro (FC) ITALY	Flumechina 10% Liquido (Ascor Chimici)	Flumequine	100mg/ml	Oral solution	Broiler	Oral
Italy	Ascor Chimici S.r.l. Via Piana 265 47032 Capocolle di Bertinoro (FC) ITALY	Flumechina 20% Liquid (Ascor Chimici)	Flumequine	200mg/ml	Oral solution	Broiler	Oral
Italy	Ascor Chimici S.r.l. Via Piana 265 47032 Capocolle di Bertinoro (FC) ITALY	Flumechina 50% (Ascor Chimici)	Flumequine	500mg/g	Powder for oral solution	Broiler	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Italy	Ascor Chimici S.r.l. Via Piana 265 47032 Capocolle di Bertinoro (FC) ITALY	Naquilene 500 MP	Flumequine	50g/100g	Premix for medicated feedingstuffs	Pigs Fish	Oral
Italy	Ascor Chimici S.r.l. Via Piana 265 47032 Capocolle di Bertinoro (FC) ITALY	Naquimox	Amoxicillin trihydrate Flumequine	No information available	No information available	No information available	No information available
Italy	Ascor Chimici S.r.l. Via Piana 265 47032 Capocolle di Bertinoro (FC) ITALY	Vasthinol	Colistin sulphate Oxolinic acid	1MUI/g Colistin sulphate 200mg/g oxolinic acid	Powder for oral solution	Calves Piglets Broilers	Oral
Italy	Azienda Terapeutica Italiana A.T.I. S.P.A. via della Libertà 1 40064 Ozzano dell' Emilia (BO) ITALY	Flumexil	Flumequine	No information available	No information available	No information available	No information available
Italy	Bayer S.p.A. Viale Certosa, 130 20156 Milano ITALY	Baytril 10% OL Oral solution	Enrofloxacin	100 mg/ml	Oral solution	Chicken (excluding laying hens) Turkey Rabbit	Oral
Italy	Bayer S.p.A. Viale Certosa, 130 20156 Milano ITALY	Baytril 0.5%	Enrofloxacin	5 mg/ml	Oral solution	Piglet Rabbit	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Italy	Bayer S.p.A. Viale Certosa, 130 20156 Milano ITALY	Baytril 10% oral solution	Enrofloxacin	100 mg/ml	Oral solution	Chickens (excluding laying hens) Turkey	Oral
Italy	Bayer S.p.A. Viale Certosa, 130 20156 Milano ITALY	Baytril 10%	Enrofloxacin	100 mg/ml	Solution injectable	Cattle Goat Sheep Pig	Subcutaneous intravenous
Italy	Bayer S.p.A. Viale Certosa, 130 20156 Milano ITALY	Baytril 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Goat Sheep Pig Rabbit	Subcutaneous intravenous
Italy	Bayer S.p.A. Viale Certosa, 130 20156 Milano ITALY	Baytril Max	Enrofloxacin	100 mg/ml	Solution for injection	Cattle	Subcutaneous
Italy	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Marbokem	Marbofloxacin	100 mg/ml	Solution for injection	Cattle	Intramuscular
Italy	Ceva Vetem Via Colleoni 15 20041 Agrate Brianza (MI) ITALY	Flumechina 20% Liquid (Ceva Vetem)	Flumequine	No information available	No information available	No information available	No information available
Italy	Ceva Vetem Via Colleoni 15 20041 Agrate Brianza (MI) ITALY	Flumechina 50% Liquid (Ceva Vetem)	Flumequine	No information available	No information available	No information available	No information available

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Italy	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Fenoflox 10%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
Italy	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Fenoflox 5%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
Italy	Chemifarma S.p.A. 16, Via Don Eugenio Servadei 47100 Forli ITALY	Colifarm 200	Flumequine	20g/100g	Premix for medicated feedingstuffs	Broiler	Oral
Italy	Chemifarma S.p.A. 16, Via Don Eugenio Servadei 47100 Forli ITALY	Flumechina 20% (Chemifarma)	Flumequine	20g/100g	Powder	Poultry Pigs	Oral
Italy	Chemifarma S.p.A. 16, Via Don Eugenio Servadei 47100 Forli ITALY	Flumechina 50% Liquid (Chemifarma)	Flumequine	500 mg/ml	Oral solution	Poulrty	Oral
Italy	DOX-AL Italia S.p.A. Via Mascagni 6 20050 Sulbiate Sup. (MI) ITALY	Doxaquin	Flumequine	10g/100g	Powder	Calves Pigs Rabbits Broilers Turkeys	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Italy	DOX-AL Italia S.p.A. Via Mascagni 6 20050 Sulbiate Sup. (MI) ITALY	Floxadox	Enrofloxacin	100 mg/ml	Oral solution	Broilers Turkeys Rabbits	Oral
Italy	DOX-AL Italia S.p.A. Via Mascagni 6 20050 Sulbiate Sup. (MI) ITALY	Flumechina 20% Liquid (Dox-al)	Flumequine	No information available	No information available	No information available	No information available
Italy	DOX-AL Italia S.p.A. Via Mascagni 6 20050 Sulbiate Sup. (MI) ITALY	Flumechina 40% Liquid (Dox-al)	Flumequine	400 mg/ml	Oral solution	Broilers Turkeys	Oral
Italy	DOX-AL Italia S.p.A. Via Mascagni 6 20050 Sulbiate Sup. (MI) ITALY	Flumechina 50% (Dox-al)	Flumequine	No information available	No information available	No information available	No information available
Italy	DOX-AL Italia S.p.A. Via Mascagni 6 20050 Sulbiate Sup. (MI) ITALY	Ossolene	Oxolinic acid, sodium salt	No information available	No information available	No information available	No information available
Italy	Fatro S.p.A., Via Emilia 285 400064 Ozzano Emilia (BO) ITALY	Valemas	Enrofloxacin	No information available	No information available	No information available	No information available
Italy	Filozoo Srl Via del Commercio, 28/30 41012 Carpi (MO) ITALY	Flumechina 20% Liquid (Filozoo)	Flumequine	No information available	No information available	No information available	No information available

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Italy	Industria Italiana Integratori TREI S.p.A. Via P. Bembo 12 411 00 Modema ITALY	Flumechina 20% Liquid (Trei)	Flumequine	No information available	No information available	No information available	No information available
Italy	Industria Italiana Integratori TREI S.p.A. Via P. Bembo 12 411 00 Modema ITALY	Flumechina 50% Liquid (Trei)	Flumequine	No information available	No information available	No information available	No information available
Italy	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil Max	Enrofloxacin	No information available	No information available	No information available	No information available
Italy	Laboratorio Vaccinogeno Pagnini Via Diaz 147/149 80052 Portici (NA) ITALY	Flumechina 2% Liquid (Vaccinogeno)	Flumequine	200 mg/ml	Oral solution	Broiler	Oral
Italy	Laboratorio Vaccinogeno Pagnini Via Diaz 147/149 80052 Portici (NA) ITALY	Flumechina 20% Liquid (Vaccinogeno)	Flumequine	200 mg/ml	Oral solution	Broiler	Oral
Italy	Laboratorios Karizoo, S.A. Polg. Industrial La Borda Mas Pujades, 11-12 08140 Caldes de Montbui (Barcelona) SPAIN	K-Flox 10%	Enrofloxacin	100mg/ml	Oral solution	Poultry Rabbits	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Italy	Le Vet. Pharma BV Willeskop 212 3421 GW Oudewater NETHERLANDS	Floxabactin	Enrofloxacin	No information available	No information available	No information available	No information available
Italy	Le Vet. Pharma BV Willeskop 212 3421 GW Oudewater THE NETHERLANDS	Enrotab	Enrofloxacin	No information available	No information available	No information available	No information available
Italy	Neofarma Srl Via Emilia Km 18n. 1854 47020 Longiano (FC) ITALY	Flumequine 50% Liquid (Neofarma)	Flumequine	No information available	No information available	No information available	No information available
Italy	Nuova ICC S.r.l. Via Walter Tobagi 7/b Peschiera Borromeo 20068 Milano ITALY	Chinogel 50 Mix	Flumequine	No information available	No information available	No information available	No information available
Italy	Nuova ICC S.r.l. Via Walter Tobagi 7/b Peschiera Borromeo 20068 Milano ITALY	Flumechina 40% Liquid (Nuova ICC)	Flumequine	400 mg/ml	Oral solution	Broiler	Oral
Italy	Nuova ICC S.r.l. Via Walter Tobagi 7/b Peschiera Borromeo 20068 Milano ITALY	Flumechina 50% (Nuova ICC)	Flumequine	50g/100g	Powder	Broiler	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Italy	Nuova ICC S.r.l. Via Walter Tobagi 7/b Peschiera Borromeo 20068 Milano ITALY	ICC-O-Flu 50%	Flumequine	50g/100g	Medicated premix	Fish	Oral
Italy	Pfizer Italia S.r.l. S.S. 156, Km 50 04010 Borgo S. Michele ITALY	Advovet 180	Danofloxacin	180 mg/ml	Solution for injection	Cattle	Subcutaneous intravenous
Italy	Pfizer Italia S.r.l. S.S. 156, Km 50 04010 Borgo S. Michele ITALY	Advovet soluzione iniettabile	Danofloxacin	25 mg/ml	Solution for injection	Cattle Pigs	Intramuscular (cattle and pig), intravenous (cattle)
Italy	S.P. Veterinaria S.A. Ctra. de Reus a Vignols km 4.1 43330 Riudoms (Tarragona) SPAIN	Colmyc injectable	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Italy	S.P. Veterinaria S.A. Ctra. de Reus a Vignols km 4.1 43330 Riudoms (Tarragona) SPAIN	Floxavex	Enrofloxacin	100 mg/ml	Oral solution	Broilers Turkeys	Oral
Italy	Sanofi Santé Nutrition Animale , La Ballestière - Bp 126 , 33051, Francia	Flumisol	Flumequine	No information available	No information available	No information available	No information available
Italy	Sintofarm S.p.A. Via Togliatti 5 42016 Guastalla ITALY	Flumechina 20% Liquid (Sintofarm)	Flumequine	No information available	No information available	No information available	No information available

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Italy	Sintofarm S.p.A. Via Togliatti 5 42016 Guastalla ITALY	Flumechina 200 (Sintofarm)	Flumequine	No information available	No information available	No information available	No information available
Italy	Tecnozoo S.n.c. Via Piave 120 - Torreselle 35017 Piombino Dese (PD) ITALY	Flumechina 20% Liquid (Tecnozoo)	Flumequine	No information available	No information available	No information available	No information available
Italy	Tecnozoo S.n.c. Via Piave 120 - Torreselle 35017 Piombino Dese (PD) ITALY	Flumet 200	Flumequine	No information available	No information available	No information available	No information available
Italy	Unione Commerciale Lombarda S.p.A. Via G. Di Vittorio, 36 25125 Brescia ITALY	Flumechina 20% Liquida	Flumequine	No information available	No information available	No information available	No information available
Italy	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 10 % solution for injection	Marbofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intravenous, intramuscular, subcutaneous
Italy	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 2 % solution for injection	Marbofloxacin	20 mg/ml	Solution for injection	Cattle Fattening pigs	Intravenous, intramuscular, subcutaneous

