Annex I

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

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Austria	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Enrotron 25, 25 mg/ml Injektionslösung für Hunde, Katzen, Schweine und Kaninchen	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats, pigs, rabbits
Austria	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Enrotron 50, 50 mg/ml Injektionslösung für Rinder (Kälber), Schweine und Hunde	Enrofloxacin	50 mg/ml	Solution for injection	Cattle (Calves), pigs, dogs
Austria	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Enrotron 100, 100 mg/ml Injektionslösung für Rinder und Schweine	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Austria	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Fenoflox 50 mg/ml Injektionslösung für Tiere	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
Austria	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Fenoflox 100 mg/ml Injektionslösung für Rinder und Schweine	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Austria	Industrial Veterinaria SA C/Esmeralda 19-21 08950 Esplugues de Llobregat Barcelona Spain	Enrodexil, 100 mg/ml, Injektionslösung für Rinder und Schweine	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Austria	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 50 mg/ml Injektionslösung für Kälber, Schweine und Hunde	Enrofloxacin	50 mg/ml	Solution for injection	Calves, pigs, dogs
Austria	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 100 mg/ml Injektionslösung für Rinder und Schweine	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Austria	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	Unisol 100 mg/ml, Injektionslösung für Rinder und Schweine	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Austria	Virbac S.A. 1ére Avenue L.I.D. 2065m 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

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Austria	Virbac S.A. 1ére Avenue L.I.D. 2065m 06516 Carros Cedex France	Powerflox 100 mg/ml Injektionslösung für Rinder und Schweine	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Belgium	Bayer SA-NV J.E. Mommaertslaan 14 1831 Diegem Machelen Belgium	BAYTRIL PIGLET	Enrofloxacin	25 mg/ml	Solution for injection	Pigs
Belgium	Bayer SA-NV J.E. Mommaertslaan 14 1831 Diegem Machelen Belgium	BAYTRIL 2,5%	Enrofloxacin	25 mg/ml	Solution for injection	Cats, dogs
Belgium	Bayer SA-NV J.E. Mommaertslaan 14 1831 Diegem Machelen Belgium	BAYTRIL 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs
Belgium	Bayer SA-NV J.E. Mommaertslaan 14 1831 Diegem Machelen Belgium	BAYTRIL SWINE	Enrofloxacin	100 mg/ml	Solution for injection	Pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Belgium	Bayer SA-NV J.E. Mommaertslaan 14 1831 Diegem Machelen Belgium	BAYTRIL 10%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle
Belgium	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	FENOFLOX 50 MG/ML	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
Belgium	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	FENOFLOX 100 MG/ML	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Belgium	EMDOKA bvba John Lijsenstraat 16 B-2321 Hoogstraten Belgium	FLOXADIL 50 MG/ML	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs
Belgium	EMDOKA bvba John Lijsenstraat 16 B-2321 Hoogstraten Belgium	FLOXADIL 100 MG/ML	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Belgium	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	ENROTRON 25 MG/ML	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats, exotic animals (small mammals, reptiles and avian species)
Belgium	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	ENROTRON 50 MG/ML	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
Belgium	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	ENROTRON 100 MG/ML	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Belgium	Industrial Veterinaria SA C/Esmeralda 19-21 08950 Esplugues de Llobregat Barcelona Spain	ENRODEXIL 100 MG/ML	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Belgium	Laboratorios Calier, S.A. c/ Barcelonès, 26 (Pla del Ramassà) 08520 Les Franqueses del Valles Barcelona Spain	ROXACIN 100 MG/ML	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Belgium	SP Veterinaria SA Ctra. Reus Vinyols km 4.1 43330 Riudoms Tarragona Spain	COLMYC 100 MG/ML	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Belgium	Vandenbussche Farma Service Brusselsesteenweg 396 1980 Eppegem Belgium	FLOXAVET 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs
Belgium	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	DORAFLOX 100 MG/ML	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Belgium	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	UNISOL 100 MG/ML	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Bulgaria	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 50 51368 Leverkusen Germany	Байтрил 5% инжективен разтвор	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs
Bulgaria	Industrial Veterinaria SA C/Esmeralda 19-21 08950 Esplugues de Llobregat Barcelona Spain	Ганадексил 5 %	Enrofloxacin	50 mg/ml	Solution for injection	cattle (calves), pigs, dogs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Bulgaria	Laboratorios Calier, S.A. c/ Barcelonès, 26 (Pla del Ramassà) 08520 Les Franqueses del Valles Barcelona Spain	Роксацин БГ инжективен	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Bulgaria	Laboratorios Calier, S.A. c/ Barcelonès, 26 (Pla del Ramassà) 08520 Les Franqueses del Valles Barcelona Spain	Ценеровиг - 10 ГБ Инж.	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs, dogs
Bulgaria	Laboratorios Hipra S.A. Avda. La Selva, 135 17170 Amer Girona Spain	Хипралона Енро - И	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs
Bulgaria	Laboratorios Syva S.A. Parroco Pablo Diez, 49 - 57 24010 Leon Spain	Сиваквинол - 100 Инжекционен разтвор	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Bulgaria