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Italy	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl Bolus	Marbofloxacin	50 mg	Tablet	Calves	Oral
Italy	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl S	Marbofloxacin	100 mg/ml	Solution for injection	No information available	No information available
Italy	VetPharma Animal Health S.L. Les Corts, 23 08028 Barcelona SPAIN	Niflox 10%	Enrofloxacin	No information available	No information available	No information available	No information available
Italy	Virbac S.A. via dei Gracchi, 30 20146 Milano (MI) ITALY	Floxatril 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Latvia	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	MARBOKEM	Marbofloxacin	100 mg/ml	Solution for injection	Cattle	Intramuscular
Latvia	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Quinocol Oral Solution	Enrofloxacin Colistin sulphate	100 mg/ml enrofloxacin 109 IU colistin sulphate	Oral solution	Chickens Turkeys	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Latvia	Fatro S.p.A., Via Emilia 285 400064 Ozzano Emilia (BO) ITALY	Atiquine P50	Flumequine	500 mg/g	Oral powder	Birds Fish	Oral
Latvia	Industrial Veterinaria S.A. Esmeralda, 19 - 4º 08950 Esplugues de Llobregat SPAIN	Ganadexil Enrofloxacin 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs	Subcutaneous, intramuscular
Latvia	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 10% injection	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Latvia	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 10% solution	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral
Latvia	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 5% injection	Enrofloxacin	50 mg/ml	Solution for injection	Sheep Goats Dogs Cattle Pigs	Subcutaneous, intramuscular
Latvia	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 5% premix	Enrofloxacin	50 mg/g	Premix for medicated feedingstuffs	Poultry Pigs	Oral
Latvia	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil Max	Enrofloxacin	100 mg/ml	Solution for injection	Cattle	Subcutaneous

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Latvia	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Flubactin solution	Flumequine	200 mg/ml	Oral solution	Kids Lambs Rabbits Pigs Poultry Cattle Fur animals	Oral
Latvia	Laboratorios Calier, S.A. Barcelonés, 26 08520 Les Franqueses del Valles SPAIN	Roxacin	Enrofloxacin	100 mg/ml	Oral solution	Chickens	Oral
Latvia	Laboratorios Calier, S.A. Barcelonés, 26 08520 Les Franqueses del Valles SPAIN	Roxacin injectable	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intramuscular
Latvia	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	Hipralona Enro-S	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral
Latvia	Lavet Gyógyszergyártó Kft. Ottó u. 14 1161 Budapest HUNGARY	Diflocin 10%	Difloxacin	10 mg/ml	Oral solution	Chickens Turkeys	Oral
Latvia	Pfizer Animal Health Ramsgate Road Sandwich, Kent CT13 9NJ UNITED KINGDOM	Advocin 180	Danofloxacin	180 mg/ml	Solution for injection	Cattle	Subcutaneous, intravenous

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Latvia	Vétoquinol Biowet Sp. z o.o. ul. Kosynierów Gdyńskich 13-14 66-400 Gorzów Wielkopolski POLAND	Enrobioflox 10%	Enrofloxacin	100 mg/ml	Oral solution	Poultry Pigeons Cats Dogs Cattle Pigs	Oral
Latvia	Vétoquinol Biowet Sp. z o.o. ul. Kosynierów Gdyńskich 13-14 66-400 Gorzów Wielkopolski POLAND	ENROBIOFLOX 5% INJ.	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs	Subcutaneous, intramuscular
Latvia	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 10%	Marbofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Latvia	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 2%	Marbofloxacin	20 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Lithuania	CENAVISA, S.A. Camí Pedra Estela S/N 43205 Reus SPAIN	E-FLOX, geriamasis tirpalas	Enrofloxacin	100 mg/ml	Oral solution	Broilers	Oral
Lithuania	Chemifarma S.p.A. 16, Via Don Eugenio Servadei 47100 Forlì ITALY	FLUMECHINA 50 %, geriamasis tirpalas	Flumequine	500g/1000ml	Oral solution	Broilers	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Lithuania	Codifar N.V. Lt. Caluwaertstraat 1 2160 Wommelgem BELGIUM	FLUMAX 50 %, geriamieji milteliai	Flumequine	500 mg/g	Oral powder	Cattle Sheep Goats Pigs Poultry Rabbit Fish	Oral
Lithuania	Dopharma Research BV Zalmweg 24 4941 VX Raamsdonksveer NETHERLANDS	ENTERFLUME 50 %	Flumequine	500 mg/g	Oral powder	Calves Pigs Poultry	Oral
Lithuania	Industrial Veterinaria S.A. Esmeralda, 19 - 4º 08950 Esplugues de Llobregat SPAIN	GANADEXIL ENROFLOXACINA 5 %, injekcinis tirpalas	Enrofloxacin	50 mg/ml	Solution for injection	Calves	Subcutaneous
Lithuania	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	ENROXIL 100 mg/ml, geriamasis tirpalas paukščiams	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral
Lithuania	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	ENROXIL 100 mg/ml, injekcinis tirpalas	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Lithuania	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	ENROXIL 50 mg/ml, injekcinis tirpalas	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Sheep Goats Pigs	Subcutaneous, intravenous, intramuscular

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Lithuania	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	ENROXIL 5g/100g, vaistinis premixas, milteliai	Enrofloxacin	5 g/100 g	Oral powder	Poultry Pigs	Oral
Lithuania	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	ENROXIL MAX 100 mg/ml, injekcinis tirpalas galvijams	Enrofloxacin	100 mg/ml	Solution for injection	Cattle	Subcutaneous
Lithuania	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	FLUBACTIN, geriamasis tirpalas	Flumequine	200 mg/ml	Oral solution	Poultry Pigs Cattle Lambs Kids Rabbits Fur animals	Oral
Lithuania	Laboratorios Calier, S.A. Barcelonés, 26 08520 Les Franqueses del Valles SPAIN	ROXACIN, injekcinis tirpalas	Enrofloxacin	100 mg/ml	Solution for injection	Pigs Bovine	Intramuscular
Lithuania	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	HIPRALONA ENRO-I, injekcinis tirpalas galvijams ir kiaulėms	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs	Intramuscular
Lithuania	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	HIPRALONA ENRO-S, geriamasis tirpalas	Enrofloxacin	100 mg/ml	Oral solution	Broilers	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Lithuania	Lavet Gyógyszergyártó Kft. Ottó u. 14 1161 Budapest HUNGARY	DIFLOCIN 10 %, geriamasis tirpalas	Difloxacin	100 g/1000 ml	Oral solution	Chickens Turkeys	Oral
Lithuania	Lavet Gyógyszergyártó Kft. Ottó u. 14 1161 Budapest HUNGARY	ENROCIN 10 %, geriamasis tirpalas	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Lithuania	Pfizer Animal Health Ramsgate Road Sandwich, Kent CT13 9NJ UNITED KINGDOM	ADVOCIN 180, injekcinis tirpalas	Danofloxacin	180 mg/ml	Solution for injection	Cattle	Subcutaneous, intravenous
Lithuania	Vétoquinol Biowet Sp. z o.o. ul. Kosynierów Gdyńskich 13-14 66-400 Gorzów Wielkopolski POLAND	ENROBIOFLOX 5 %, injekcinis tirpalas	Enrofloxacin	5 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Lithuania	Vétoquinol Biowet Sp. z o.o. ul. Kosynierów Gdyńskich 13-14 66-400 Gorzów Wielkopolski POLAND	ENROBIOFLOX 10 %, geriamasis tirpalas	Enrofloxacin	100 mg/ml	Oral solution	Poultry Bovine Pigs Pigeons	Oral
Lithuania	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	MARBOCYL 10 %, injekcinis tirpalas	Marbofloxacin	100 mg/ml	Solution for injection	Cattle Sows	Intramuscular, subcutaneous, intramuscular

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Lithuania	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	MARBOCYL 2 %, injekcinis tirpalas	Marbofloxacin	20 mg/ml	Solution for injection	Calves Pigs	Intramuscular, subcutaneous, intravenous
Malta	Fatro S.p.A., Via Emilia 285 400064 Ozzano Emilia (BO) ITALY	Flumexil	Flumequine	10 mg/100 ml	Water soluble granules	Calves, Lambs, Kids, Foals, Pigs	No information available
Malta	Fatro S.p.A., Via Emilia 285 400064 Ozzano Emilia (BO) ITALY	Flumexil 1.5%	Flumequine	15 mg/ml	Oral paste	Lambs, Kids, Piglets, Rabbits, Dogs	No information available
Malta	Fatro S.p.A., Via Emilia 285 400064 Ozzano Emilia (BO) ITALY	Flumexil 5%	Flumequine	50 mg/ml	Solution for injection	Cattle Pigs Sheep Goats Rabbits Horses Foals Dogs Cats	No information available
Malta	Industrial Veterinaria S.A. Esmeralda, 19 - 4º 08950 Esplugues de Llobregat SPAIN	Gandexil Enrofloxacin	Enrofloxacin	100 mg/ml	Oral solution	Broilers Rabbits	Oral
Malta	Industrial Veterinaria S.A. Esmeralda, 19 - 4º 08950 Esplugues de Llobregat SPAIN	Gandexil Enrofloxacin 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs	Subcutaneous, intramuscular

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Malta	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	Hipralona Enro S	Enrofloxacin	100 mg/ml	Oral solution	Chickens Rabbits	Oral
Norway	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril vet	Enrofloxacin	15 mg	Tablets	Cattle Pigs Dogs Cats	Oral
Norway	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril vet	Enrofloxacin	50 mg	Tablets	Cattle Pigs Dogs Cats	Oral
Norway	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril vet	Enrofloxacin	150 mg	Tablets	Cattle Pigs Dogs Cats	Oral
Norway	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril vet	Enrofloxacin	250 mg	Tablets	Cattle Pigs Dogs Cats	Oral
Norway	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril vet	Enrofloxacin	25 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intravenous, intramuscular
Norway	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril vet	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intravenous, intramuscular

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Norway	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Fenoflox	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Norway	T. Skretting A/S P.O. Box 319 4002 Stavanger NORWAY	Oxolinsyre vet	Oxolinic acid	5 g/kg	Premix for medicated feedingstuffs	Salmonids	Oral
Poland	Bayer HealthCare AG Animal Health Division 51368 Leverkusen GERMANY	Baytril 5% inj enrofloksacyna 50 mg/ml solution for injection for cattle and pig	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs	Intramuscular, subcutaneous
Poland	Bayer HealthCare AG Animal Health Division 51368 Leverkusen GERMANY	Baytril One 100mg/ml solution for injection for cattle	Enrofloxacin	100 mg	Solution for injection	Cattle	Subcutaneous, intravenous
Poland	Biofaktor Sp. z o.o. ul. Czysa 4 96-100 Skierniewice POLAND	Enrofloxan 10% solution, enrofloksacyna 100mg/ml Solution for use in drinking water/milk for pig, chicken and pigeons	Enrofloxacin	100 mg/ml	Oral solution	Chickens Pigs Pigeons	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Poland	Biowet Puławy Sp. z o.o. ul. Arciucha 2 24-100 Puławy POLAND	Enflocyna SOL 50mg/ml oral solution for cattle, pig, dog, chicken, tureky and pigeons	Enrofloxacin	50 mg/ml	Oral solution	Cattle Pigs Dog Chickens Pigeons Turkeys	Oral
Poland	Biowet Puławy Sp. z o.o. ul. Arciucha 2 24-100 Puławy POLAND	Enroflocyna iNJ 100 mg/ml solution for injection for cattle, pig, dog, cat	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Intramuscular, subcutaneous
Poland	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Flumiquil 50% oral powder for chicken, tureky, pig, cattle, sheep, trout and eel	Flumequine	50 g/100 g	Oral powder	Chickens Turkeys Pigs Cattle Sheep Trout Eel	Oral
Poland	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Flumisol 100mg/ml oral solution for chicken, tureky, pig, cattle and sheep	Flumequine	100 mg/ml	Oral solution	Chickens Turkeys Pigs Cattle Sheep	Oral
Poland	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Quinoex-10, 100mg/ml oral solution for chicken and tureky	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Poland	Drwalewskie Zakłady Przemysłu Bioweterynaryjnego S.A. ul. Grójecka 6 05-651 Drwalew POLAND	Enrofloksacyna 10% enrofloksacyna 100 mg/ml oral solution for chicken, turkey and pigeons	Enrofloxacin	10 g/100 ml	Oral solution	Chickens Turkeys Pigeons	Oral
Poland	Drwalewskie Zakłady Przemysłu Bioweterynaryjnego S.A. ul. Grójecka 6 05-651 Drwalew POLAND	Enrofloksacyna 10% inj, 100mg/ml solution for injection for cattle	Enrofloxacin	10 g/100 ml	Solution for injection	Cattle	Subcutaneous
Poland	Drwalewskie Zakłady Przemysłu Bioweterynaryjnego S.A. ul. Grójecka 6 05-651 Drwalew POLAND	Imequyl 10% 100mg/g powder for use in drinking water/milk for cattle, chicken and turkey	Flumequine	10 g/100 g	Powder	Cattle Chickens Turkeys	Oral
Poland	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 10% , enrofloksacyna 100mg/ml solution for injection for cattle and pig	Enrofloxacin	10 g/100 ml	Solution for injection	Cattle Pigs	Intramuscular, subcutaneous
Poland	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 10% oral , enrofloksacyna 100mg/ml solution for use in drinking water for chicken	Enrofloxacin	10 g/100 ml	Oral solution	Chickens	Oral
Poland	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 5%, enrofloksacyna 100mg/ml solution for injection for cattle,pig and dog	Enrofloxacin	5 g/100 ml	Solution for injection	Cattle Pigs Dogs	Intramuscular, subcutaneous

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Poland	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil Max 100 mg/ml solution for injection for cattle	Enrofloxacin	100 mg/ml	Solution for injection	Cattle	Subcutaneous
Poland	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Flubactin 20%, 200mg/ml oral solution for cattle, sheep, chicken, pig, mink, coypu and rabbit	Flumequine	200 mg/ml	Oral solution	Cattle Sheep Chickens Pigs Mink Coypu Rabbits	Oral
Poland	Laboratorios Calier, S.A. Barcelonés, 26 08520 Les Franqueses del Valles SPAIN	Roxacin 10% oral solution, enrofloksacyna 100mg/ml, oral solution for chicken	Enrofloxacin	100 mg/ml	Oral solution	Chickens	Oral
Poland	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	Hipralona Enro-I	Enrofloxacin	50 mg/ml	Solution for injection	Pigs Cattle	No information available
Poland	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	Hipralona Enro-S	Enrofloxacin	100 mg/ml	Oral solution	Chickens	Oral
Poland	Pfizer Trading Polska Sp. z o.o. ul. Rzymowskiego 34 02-697 Warszawa POLAND	Advocin 180	Danofloxacin	180 mg/ml	Solution for injection	Cattle	Subcutaneous

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Poland	Pharmagal, s.r.o. Murgašova 5 949 01 Nitra SLOVAK REPUBLIC	Enrogal 50mg/ml solution for injection	Enrofloxacin	5 g/100 ml	Solution for injection	Cattle Pigs Dogs	Intramuscular, subcutaneous
Poland	Przedsiębiorstwo Farmaceutyczne Okoniewscy "VETOS-FARMA" Sp. z o.o. ul. Dzierżoniewska 21 58-260 Bielawa POLAND	Enrofloxacyna 10% iniekcja, enrofloksacyna 10 mg/100 solution for injection for cattle, pig, dog and cat	Enrofloxacin	10 g/100 ml	Solution for injection	Cattle Pigs Dogs Cats	Intramuscular, subcutaneous
Poland	Przedsiębiorstwo Farmaceutyczne Okoniewscy "VETOS-FARMA" Sp. z o.o. ul. Dzierżoniewska 21 58-260 Bielawa POLAND	Enrofloxacyna 5% iniekcja, enrofloksacyna 5 mg/100 solution for injection for cattle, pig, dog and cat	Enrofloxacin	5 g/100 ml	Solution for injection	Cattle Pigs Dogs Cats	Intramuscular, subcutaneous
Poland	Przedsiębiorstwo Farmaceutyczne Okoniewscy "VETOS-FARMA" Sp. z o.o. ul. Dzierżoniewska 21 58-260 Bielawa POLAND	Flumequina 10% - powder flumechina 10g/100g powder for use in drinking water	Flumequine	10 g/100 g	Powder	Chickens Cattle	Oral
Poland	Przedsiębiorstwo Farmaceutyczne Okoniewscy "VETOS-FARMA" Sp. z o.o. ul. Dzierżoniewska 21 58-260 Bielawa POLAND	Flumequina 10% - solution flumechina 10g/100g oral solution	Flumequine	10 g/100 g	Oral solution	Chickens Cattle	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Poland	Przedsiębiorstwo Farmaceutyczne Okoniewscy "VETOS-FARMA" Sp. z o.o. ul. Dzierżoniewska 21 58-260 Bielawa POLAND	Enrofloksacyna 10% liquid, enrofloksacyna 100mg/ml oral solution for chicken	Enrofloxacin	100 mg/ml	Oral solution	Chickens	Oral
Poland	Przedsiębiorstwo Wielobranżowe "Vet Agro" Sp. zo.o. ul. Gliniana 32 20-616 Lublin POLAND	Enrocin 10% oral, enrofloksacyna 100mg/ml oral solution for chicken and pigeons	Enrofloxacin	10 g/100 ml	Oral solution	Chickens Pigeons	Oral
Poland	Przedsiębiorstwo Wielobranżowe "Vet Agro" Sp. zo.o. ul. Gliniana 32 20-616 Lublin POLAND	Enrocin 5% inj., enrofloksacyna 50mg/ml solution for injection for cattle and pig	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs	Intramuscular, subcutaneous
Poland	Scan Vet Poland Sp. z o.o. ul. Kiszowska 9 Skierszewo 62-200 Gniezno POLAND	Difloxy 10 % oral solution for chicken and turkey	Difloxacin hydrochloride	10 mg/ml	Oral solution	Chickens Turkeys	Oral
Poland	Scan Vet Poland Sp. z o.o. ul. Kiszowska 9 Skierszewo 62-200 Gniezno POLAND	Scanoflox 10% oral solution	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys Pigeons	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Poland	Vétoquinol Biowet Sp. z o.o. ul. Kosynierów Gdyńskich 13-14 66-400 Gorzów Wielkopolski POLAND	Enrobioflox 10% 100mg/ml oral solution for chicken, cattle, pig, dog, cat and pigeons	Enrofloxacin	10 g/100 ml	Oral solution	Chickens Cattle Dogs Cats Pigeons	Oral
Poland	Vétoquinol Biowet Sp. z o.o. ul. Kosynierów Gdyńskich 13-14 66-400 Gorzów Wielkopolski POLAND	Enrobioflox 5% injection, 50mg/ml solution for injection for pig, cattle and dog	Enrofloxacin	10 g/100 ml	Solution for injection	Cattle Pigs Dogs	Intramuscular, subcutaneous
Poland	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 10, 100 mg/ml solution for injection for cattle and pig	Marbofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intramuscular, subcutaneous
Poland	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl S 10% solution for injection	Marbofloxacin	100 mg/ml	Solution for injection	Cattle	Intramuscular
Poland	VMD N.V. Hoge Mauw 900 2370 Arendonk BELGIUM	Flumeq 50-S 500 mg/g Powder for use in drinking water /milk for cattle and chicken	Flumequine	500 mg/g	Powder	Cattle Chickens	Oral
Portugal	Bayer Portugal SA Rua Quinta do Pinheiro, 5 2794-003 Carnaxide PORTUGAL	BAYTRIL 0,5% solução oral	Enrofloxacin	5 mg/ml	Oral solution	Pigs	Oral
Portugal	Bayer Portugal SA Rua Quinta do Pinheiro, 5 2794-003 Carnaxide PORTUGAL	BAYTRIL 10% solução injectável	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Portugal	Bayer Portugal SA Rua Quinta do Pinheiro, 5 2794-003 Carnaxide PORTUGAL	BAYTRIL 10% solução oral	Enrofloxacin	100 mg/ml	Oral solution	Chickens Broilers Turkeys	Oral
Portugal	Bayer Portugal SA Rua Quinta do Pinheiro, 5 2794-003 Carnaxide PORTUGAL	BAYTRIL 5% solução injectável	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous
Portugal	Bayer Portugal SA Rua Quinta do Pinheiro, 5 2794-003 Carnaxide PORTUGAL	Baytril One - 100 mg/ml solução injectável para bovinos	Enrofloxacin	100 mg/ml	Solution for injection	Cattle	Subcutaneous, intravenous
Portugal	Calier Portugal-Medicamentos e Produtos Veterinários SA R Pé Mouro Edifício C - Linhó 2710-335 Sintra PORTUGAL	Roxacin injectável	Enrofloxacin	10 mg/ml	Solution for injection	Pigs	Intramuscular
Portugal	Calier Portugal-Medicamentos e Produtos Veterinários SA R Pé Mouro Edifício C - Linhó 2710-335 Sintra PORTUGAL	Roxacin oral	Enrofloxacin	100 g/l	Oral solution	Broilers	Oral
Portugal	CENAVISA, S.A. Camí Pedra Estela S/N 43205 Reus SPAIN	ACROLIN 10, solução oral para frangos de carne	Enrofloxacin	100 mg/ml	Oral solution	Chickens	Oral
Portugal	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Marbokem 100 mg/ml solução injectável	Enrofloxacin	100 mg/ml	Solution for injection	Cattle	Intramuscular

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Portugal	Ceva Saúde Animal - Produtos Farmacêuticos e Imunológicos, Lda. Rua Doutor António Loureiro Borges, 9/9A – 9ºA Miraflores 1495-131 Algés PORTUGAL	FLUMISOL 36%	Flumequine	360 mg/ml	Oral solution	Broilers, Turkeys, Cattle	Oral
Portugal	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Fenoflox 10% solução injectável	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
Portugal	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Fenoflox 5% solução injectável	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
Portugal	Esteve Farma, Lda Av. Do Forte, 3 - Edifício Suécia II, Piso 4A 2794-044 Carnaxide PORTUGAL	ALSIR 10 solução oral	Enrofloxacin	100 mg/ml	Oral solution	Chickens Broilers Turkeys	Oral

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Portugal	Esteve Farma, Lda Av. Do Forte, 3 - Edifício Suécia II, Piso 4A 2794-044 Carnaxide PORTUGAL	ALSIR 5% solução injectável	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Portugal	Esteve Farma, Lda Av. Do Forte, 3 - Edifício Suécia II, Piso 4A 2794-044 Carnaxide PORTUGAL	ALSIR LEITÕES	Enrofloxacin	5 mg	Oral solution	Pigs	Oral
Portugal	IAPSA Portuguesa Pecuária, Lda. Rua 1-Complexo i Vialonga armz a-4 2600-135 Vila Franca de Xira (Vialonga) PORTUGAL	FLUYESYVA suspensão injectável	Flumequine	7.5 g/100 ml	Suspension for injection	Cattle Pigs	Intramuscular
Portugal	IBERIL - Soc. Comercial de Produtos Agro-Pecuários, Lda Praça Dr. Francisco Sá Carneiro, n.º 7-5º esquerdo 1000-159 Lisboa PORTUGAL	Inoxyl suspensão oral	Oxolinic acid	2 g/100 ml	Oral solution	Pigs	Oral
Portugal	IBERIL - Soc. Comercial de Produtos Agro-Pecuários, Lda Praça Dr. Francisco Sá Carneiro, n.º 7-5º esquerdo 1000-159 Lisboa PORTUGAL	Inoxyl pó solúvel	Oxolinic acid, sodium salt	11.5 g/100 g	Oral powder	Cattle Pigs Chickens Broilers	Oral

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Portugal	IBERIL - Soc. Comercial de Produtos Agro-Pecuários, Lda Praça Dr. Francisco Sá Carneiro, n.º 7-5º esquerdo 1000-159 Lisboa PORTUGAL	Inoxyl Premix	Oxolinic acid	24 g	Premix for medicated feedingstuffs	Pigs	Oral
Portugal	IBERIL - Soc. Comercial de Produtos Agro-Pecuários, Lda Praça Dr. Francisco Sá Carneiro, n.º 7-5º esquerdo 1000-159 Lisboa PORTUGAL	Inoxyl solução oral	Oxolinic acid	5 g/100 ml	Oral solution	Chickens Broilers	Oral
Portugal	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Powerflox Max 100mg/ml solução injectável para bovinos	Enrofloxacin	100 mg/ml	Solution for injection	Cattle	Subcutaneous
Portugal	Laboratorios Karizoo, S.A. Polg. Industrial La Borda Mas Pujades, 11-12 08140 Caldes de Montbui (Barcelona) SPAIN	K-FLOX 100 mg/ml solução oral para frangos de carne e coelhos	Enrofloxacin	100 mg/ml	Oral solution	Poultry Rabbits	Oral
Portugal	Laboratórios Pfizer Lda Lagoas Park, Edifício 10 2740-271 Porto Salvo PORTUGAL	ADVOCIN 180, 180 mg/ml, solução injectável para bovinos	Danofloxacin	180 mg/ml	Solution for injection	Cattle	Subcutaneous, intravenous
Portugal	REAGRO - Importação e Exportação, S.A Avenida de Roma, n.º 15 2º esq. 1049-045 Lisboa PORTUGAL	HV - 36	Colistin sulphate Oxolinic acid	Colistine sulphate 12 g Oxolinic acid 100g	Premix for medicated feedingstuffs	Pigs, Sheep, Birds	Oral

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Portugal	S.P. Veterinaria S.A. Ctra. de Reus a Vignols km 4.1 43330 Riudoms (Tarragona) SPAIN	Colmyc injectável	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Portugal	VetPharma Animal Health S.L. Les Corts, 23 08028 Barcelona SPAIN	LEVOFLOK 100 mg/ml Solução oral para frangos de carne e coelhos	Enrofloxacin	10 g/100 ml	Oral solution	Poultry Rabbits	Oral
Portugal	Vetlima - Soc. Distribuidora de Pro. Agro-Pecuários, Lda Avenida 5 Outubro 35, 3º-E 1050-047 Lisboa PORTUGAL	VETAFLOR 100 mg/ml solução oral para frangos de engorda e coelhos	Enrofloxacin	100 mg/ml	Oral solution	Broilers Rabbits	Oral
Portugal	Dopharma Research BV Zalmweg 24 4941 VX Raamsdonksveer NETHERLANDS	VETAFLUMINA 5%	Flumequine	50 mg/ml	Oral solution	Cattle Birds	Oral
Portugal	Dopharma Research BV Zalmweg 24 4941 VX Raamsdonksveer NETHERLANDS	VETAFLUMINA 50%	Flumequine	500 mg/ml	Oral solution	Cattle Birds	Oral
Portugal	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	MARBOCYL 10%, solução injectável para suínos e bovinos	Marbofloxacin	100 mg	Solution for injection	Cattle Sows	Subcutaneous, intramuscular

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Portugal	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	MARBOCYL 2% solução injectável para suínos e bovinos	Marbofloxacin	20 mg	Solution for injection	Cattle Fattening pigs	Subcutaneous, Intravenous, intramuscular
Portugal	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	MARBOCYL BOLUS 50 MG comprimidos para vitelos	Marbofloxacin	50 mg	Tablets	Cattle	Oral
Portugal	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl S 10%, Solução Injectável	Marbofloxacin	100 mg	Solution for injection	Cattle	Intramuscular
Portugal	VIRBAC - Portugal Laboratórios Lda.Beloura Oficial Parque Edif. 13 - piso 1 escritorio 3 Quinta da Beloura 2710-444 Sintra PORTUGAL	Oxomid 20	Oxolinic acid	20 g/100 g	Oral powder	Birds	Oral
Portugal	VIRBAC - Portugal Laboratórios Lda.Beloura Oficial Parque Edif. 13 - piso 1 escritorio 3 Quinta da Beloura 2710-444 Sintra PORTUGAL	Oxomid 5	Oxolinic acid	5 g/100 g	Oral powder	Cattle Pigs	Oral

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Portugal	VIRBAC - Portugal Laboratórios Lda.Beloura Oficial Parque Edif. 13 - piso 1 escritorio 3 Quinta da Beloura 2710-444 Sintra PORTUGAL	Oxomid Premix	Oxolinic acid	50 g	Premix for medicated feedingstuffs	Cattle Pigs Poultry Rabbits	Oral
Romania	Ascor Chimici S.r.l. Via Piana 265 47032 Capocolle di Bertinoro (FC) ITALY	Amoxicillin 22,5% + Flumequine 15%	Flumequine Amoxicillin trihydrate	150 mg/g	Oral powder	Pigs Broilers Turkeys	Oral
Romania	Bayer HealthCare AG Animal Health Division 51368 Leverkusen GERMANY	Baytril 10%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intravenous, intramuscular
Romania	Bayer HealthCare AG Animal Health Division 51368 Leverkusen GERMANY	Baytril 10%	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Romania	Bayer HealthCare AG Animal Health Division 51368 Leverkusen GERMANY	Baytril 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs	Subcutaneous, intramuscular
Romania	Bayer HealthCare AG Animal Health Division 51368 Leverkusen GERMANY	Baytril Max	Enrofloxacin	100 mg/ml	Solution for injection	Cattle	Subcutaneous

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Romania	CENAVISA, S.A. Camí Pedra Estela S/N 43205 Reus SPAIN	Cenamicina 10 Plus	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs Dogs	Subcutaneous, intramuscular
Romania	CENAVISA, S.A. Camí Pedra Estela S/N 43205 Reus SPAIN	E - Flox	Enrofloxacin	100 mg/ml	Oral solution	Broilers	Oral
Romania	Ceva Santé Animale Romania SRL 5 Chindiei, sector 4 040185 Bucharest ROMANIA	Flumiquil (Fluquick) 50%	Flumequine	500 mg/g	Soluble powder	Pigs Cattle Poultry Fish	Oral
Romania	Ceva Santé Animale Romania SRL 5 Chindiei, sector 4 040185 Bucharest ROMANIA	Marbokem	Marbofloxacin	100 mg/ml	Solution for injection	Cattle	Intramuscular
Romania	Ceva Santé Animale Romania SRL 5 Chindiei, sector 4 040185 Bucharest ROMANIA	Quinoex 10 oral solution	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral
Romania	CEVASA Cervantes 1543/45 1407 Buenos Aires ARGENTINA	Bromeflox	Enrofloxacin Bromhexine	200 mg/ml	Oral solution	Poultry	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Romania	CEVASA Cervantes 1543/45 1407 Buenos Aires ARGENTINA	C-Enrox 10%	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral
Romania	Chemifarma S.p.A. 16, Via Don Eugenio Servadei 47100 Forli ITALY	Colifarm 20	Flumequine	200 mg/ml	Oral solution	Poultry	Oral
Romania	Chemifarma S.p.A. 16, Via Don Eugenio Servadei 47100 Forli ITALY	Flumechina 50%	Flumequine	500 mg/g	Oral solution	Poultry	Oral
Romania	Dar al Dawa Veterinary & Agricultural Industrial Co. Ltd. Jordan Na`ur 11710 PO BOX 285 JORDANIA	Dadtril 10%	Enrofloxacin	100 mg/ml	Oral solution	Poultry Calves Dogs Cats	Oral
Romania	Dar al Dawa Veterinary & Agricultural Industrial Co. Ltd. Jordan Na`ur 11710 PO BOX 285 JORDANIA	Flumequine 10%	Flumequine	100 mg/g	Soluble powder	Poultry Cattle Rabbits	Oral
Romania	DELOS IMPEX' 96 SRL Str. Horia Cloșca și Crișan, nr. 81 Otopeni, Jud. Ilfov ROMANIA	Enrodem 10%	Enrofloxacin	100 mg/ml	Oral solution	Poultry Pigs	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Romania	DELOS IMPEX' 96 SRL Str. Horia Cloșca și Crișan, nr. 81 Otopeni, Jud. Ilfov ROMANIA	Enrodem 50	Enrofloxacin	500 mg/g	Soluble powder	Poultry Pigs Fish	Oral
Romania	Divasa-Farmavic S.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	Enrovet 10%	Enrofloxacin	100 mg/ml	Oral solution	Poultry (broilers and turkeys)	Oral
Romania	Dopharma Research BV Zalmweg 24 4941 VX Raamsdonksveer THE NETHERLANDS	Flumequine 50% WSP	Flumequine	500 mg/g	Soluble powder	Cattle Pigs Poultry	Oral
Romania	Golashpharma Ltd. 33, Pobeda Str. 2650 Sapareva Banya BULGARIA	Enrofloxin 15 mg	Enrofloxacin	15 mg/tablet	Tablets	Poultry (chicken and turkeys) Pigeons Rabbits Rodents (rabbit, guinea pigs, mice, hamsters) Hunting birds Exotic birds Dogs Cats	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Romania	Golashpharma Ltd. 33, Pobeda Str. 2650 Sapareva Banya BULGARIA	Enrofloxin 50 mg	Enrofloxacin	50 mg/tablet	Tablets	Poultry (chicken and turkeys) Pigeons Rabbits Rodents (rabbit, guinea pigs, mice, hamsters) Hunting birds Exotic birds Dogs Cats	Oral
Romania	Industrial Veterinaria S.A. Esmeralda, 19 - 4º 08950 Esplugues de Llobregat SPAIN	Ganadexil Enrofloxacin	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral
Romania	Industrial Veterinaria S.A. Esmeralda, 19 - 4º 08950 Esplugues de Llobregat SPAIN	Ganadexil Enrofloxacin 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs	Subcutaneous, intramuscular
Romania	Kepro B.V. Maagdenburgstraat 38 7421 ZE Deventer NETHERLANDS	Kenflox 20% Oral	Enrofloxacin	200 mg/ml	Oral solution	Poultry	Oral
Romania	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 10%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Romania	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 10%	Enrofloxacin	100 mg/g	Oral solution	Poultry	Oral
Romania	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Sheep Goats Pigs Dogs	Subcutaneous, intravenous, intramuscular
Romania	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil 5%	Enrofloxacin	50 mg/g	Powder	Poultry Pigs	Oral
Romania	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxyl Max	Enrofloxacin	100 mg/ml	Solution for injection	Cattle	Subcutaneous
Romania	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	Hipralona Enro I	Enrofloxacin	50 mg/ml	Solution for injection	Pigs Calves	Intramuscular
Romania	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	Hipralona Enro S	Enrofloxacin	100 mg/ml	Oral solution	Broilers	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Romania	Laboratorios Karizoo, S.A. Polg. Industrial La Borda Mas Pujades, 11-12 08140 Caldes de Montbui (Barcelona) SPAIN	Anka-floxacin 10%	Enrofloxacin	100 mg/ml	Oral solution	Poultry (chickens and turkeys)	Oral
Romania	Laboratorios Syva, S.A. Avda Parroco Pablo Diez 49-57 24010 Trobajo del Camino SPAIN	Flumesyva Liquid 20%	Flumequine	200 mg/ml	Oral solution	Poultry Pigs Lambs Kids Calves	Oral
Romania	Laboratorios Syva, S.A. Avda Parroco Pablo Diez 49-57 24010 Trobajo del Camino SPAIN	Flumesyva Oral paste	Flumequine	30 mg/g	Oral paste	Piglets Lambs Kids	Oral
Romania	Laboratorios Syva, S.A. Avda Parroco Pablo Diez 49-57 24010 Trobajo del Camino SPAIN	Flumesyva 10% powder	Flumequine	100 mg/ml	Soluble powder	Poultry Pigs Lambs Kids Calves Rabbits Fish	Oral
Romania	Laboratorios Syva, S.A. Avda Parroco Pablo Diez 49-57 24010 Trobajo del Camino SPAIN	Syvaquinol 10%	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Romania	Laboratorios Syva, S.A. Avda Parroco Pablo Diez 49-57 24010 Trobajo del Camino SPAIN	Syvaquinol 100 injectable	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Romania	Laboratorios Syva, S.A. Avda Parroco Pablo Diez 49-57 24010 Trobajo del Camino SPAIN	Syvaquinol 25 injectable	Enrofloxacin	25 mg/ml	Solution for injection	Cattle Piglets Dogs	Subcutaneous, intramuscular
Romania	Lavet Gyógyszergyártó Kft. Ottó u. 14 1161 Budapest HUNGARY	Enrocín 10%	Enrofloxacin	100 mg/ml	Oral solution	Poultry (chickens and turkeys)	Oral
Romania	Lavet Gyógyszergyártó Kft. Ottó u. 14 1161 Budapest HUNGARY	QUINOCOL	Enrofloxacin Colistin sulphate	100 mg/ml enrofloxacin 109 IU colistin sulphate	Oral solution	Chickens Turkeys	Oral
Romania	Orion Corporation Orionintie 1A 02200 Espoo FINLAND	EFRION 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Romania	Pasteur - Filiala Filipești Srl Str. Principala nr. 944 107245 Filipeștii de Pădure, Jud. Prahova ROMANIA	Enrofloxacină 10%	Enrofloxacin	100 mg/ml	Oral solution	Poultry Cattle Lambs Kids Piglets Dogs Cats	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Romania	Pasteur - Filiala Filipesti Srl Str. Principala nr. 944 107245 Filipestii de Padure, Jud. Prahova ROMANIA	Enrofloxacin 10%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Sheep Goats Pigs Dogs Cats	Subcutaneous, intramuscular
Romania	Pasteur - Filiala Filipesti Srl Str. Principala nr. 944 107245 Filipestii de Padure, Jud. Prahova ROMANIA	Enrofloxacin 10% Premix	Enrofloxacin	100 mg/g	Medicated premix	Pigs Poultry	Oral
Romania	Pasteur - Filiala Filipesti Srl Str. Principala nr. 944 107245 Filipestii de Padure, Jud. Prahova ROMANIA	Enrofloxacin 25	Enrofloxacin	25 mg/tablet	Tablets	Poultry Pigs Dogs Cats	Oral
Romania	Pasteur - Filiala Filipesti Srl Str. Principala nr. 944 107245 Filipestii de Padure, Jud. Prahova ROMANIA	Enrofloxacin 5	Enrofloxacin	5 mg/tablet	Tablets	Poultry Pigs Dogs Cats	Oral
Romania	Pasteur - Filiala Filipesti Srl Str. Principala nr. 944 107245 Filipestii de Padure, Jud. Prahova ROMANIA	Enrofloxacin 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Sheep Goats Pigs Dogs Cats	Subcutaneous, intramuscular

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Romania	Pasteur - Filiala Filipesti Srl Str. Principala nr. 944 107245 Filipestii de Padure, Jud. Prahova ROMANIA	Enrofloxacin 50	Enrofloxacin	50 mg/tablet	Tablets	Pigs Dogs Cats	Oral
Romania	Pasteur - Filiala Filipesti Srl Str. Principala nr. 944 107245 Filipestii de Padure, Jud. Prahova ROMANIA	Enrofloxacin Premix	Enrofloxacin	50 mg/g	Medicated premix	Pigs Poultry	Oral
Romania	Pfizer Animal Health Ramsgate Road Sandwich, Kent CT13 9NJ UNITED KINGDOM	ADVOCIN 180	Danofloxacin	180 mg/ml	Solution for injection	Cattle	Subcutaneous, intravenous
Romania	Pharmaqua-D. Kokkoris and Bros D. Solomou 28 14451 Metamorfozi Attikis GREECE	Vitaquin 500	Flumequine	500 mg/g	Soluble powder	Broilers	Oral
Romania	Pharmateka BT Szőgyártó str. 10 1048 Budapest HUNGARY	Flumequine 10% pulvis	Flumequine	100 mg/g	Soluble powder	Chickens	Oral
Romania	S.C. CRIDA PHARM S.R.L. Str. Stadionului nr. 1 Oltenita ROMANIA	Enrofloxacin 10%	Enrofloxacin	100 mg/g	Oral solution	Poultry Pigs	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Romania	S.C. CRIDA PHARM S.R.L. Str. Stadionului nr. 1 Oltenita ROMANIA	Enroflox pulv. 10%	Enrofloxacin	100 mg/g	Powder	Cattle Sheep Goats Pigs	Oral
Romania	S.C. CRIDA PHARM S.R.L. Str. Stadionului nr. 1 Oltenita ROMANIA	Enroflox pulv. 40%	Enrofloxacin	400 mg/g	Powder	Poultry Pigs	Oral
Romania	S.C. ROMVAC COMPANY S.A. Șos. Centurii, nr. 7 077190 Voluntari, Jud. Ilfov ROMANIA	Enrocol	Enrofloxacin Colistin sulphate Vitamin C	5 mg/tablet	Tablets	Poultry	Oral
Romania	S.C. ROMVAC COMPANY S.A. Șos. Centurii, nr. 7 077190 Voluntari, Jud. Ilfov ROMANIA	Enrofloxarom 10%	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral
Romania	S.C. ROMVAC COMPANY S.A. Șos. Centurii, nr. 7 077190 Voluntari, Jud. Ilfov ROMANIA	Enrofloxarom 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Sheep Pigs Dogs	Subcutaneous, intramuscular
Romania	S.C. ROMVAC COMPANY S.A. Șos. Centurii, nr. 7 077190 Voluntari, Jud. Ilfov ROMANIA	Enrofloxarom C	Enrofloxacin	5 mg/tablet	Tablets	Poultry Pigs Dogs Cats	Oral
Romania	S.C. ROMVAC COMPANY S.A. Șos. Centurii, nr. 7 077190 Voluntari, Jud. Ilfov ROMANIA	Enrofloxarom Forte	Enrofloxacin	50 mg/tablet	Tablets	Poultry Pigs Dogs Cats	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Romania	S.C. ROMVAC COMPANY S.A. Șos. Centurii, nr. 7 077190 Voluntari, Jud. Ilfov ROMANIA	Flumequinorom 10%	Flumequine	100 mg/ml	Oral solution	Cattle Lambs Kids Piglets Poultry Rabbits	Oral
Romania	S.C. ROMVAC COMPANY S.A. Șos. Centurii, nr. 7 077190 Voluntari, Jud. Ilfov ROMANIA	Metrosept E	Enrofloxacin Oxytetracycline hydrochloride Iodoform	25 mg/ml	Oily suspension	Cattle Sheep Goats Sows	Intrauterine
Romania	S.C. Vetorex Srl Str. Turda, nr. 119 011322 Bucharest ROMANIA	Farmequine 20% L	Flumequine	200 mg/ml	Oral solution	Poultry Pigs Cattle	Oral
Romania	Universal Farma, S.L Gran Via Carlos III 98-7a 08028 Barcelona SPAIN	Lanflox 2,5%	Enrofloxacin	25 mg/ml	Oral solution	Pre-ruminant Cattle	Oral
Romania	Veterina Ltd. Svetonedeljska 2, Kalinovica 10436 Rakov Potok CROATIA	Vetoflok 10%	Enrofloxacin	100 mg/ml	Oral solution	Fattening Chickens Fattening Turkeys	Oral
Romania	Veterina Ltd. Svetonedeljska 2, Kalinovica 10436 Rakov Potok CROATIA	Vetoflok 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Sheep Goats Rabbits Dogs Cats	Subcutaneous, intramuscular

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Romania	Vétoquinol Biowet Sp. z o.o. ul. Kosynierów Gdyńskich 13-14 66-400 Gorzów Wielkopolski POLAND	Enrobioflox 10%	Enrofloxacin	100 mg/ml	Oral solution	Poultry Cattle Pigs	Oral
Romania	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 10%	Marbofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Romania	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 2%	Marbofloxacin	20 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Slovak Republic	Bayer s.r.o Litvínovská 609/3 190 21 Praha 9 CZECH REPUBLIC	Baytril 5%	Enrofloxacin	50 mg/ml	Solution for injection	Pigs Calves Dogs	Subcutaneous, intramuscular
Slovak Republic	Bayer s.r.o Litvínovská 609/3 190 21 Praha 9 CZECH REPUBLIC	Baytril Max	Enrofloxacin	10 mg/ml	Solution for injection	Cattle	Subcutaneous
Slovak Republic	Bayer s.r.o Litvínovská 609/3 190 21 Praha 9 CZECH REPUBLIC	Baytril oral solution	Enrofloxacin	5 mg/ml	Oral solution	Piglets	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Slovak Republic	Ceva Animal Health Slovakia s.r.o. Račianska 77 831 02 Bratislava SLOVAK REPUBLIC	Flumiquil 50%	Flumequine	50 g/100 g	Oral powder	Pigs Cattle Sheep Chickens Hens Turkeys Fish (trout)	Oral
Slovak Republic	Ceva Animal Health Slovakia s.r.o. Račianska 77 831 02 Bratislava SLOVAK REPUBLIC	Quinocol	Enrofloxacin Colistin sulphate	100 mg/ml enrofloxacin 109 IU colistin sulphate	Oral solution	Chickens Turkeys	Oral
Slovak Republic	Ceva Animal Health Slovakia s.r.o. Račianska 77 831 02 Bratislava SLOVAK REPUBLIC	Quinoex 10	Enrofloxacin	100 mg/ml	Oral solution	Broiler chickens Breeding hens Turkeys	Oral
Slovak Republic	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Sheep Goats Pigs Dogs	Subcutaneous, intramuscular
Slovak Republic	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	No information available
Slovak Republic	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil	Enrofloxacin	100 mg/ml	Oral solution	Young poultry (chickens and turkeys)	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Slovak Republic	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil Max	Enrofloxacin	100 mg/ml	Solution for injection	Cattle	Subcutaneous
Slovak Republic	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Flubactin	Flumequine	200 mg/ml	Oral solution	Poultry Pigs Cattle Lambs Yearlings Rabbits Fur animals	Oral
Slovak Republic	Laboratorios Calier, S.A. Barcelonés, 26 08520 Les Franqueses del Valles SPAIN	Roxacin	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intramuscular
Slovak Republic	Laboratorios Calier, S.A. Barcelonés, 26 08520 Les Franqueses del Valles SPAIN	Roxacin	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral
Slovak Republic	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	Hipralona Enro - I	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs	Intramuscular
Slovak Republic	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	Hipralona Enro - S	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Slovak Republic	Lavet Gyógyszergyártó Kft. Ottó u. 14 1161 Budapest HUNGARY	Diflocin	Difloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
Slovak Republic	Pfizer Animal Health Dúbravská cesta 2 841 01 Bratislava SLOVAK REPUBLIC	Advocin 180	Danofloxacin	180 mg/ml	Solution for injection	Cattle	Intravenous, subcutaneous
Slovak Republic	Pharmagal, s.r.o. Murgašova 5 949 01 Nitra SLOVAK REPUBLIC	Enrogal	Enrofloxacin	50 mg/ml	Solution for injection	Pigs Cattle Dogs	Subcutaneous, intramuscular
Slovak Republic	Pharmagal, s.r.o. Murgašova 5 949 01 Nitra SLOVAK REPUBLIC	Enrogal	Enrofloxacin	100 mg/ml	Oral solution	Pigs Cattle Lambs Goats Yeanlings Poultry	Oral
Slovak Republic	Pharmagal, s.r.o. Murgašova 5 949 01 Nitra SLOVAK REPUBLIC	Flumigal 4%	Flumequine	4 g/100 g	Oral powder	Pigs Cattle Lambs Yeanlings Poultry Birds Rabbits	Oral
Slovak Republic	Pharmagal, s.r.o. Murgašova 5 949 01 Nitra SLOVAK REPUBLIC	Flumigal 5%	Flumequine	50 mg /ml	Oral solution	Poultry Rabbits Lambs Yeanlings Cattle	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Slovak Republic	Vétoquinol s.r.o. Zámečnická 411 288 02 Nymburk CZECH REPUBLIC	Marbocyl 10 % solution for injection	Marbofloxacin	100 mg/ml	Solution for injection	Cattle	Intramuscular
Spain	CENAVISA, S.A. Camí Pedra Estela S/N 43205 Reus SPAIN	Floxicen	Enrofloxacin	100 mg/ml	Oral solution	Broilers	Oral
Spain	CEVA SALUD ANIMAL, S.A. Carabela La Niña nº 12 5ª planta 08017 Barcelona SPAIN	Fluquick Liquido	Flumequine	10 g/100 ml	Oral solution	Cattle Pigs Poultry	Oral
Spain	CEVA SALUD ANIMAL, S.A. Carabela La Niña nº 12 5ª planta 08017 Barcelona SPAIN	Marbokem	Marbofloxacin	10%	Solution for injection	Cattle	Intramuscular
Spain	CEVA SALUD ANIMAL, S.A. Carabela La Niña nº 12 5ª planta 08017 Barcelona SPAIN	Quinoex 10% Injectable	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Spain	CEVA SALUD ANIMAL, S.A. Carabela La Niña nº 12 5ª planta 08017 Barcelona SPAIN	Quinoex-10	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Spain	Chemo Iberica, S.A. Gran Via Carlos III, 98 7ª - Edificio Trade 08028 Barcelona SPAIN	Enrofloxacin Chemo 10%	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral
Spain	Divasa-Farmavic S.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	Enrovet 10%	Enrofloxacin	100 mg/ml	Oral solution	Poultry Turkey	Oral
Spain	Divasa-Farmavic S.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	Enrovet Inyectable 100	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Spain	Fatro Uriach Veterinaria, S.L. Constitucion, 1 08960 Sant Just Desvern SPAIN	Fatroflox	Enrofloxacin	10 g/100 ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Spain	Industrial Veterinaria S.A. Esmeralda, 19 - 4º 08950 Esplugues de Llobregat SPAIN	Fenutin	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral
Spain	Industrial Veterinaria S.A. Esmeralda, 19 - 4º 08950 Esplugues de Llobregat SPAIN	Ganadexil Enrofloxacin 5% Solucion Inyectable	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs	Subcutaneous, intramuscular
Spain	Industrial Veterinaria S.A. Esmeralda, 19 - 4º 08950 Esplugues de Llobregat SPAIN	Ganadexil Enrofloxacin Solucion Oral	Enrofloxacin	100 mg/ml	Oral solution	Poultry Rabbits	Oral

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Spain	Industrial Veterinaria S.A. Esmeralda, 19 - 4º 08950 Esplugues de Llobregat SPAIN	Ganadil Flumequina Polvo Oral	Flumequine	30 mg/g	Oral powder	Pigs Lambs Cattle Hens Turkeys	Oral
Spain	Industrial Veterinaria S.A. Esmeralda, 19 - 4º 08950 Esplugues de Llobregat SPAIN	Ganadil Flumequina Suspension. Inyectable.	Flumequine	30 mg/ml	Suspension for injection	Cattle Lambs Pigs	Intramuscular
Spain	Labiana Life Science, S.A. Venus 26 - Can Parellada Industrial 08228 Tarrasa SPAIN	Kin-O-Flox	Enrofloxacin	100 g/1000 ml	Oral solution	Poultry	Oral
Spain	Laboratorios Syva, S.A. Parroco Pablo Diez, 49-57 24010 Trobajo Del Camino SPAIN	Syvaquinol 100 Inyectable	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Spain	Laboratorios Syva, S.A. arroco Pablo Diez, 49-57 24010 Trobajo Del Camino SPAIN	Syvaquinol 25 Inyectable	Enrofloxacin	25 mg/ml	Solution for injection	Cattle Pigs Dogs	Subcutaneous, intramuscular
Spain	Laboratorios Syva, S.A. Parroco Pablo Diez, 49-57 24010 Trobajo Del Camino SPAIN	Syvaquinol-10% Oral	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral
Spain	Laboratorio Jaer S.A. Barcelona, 411 08620 San Vicens del Horts SPAIN	Soranox	Enrofloxacin	100 mg/ml	Oral solution	Poultry Turkeys	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Spain	Laboratorio Maymo, S.A. Via Augusta, 302 08017 Barcelona SPAIN	Mayflus Suspension Oral	Flumequine	45 g/L	Oral suspension	Birds	Oral
Spain	Laboratorio Maymo, S.A. Via Augusta, 302 08017 Barcelona SPAIN	Quimiocoli	Enrofloxacin	101 mg/ml	Oral solution	Broilers	Oral
Spain	Laboratorios Calier, S.A. Barcelonés, 26 08520 Les Franqueses del Valles SPAIN	Roxacin	Enrofloxacin	100 mg/ml	Oral solution	Broilers	Oral
Spain	Laboratorios Calier, S.A. Barcelonés, 26 08520 Les Franqueses del Valles SPAIN	Roxacin Inyectable	Enrofloxacin	100 mg/ml	Solution for injection	Pigs	Intramuscular
Spain	Laboratorios Dr Esteve, S.A. Avda. Mare de Déu de Montserrat, 221 08041 Barcelona SPAIN	Alsir 10% Solucion Oral	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral
Spain	Laboratorios Dr Esteve, S.A. Avda. Mare de Déu de Montserrat, 221 08041 Barcelona SPAIN	Alsir 5% Solucion Inyectable	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs Dogs	Subcutaneous, intramuscular

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Spain	Laboratorios Dr Esteve, S.A. Avda. Mare de Déu de Montserrat, 221 08041 Barcelona SPAIN	Alsir Lechones Solucion Oral	Enrofloxacin	5 mg/ml	Oral solution	Piglets	Oral
Spain	Laboratorios e Industrias Iven, S.A. Polígono Industrial Vallecas Luis I, 56 28031 Madrid SPAIN	Floxaciven	Enrofloxacin	100 mg/ml	Oral solution	Broilers	Oral
Spain	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	Hipralona Enro-I	Enrofloxacin	50 mg/ml	Solution for injection	Pigs Cattle	Intramuscular
Spain	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	Hipralona Enro-S	Enrofloxacin	100 mg/ml	Oral solution	Poultry Rabbits	Oral
Spain	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	Hipralona/Flu-S	Flumequine	120 mg/ml	Oral solution	Hens Turkeys Cattle Lambs Kids Pigs	Oral
Spain	Laboratorios Hipra, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN	Oxolipra	Oxolinic acid	100 mg/g	Powder	Cattle Pigs Hen	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Spain	Laboratorios Karizoo, S.A. Polg. Industrial La Borda Mas Pujades, 11-12 08140 Caldes de Montbui (Barcelona) SPAIN	Enrokarizoo 10%	Enrofloxacin	10 g/100 ml	Oral solution	Poultry	Oral
Spain	Laboratorios Karizoo, S.A. Polg. Industrial La Borda Mas Pujades, 11-12 08140 Caldes de Montbui (Barcelona) SPAIN	K-Flox 10%	Enrofloxacin	10 g/100 ml	Oral solution	Poultry Rabbits	Oral
Spain	Laboratorios Ovejero, S. A. Ctra. León-Vilecha, Nº30 24192 León SPAIN	Quinovet F	Enrofloxacin	10 g/100 ml	Oral solution	Poultry Turkey	Oral
Spain	Laboratorios Serra Pamies, S.A. Ctra. de Castellvell nº 24 43206 Reus (Tarragona) SPAIN	E-Flox Solucion Oral	Enrofloxacin	100 mg/ml	Oral solution	Broilers	Oral
Spain	Laboratorios Syva, S.A. Avda Parroco Pablo Diez 49- 57 24010 Trobajo del Camino SPAIN	Fluyesyva Inyectable	Flumequine	75 mg/ml	Suspension for injection	Cattle Ovine Pigs Dogs	Intramuscular
Spain	Laboratorios Syva, S.A. Avda Parroco Pablo Diez 49- 57 24010 Trobajo del Camino SPAIN	Flumesyva Liquido 20 %	Flumequine	2%	Oral liquid	Pigs Lambs Cattle Hens Turkeys	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Spain	Laboratorios Syva, S.A. Avda Parroco Pablo Diez 49-57 24010 Trobajo del Camino SPAIN	Flumesyva Pasta Oral	Flumequine	30 mg/g	Oral paste	Pigs Lambs	Oral
Spain	Laboratorios Syva, S.A. Avda Parroco Pablo Diez 49-57 24010 Trobajo del Camino SPAIN	Flumesyva Polvo	Flumequine	100 g/1000 g	Oral powder	Poultry Pigs Sheep Cattle Fish	Oral
Spain	Laboratorios Syva, S.A. Avda Parroco Pablo Diez 49-57 24010 Trobajo del Camino SPAIN	Flumesyva Premezcla	Flumequine	100 mg/g	Premix for medicated feedingstuffs	Fish (trout)	Oral
Spain	MEVET, S. A. Poligono Industrial el Segre, Parcela 409-410 25191 Lérida SPAIN	Enrovall	Enrofloxacin	5 g/100 ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Spain	MEVET, S. A. Poligono Industrial el Segre, Parcela 409-410 25191 Lérida SPAIN	Enrovall Oral	Enrofloxacin	10 g/100 ml	Oral solution	Poultry	Oral
Spain	Pfizer, S.A. Avda. de Europa 20 B 28108 Alcobendas SPAIN	Advocin 180	Danofloxacin	180 mg/ml	Solution for injection	Cattle	Intramuscular, subcutaneous

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Spain	Polichem, S.A. Ctra. Reus-Cambrils, Km. 3 43206 Reus SPAIN	Polistar	Enrofloxacin	100 g/1000 ml	Oral solution	Poultry	Oral
Spain	Quimica Farmaceutica Bayer, S.L. Av. Baix Llobregat, 3-5 08970 Sant Joan Despi (Barcelona) SPAIN	Baytril 0,5% Solucion Oral	Enrofloxacin	5 mg/ml	Oral solution	Piglets	Oral
Spain	Quimica Farmaceutica Bayer, S.L. Av. Baix Llobregat, 3-5 08970 Sant Joan Despi (Barcelona) SPAIN	Baytril 10% Solucion Inyectable	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
Spain	Quimica Farmaceutica Bayer, S.L. Av. Baix Llobregat, 3-5 08970 Sant Joan Despi (Barcelona) SPAIN	Baytril 10% Solucion Oral	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral
Spain	Quimica Farmaceutica Bayer, S.L. Av. Baix Llobregat, 3-5 08970 Sant Joan Despi (Barcelona) SPAIN	Baytril 2,5% Solucion Oral	Enrofloxacin	25 mg/ml	Oral solution	Cattle	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Spain	Quimica Farmaceutica Bayer, S.L. Av. Baix Llobregat, 3-5 08970 Sant Joan Despi (Barcelona) SPAIN	Baytril 5% Solucion Inyectable	Enrofloxacin	5 g/100 ml	Solution for injection	Cattle Pigs Dogs	Subcutaneous, intramuscular
Spain	Quimica Farmaceutica Bayer, S.L. Av. Baix Llobregat, 3-5 08970 Sant Joan Despi (Barcelona) SPAIN	Baytriluno 100 mg/ml Solucion Inyectable para Bovino	Enrofloxacin	100 mg/ml	Solution for injection	Cattle	Subcutaneous, intravenous
Spain	S.P. Veterinaria S.A. Ctra. de Reus a Vignols km 4.1 43330 Riudoms (Tarragona) SPAIN	Colmyc-C	Enrofloxacin	10 g/100 ml	Oral solution	Poultry Rabbits	Oral
Spain	S.P. Veterinaria S.A. Ctra. de Reus a Vignols km 4.1 43330 Riudoms (Tarragona) SPAIN	Floxavex 100 mg/ml Concentrado Para Solucion oral pollos Y pavos	Enrofloxacin	100 mg/ml	Concentrate for oral solution	Poultry Turkey	Oral
Spain	S.P. Veterinaria S.A. Ctra. de Reus a Vignols km 4.1 43330 Riudoms (Tarragona) SPAIN	Fluquinol 10	Flumequine	10%	Oral solution	Birds Pigs Lambs Kids Cattle	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Spain	S.P. Veterinaria S.A. Ctra. de Reus a Vignols km 4.1 43330 Riudoms (Tarragona) SPAIN	Oxolin 100	Oxolinic acid, sodium salt	100 mg/g	Oral powder	Cattle Pigs Poultry	Oral
Spain	Universal Farma, S.L Gran Via Carlos III 98-7a 08028 Barcelona SPAIN	Enrofloxacin Universal 10%	Enrofloxacin	10 g/100 ml	Oral solution	Poultry Rabbits	Oral
Spain	Vetoquinol Especialidades Veterinarias, S.A. Parque Empresarial San Fernando - Edificio Italia 28830 San Fernando de Henares SPAIN	Marbocyl 10%	Marbofloxacin	10%	Solution for injection	Cattle Sows	Subcutaneous, intramuscular
Spain	Vetoquinol Especialidades Veterinarias, S.A. Parque Empresarial San Fernando - Edificio Italia 28830 San Fernando de Henares SPAIN	Marbocyl 2 %	Marbofloxacin	2%	Solution for injection	Cattle Fattening pigs	Subcutaneous, intramuscular
Spain	Vetoquinol Especialidades Veterinarias, S.A. Parque Empresarial San Fernando - Edificio Italia 28830 San Fernando de Henares SPAIN	Marbocyl Bolus	Marbofloxacin	50 mg	Tablets	Cattle	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Spain	Vetoquinol Especialidades Veterinarias, S.A. Parque Empresarial San Fernando - Edificio Italia 28830 San Fernando de Henares SPAIN	Marbocyl Bovino	Marbofloxacin	10%	Solution for injection	Cattle	Intramuscular
Spain	VIRBAC ESPAÑA, S.A. Angel Guimera, 179-181 08950 Esplugues de Llobregat SPAIN	Oxomid	Oxolinic acid, sodium salt	57.5 mg/g	Powder	Cattle	Oral
Sweden	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril Vet	Enrofloxacin	25 mg/ml	Solution for injection	Dogs Cats Cattle Pigs	Subcutaneous, intramuscular
Sweden	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril Vet	Enrofloxacin	100 mg/ml	Solution for injection	Dogs Cats Cattle Pigs	Subcutaneous, intramuscular
Sweden	Bayer Animal Health GmbH 51368 Leverkusen GERMANY	Baytril Vet	Enrofloxacin	100 mg/ml	Oral solution	Poultry	Oral
Sweden	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Fenoflox 10%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
Sweden	Pfizer Oy, Animal Health Tietokuja 4 00330 Helsinki FINLAND	Advocin 180	Danofloxacin	180 mg/ml	Solution for injection	Cattle	Subcutaneous, intravenous
The Netherlands	Bayer B.V. Animal Health Division Energieweg 1 3641 RT Mijdrecht THE NETHERLANDS	BAYTRIL 10 % INJECTIEOPLOSSING	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intramuscular, subcutaneous
The Netherlands	Bayer B.V. Animal Health Division Energieweg 1 3641 RT Mijdrecht THE NETHERLANDS	BAYTRIL 10% OPLOSSING-ORAAL	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
The Netherlands	Bayer B.V. Animal Health Division Energieweg 1 3641 RT Mijdrecht THE NETHERLANDS	Baytril piglet 25 mg/ml	Enrofloxacin	25 mg/ml	Solution for injection	Pigs	Intramuscular
The Netherlands	Bayer B.V. Animal Health Division Energieweg 1 3641 RT Mijdrecht THE NETHERLANDS	Baytril 5 % injectieoplossing	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs	Intramuscular, subcutaneous
The Netherlands	Bayer B.V. Animal Health Division Energieweg 1 3641 RT Mijdrecht THE NETHERLANDS	BAYTRIL 5% Injektievloeistof	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs	Intramuscular, intravenous, subcutaneous

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
The Netherlands	Bayer B.V. Animal Health Division Energieweg 1 3641 RT Mijdrecht THE NETHERLANDS	BAYTRIL Injektievloeistof 10%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle Pigs	Intramuscular, intravenous, subcutaneous
The Netherlands	Bayer B.V. Animal Health Division Energieweg 1 3641 RT Mijdrecht THE NETHERLANDS	BAYTRIL Oplossing 0,5% Oraal	Enrofloxacin	5 mg/ml	Oral solution	Pigs	Oral
The Netherlands	Bayer B.V. Animal Health Division Energieweg 1 3641 RT Mijdrecht THE NETHERLANDS	BAYTRIL Oplossing 2,5% Oraal	Enrofloxacin	25 mg/ml	Oral solution	Cattle	Oral
The Netherlands	Dopharma Research BV Zalmweg 24 4941 VX Raamsdonksveer THE NETHERLANDS	Drinkmix flumequine	Flumequine	500 mg/g	Powder	Pigs	Oral
The Netherlands	Dopharma Research BV Zalmweg 24 4941 VX Raamsdonksveer THE NETHERLANDS	Flumequine 10% WSP	Flumequine	100 mg/g	Powder	Cattle Chickens	Oral
The Netherlands	Dopharma Research BV Zalmweg 24 4941 VX Raamsdonksveer THE NETHERLANDS	Flumequine 50 % WSP	Flumequine	500 mg/g	Powder	Cattle Chickens	Oral
The Netherlands	Eurovet Animal Health B.V. Handelsweg 25 5531 AE Bladel THE NETHERLANDS	Flumix 50% super WO	Flumequine	500 mg/g	Powder	Cattle Chickens	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
The Netherlands	Eurovet Animal Health B.V. Handelsweg 25 5531 AE Bladel THE NETHERLANDS	Flumesol 10%	Flumequine	100 mg/ml	Oral solution	Cattle Chickens	Oral
The Netherlands	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	ENROX	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
The Netherlands	Pfizer Animal Health B.V. Rivium Westlaan 142 2909 LD Capelle a/d IJssel THE NETHERLANDS	ADVOCIN 180	Danofloxacin	180 mg/ml	Solution for injection	Cattle Cattle	Intravenous, subcutaneous
The Netherlands	Pfizer Animal Health B.V. Rivium Westlaan 142 2909 LD Capelle a/d IJssel THE NETHERLANDS	DANOCIN 180	Danofloxacin	180 mg/ml	Solution for injection	Cattle	Intravenous, subcutaneous
The Netherlands	Schippers Europe B.V. Bleijenhoek 17 5531 BK Bladel NETHERLAND	Baytril 50 mg/ml	Enrofloxacin	50 mg/ml	Solution for injection	Cattle Pigs	Intramuscular, subcutaneous
The Netherlands	Vétoquinol B.V. Bruistensingel 310 5232 AE Den Bosch THE NETHERLANDS	MARBOCYL 2%	Marbofloxacin	20 mg/ml	Solution for injection	Pigs Cattle	Intramuscular, subcutaneous
The Netherlands	Vétoquinol B.V. Bruistensingel 310 5232 AE Den Bosch THE NETHERLANDS	MARBOCYL BOLUS	Marbofloxacin	50 mg	Tablets	Cattle	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
The Netherlands	Vétoquinol B.V. Bruistensingel 310 5232 AE Den Bosch THE NETHERLANDS	MARBOCYL S, SOLUTION FOR INJECTION	Marbofloxacin	100 mg/ml	Solution for injection	Cattle	Intramuscular
The Netherlands	Wirtz Farma B.V. Leijsendwarsstraat 26 4901 PG Oosterhout THE NETHERLANDS	Enroxil 10% oral solution	Enrofloxacin	100 mg/ml	Oral solution	Chickens Turkeys	Oral
United Kingdom	Animalcare Ltd Common Road Dunnington York YO19 5RU UNITED KINGDOM	Enrocare 10% Solution for Injection for Cattle and Pigs	Enrofloxacin	10%	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
United Kingdom	Animalcare Ltd Common Road Dunnington York YO19 5RU UNITED KINGDOM	Enrocare 5% Solution for Injection for cattle, pigs, dogs and cats	Enrofloxacin	5%	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
United Kingdom	Bayer plc Animal Health Division Bayer House Strawberry Hill Newbury Berkshire RG14 1JA UNITED KINGDOM	Baytril 10% Oral Solution	Enrofloxacin	10%	Oral solution	Chickens Turkeys	Oral

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
United Kingdom	Bayer plc Animal Health Division Bayer House Strawberry Hill Newbury Berkshire RG14 1JA UNITED KINGDOM	Baytril 10% Solution for Injection	Enrofloxacin	10%	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
United Kingdom	Bayer plc Animal Health Division Bayer House Strawberry Hill Newbury Berkshire RG14 1JA UNITED KINGDOM	Baytril 2.5% Oral Solution	Enrofloxacin	2.5%	Oral solution	Cattle Exotic animals	Oral
United Kingdom	Bayer plc Animal Health Division Bayer House Strawberry Hill Newbury Berkshire RG14 1JA UNITED KINGDOM	Baytril 5% Solution for Injection	Enrofloxacin	5%	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
United Kingdom	Bayer plc Animal Health Division Bayer House Strawberry Hill Newbury Berkshire RG14 1JA UNITED KINGDOM	Baytril Max 10% Solution for Injection	Enrofloxacin	10%	Solution for injection	Cattle	Subcutaneous

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
United Kingdom	Bayer plc Animal Health Division Bayer House Strawberry Hill Newbury Berkshire RG14 1JA UNITED KINGDOM	Baytril Piglet Doser 0.5% Oral Solution	Enrofloxacin	0.5%	Oral solution	Pigs	Oral
United Kingdom	Ceva Animal Health Ltd 90 The Broadway Chesham Buckinghamshire HP5 1EG UNITED KINGDOM	Marboken	Marbofloxacin	100 mg	Solution for injection	Cattle	Intramuscular
United Kingdom	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Fenoflox 10% Solution Injectable	Enrofloxacin	100 mg	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular
United Kingdom	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Fenoflox 5% Solution Injectable	Enrofloxacin	50 mg	Solution for injection	Cattle Pigs Dogs Cats	Subcutaneous, intramuscular

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
United Kingdom	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Floxibac 10% solution for injection	Enrofloxacin	100 mg	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
United Kingdom	Chanelle Pharmaceuticals Manufacturing Limited IDA Business & Technology Park Loughrea Co Galway IRELAND	Floxibac 5% solution for injection	Enrofloxacin	50 mg	Solution for injection	Cattle Dogs Pigs Cats	Subcutaneous, intramuscular
United Kingdom	Krka, d.d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil Oral Solution 100mg/ml for Chickens and Turkeys	Enrofloxacin	10%	Oral solution	Chickens Turkeys	Oral
United Kingdom	Krka, d.d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil Solution for Injection 100mg/ml for Cattle and Pigs	Enrofloxacin	10%	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
United Kingdom	Krka, d.d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil Solution for Injection 50 mg/ml for calves, pigs and dogs	Enrofloxacin	5%	Solution for injection	Cattle Pigs Dogs	Subcutaneous, intramuscular, intravenous

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
United Kingdom	Krka, d. d., Novo mesto Šmarješka cesta 6 8501 Novo mesto SLOVENIA	Enroxil Max 100 mg/ml Solution for Injection for Cattle	Enrofloxacin	10%	Solution for injection	Cattle	Subcutaneous,
United Kingdom	Pfizer Animal Health Ramsgate Road Sandwich, Kent CT13 9NJ UNITED KINGDOM	Advocin 180, 180 mg/ml, Solution for Injection for Cattle	Danofloxacin	180 mg/ml	Solution for injection	Cattle	Subcutaneous, intravenous
United Kingdom	Pfizer Animal Health Ramsgate Road Sandwich, Kent CT13 9NJ UNITED KINGDOM	Advocin 2.5% Solution for Injection	Danofloxacin	2.5%	Solution for injection	Cattle Pigs	Subcutaneous, intramuscular
United Kingdom	Universal Farma, S.L Gran Via Carlos III 98-7a 08028 Barcelona SPAIN	Aviflox 0.5%	Enrofloxacin	0.5%	Oral solution	Piglets	Oral
United Kingdom	Universal Farma, S.L Gran Via Carlos III 98-7a 08028 Barcelona SPAIN	Aviflox 2.5%	Enrofloxacin	2.5%	Oral solution	Cattle	Oral
United Kingdom	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 10% Solution for Injection	Marbofloxacin	10% w/v	Solution for injection	Cattle Pigs	Subcutaneous

Member State/EEA	Applicant/ Marketing Authorisation Holder	Invented name	Active substance(s)	Strength	Pharmaceutical form	Animal species	Route(s) of administration
United Kingdom	Vétoquinol S. A. Magny Vernois B.P. 189 70204 Lure cedex FRANCE	Marbocyl 2% Solution for Injection	Marbofloxacin	2% w/v	Solution for injection	Cattle Pigs	Intramuscular
United Kingdom	Vetoquinol UK Ltd Great Slade, Buckingham Industrial Estate Buckingham Buckinghamshire MK18 1PA UNITED KINGDOM	Marbocyl 50mg Bolus	Marbofloxacin	50 mg	Tablets	Cattle	Oral
United Kingdom	Vetoquinol UK Ltd Great Slade, Buckingham Industrial Estate Buckingham Buckinghamshire MK18 1PA UNITED KINGDOM	Marbocyl Solo 10% Solution for Injection	Marbofloxacin	10% w/v	Solution for injection	Cattle	Intramuscular
United Kingdom	Virbac S.A. 1ere Avenue 2065 M LID B.P. 27 06516 Carros Cedex FRANCE	Powerflox 100 mg/ml Solution for Injection for Cattle and Pigs	Enrofloxacin	100 mg	Solution for injection	Cattle Pigs	Subcutaneous
United Kingdom	Virbac S.A. 1ere Avenue 2065 M LID B.P. 27 06516 Carros Cedex FRANCE	Powerflox 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats	Enrofloxacin	50 mg	Solution for injection	Cats Cattle Dogs Pigs	Subcutaneous, intramuscular

Annex II

Scientific conclusions and grounds for amendment of the summary of product characteristics and package leaflet

Overall summary of the scientific evaluation of veterinary medicinal products containing (fluoro)quinolones (*see annex I*)

1. Introduction

Quinolones including fluoroquinolones are very potent antimicrobials used in human and veterinary medicine which have a unique mechanism of action not related to conventional antimicrobials. They are well distributed in the body after administration and are active against a wide range of microorganisms.

The older generation of quinolones were licensed for use in food producing animals at the beginning of the 1980's and the first fluoroquinolone (enrofloxacin) during the late 1980's and early 1990's. Since then additional fluoroquinolone molecules have been authorised and a number of different veterinary medicines are now available on the market.

(Fluoro) quinolones for use in food-producing species have been authorised in the European Union via the national, mutual recognition and centralised procedures. The number of authorised products containing (fluoro) quinolones varies between different European Union countries. Moreover the indications for use of the products are not the same in all countries and marketing authorisations can differ between countries.

Quinolones represent a class of antimicrobials that is most important in the treatment of severe and invasive infections in humans and animals and are therefore of special interest for public and animal health.

On 15 February 2007 the CVMP adopted a "Public Statement on the use of (fluoro)quinolones in food-producing animals in the European Union: Development of Resistance and Impact on Human Health" (EMEA/SAGAM/184651/2005) concluding that the use of (fluoro)quinolones in animals has selected for resistance in animal pathogens and food borne zoonotic pathogens and that there was a need for risk management interventions. The CVMP suggested that prudent use of fuoroquinolones should be strongly promoted through recommendations in the SPC and that there was a need to harmonise the prudent use instructions in the product literature of these products. Following a focus group meeting of the CVMP with Interested Parties and Member States, the CVMP adopted a Reflection paper on the use of Fluoroquinolones in food-producing animals – Precautions for use in the SPC regarding prudent use guidance (EMEA/CVMP/416168/2006) detailing the precautionary phrases to be included in the Summary of the Product Characteristics, as follows:

- **Fluoroquinolone products**

"Official and local antimicrobial policies should be taken into account when the product is used."

"Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials."

"Whenever possible, fluoroquinolones should only be used based on susceptibility testing."

"Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance."

Quinolone products¹ (e.g. flumequine, oxolinic acid)

“Official and local antimicrobial policies should be taken into account when the product is used.”

“Whenever possible, quinolones should only be used based on susceptibility testing.”

“Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the quinolones and may decrease the effectiveness of treatment with other (fluoro) quinolones due to the potential for cross resistance.”

The implementation of the CVMP recommendations was foreseen to be achieved following voluntary action and collaboration between national authorities and industry. The last analysis in late 2008 of the success of the agreed approach showed that the CVMP recommendations had not been fully implemented yet and that further action was necessary.

In the light of the increase in bacterial resistance to antimicrobial substances, the European Council has called upon the European Commission and Member States to take steps as regards food- and animal-borne resistance to promote the prudent use of antimicrobials. Subsequently, the European Commission invoked Community interest and referred all veterinary medicinal products containing quinolones including fluoroquinolones intended for use in food-producing species to the Agency in order to ensure that the warnings on prudent use included in the Summary of the Product Characteristics for these classes of products were harmonised in line with those recommended in the CVMP Reflection paper.

The European Commission clarified on 30 July 2009 that prudent use warnings already contained in the product literature of the concerned products could be maintained even if they were not an exact reproduction of the CVMP recommendation provided that they convey the same key messages.

The referral procedure involved 696 veterinary products containing (fluoro)quinolones as identified by the Member States (see Annex I). The fluoroquinolone products concerned contain the active substances enrofloxacin, marbofloxacin, danofloxacin and difloxacin, and the quinolone products contain flumequine and oxolinic acid.

2. Discussion

Summary of Product Characteristics concerning 564 products of the 696 included in the referral were submitted by the Applicant/Marketing Authorisation Holders and competent national authorities to the CVMP for review.

In order to evaluate the situation concerning the existing prudent use warnings in the concerned products the CVMP agreed to define the following groups:

- Group 1. Veterinary medicinal products containing all the correct prudent use warnings in section 4 of the SPC (Special precautions for use), exactly as the CVMP recommendation and veterinary medicinal products containing all the prudent use warnings in section 4 of the SPC, which is however not exactly the text recommended by the CVMP, but conveys the same key messages;
- Group 2. Veterinary medicinal products that contain prudent use warnings in section 4 of the SPC but which do not adequately reflect the CVMP recommendations;
- Group 3. Veterinary medicinal products that do not contain prudent use warnings in section 4 of the SPC

¹ Not for decoquinat.

Group 4 Products for which no information was submitted by the Applicants/Marketing Authorisation Holders or competent national authorities and for which no assessment of the existing SPC warnings was therefore possible.

Further to the evaluation of all information made available to the Committee the following conclusions were made concerning the inclusion of prudent use warnings in the Summary of the Product Characteristics of the concerned products:

Group		No.
1	Veterinary medicinal products containing all the correct prudent use warnings in section 4 of the SPC, exactly as the CVMP recommendation and Veterinary medicinal products containing all the prudent use warnings in section 4 of the SPC, which are however not exactly the text recommended by the CVMP, but conveys the same key messages	318
2	Veterinary medicinal products that contain prudent use warnings in section 4 of the SPC but which do not adequately reflect the CVMP recommendations	163
3	Veterinary medicinal products that do not contain the prudent use warnings in of section 4 of the SPC	83
4	Veterinary medicinal products for which no information was submitted by the Applicants/Marketing Authorisation Holders or competent national authorities and for which no assessment of the existing SPC warnings was therefore possible	132
	Total	696

The (fluoro)quinolone SPC warnings were satisfactory for 318 products, and therefore no further action needs to be taken for these products.

For 163 products the SPC warnings were not adequate because they do not contain all the prudent use warnings in section 4 of the SPC or warnings for fluoroquinolone were used instead of quinolone warnings, or vice versa. Therefore, further action is required in order to ensure that adequate prudent use warnings are included.

In addition, for 83 products no prudent use warnings are included in the Summary of the Product Characteristics and therefore further action is required in order to ensure that adequate prudent use warnings in line with the recommendations from the Committee are included.

With regard to 132 products no information was submitted by the Applicants/Marketing Authorisation Holders or competent national authorities and therefore an assessment of the concerned Summary of the Product Characteristics could not be made.

The Committee also noted that not all veterinary medicinal products containing quinolones including fluoroquinolones authorised in the EEA-EU have been included in the scope of the referral as either some products were not notified to the Agency by the competent national authorities or the information was not received on time to allow the inclusion of these products in the referral procedure.

Grounds for amendment of the summary of product characteristics and package leaflet

Whereas:

- quinolones including fluoroquinolones are critical, efficient and valuable antimicrobials for animals and for some serious animal indications, fluoroquinolones are the only effective treatment available;
- the use of (fluoro)quinolones in animals has selected for antimicrobial resistance in animal pathogens and food borne zoonotic pathogens;
- there is a need for risk management interventions regarding the use of (fluoro)quinolones for humans and animals;
- the inclusion of specific warnings in the Summary of the Product Characteristics and Package Leaflet of the concerned products is intended to encourage prudent use and help maintain the positive benefit:risk balance for (fluoro)quinolone products;
- adequate precautionary phrases related to the use of (fluoro)quinolones intended for food-producing species have been included in Summary of the Product Characteristics for 318 products concerned by this referral;
- precautionary phrases related to the use of (fluoro)quinolones intended for food-producing species have been included in Summary of the Product Characteristics for 163 products which however do not adequately reflect the CVMP recommendations;
- no precautionary phrases related to the use of (fluoro)quinolones intended for food-producing species have been included in Summary of the Product Characteristics of 83 products concerned by this referral;
- for 132 the products identified by the Member States no or insufficient information was made available to the CVMP by the Applicants/Marketing Authorisation Holders or national authorities and therefore no conclusion on the availability or assessment the adequacy of precautionary phrases in the Summary of the Product Characteristics was possible;

the Committee recommends the variation of the terms of the marketing authorisations of products containing quinolones including fluoroquinolones intended for food producing species as referred in Annex I in order to amend the Summary of the Product Characteristics and Package Leaflets in those cases where there are not in line with the CVMP Reflection Paper (EMEA/CVMP/416168/2006). The warnings to be included in the Summary of the Product Characteristics and Package Leaflet should be reviewed to reflect the text set out in Annex III.

In addition the Committee notes that the list of products in Annex I does not include all veterinary medicinal products containing quinolones including fluoroquinolones authorised in the EEA-EU, as either some products were not notified to the Agency by the competent national authorities or the information was not received in time to include these products in the current referral. However, following the adoption of the Commission's Decision on this referral, Member States should identify and review information on the outstanding products and consider whether any action is appropriate as regards products authorised by them, and should act accordingly.

Annex III

Amendment to the summary of product characteristics and package leaflet

Amendments to be included in the relevant sections of the summary of product characteristics

A. For products listed in Annex I containing fluoroquinolones (enrofloxacin, marbofloxacin, danofloxacin and difloxacin):

4.5 Special precautions for use

i) Special precautions for use in animals

Recommendations for prudent use

"Official and local antimicrobial policies should be taken into account when the product is used."

"Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials."

"Whenever possible, fluoroquinolones should only be used based on susceptibility testing."

"Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance."

B. For products listed in Annex I containing quinolones (flumequine, oxolinic acid):

4.5 Special precautions for use

i) Special precautions for use in animals

Recommendations for prudent use

"Official and local antimicrobial policies should be taken into account when the product is used."

"Whenever possible, quinolones should only be used based on susceptibility testing."

"Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the quinolones and may decrease the effectiveness of treatment with other (fluoro)quinolones due to the potential for cross resistance."

Amendments to be included in the relevant sections of the package leaflet

A. For products listed in Annex I containing fluoroquinolones (enrofloxacin, marbofloxacin, danofloxacin and difloxacin):

12. Special warning(s)

"Official and local antimicrobial policies should be taken into account when the product is used."

"Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials."

"Whenever possible, fluoroquinolones should only be used based on susceptibility testing."

"Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance."

B. For products listed in Annex I containing quinolones (flumequine, oxolinic acid):

12. Special warning(s)

"Official and local antimicrobial policies should be taken into account when the product is used."

"Whenever possible, quinolones should only be used based on susceptibility testing."

"Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the quinolones and may decrease the effectiveness of treatment with other (fluoro)quinolones due to the potential for cross resistance."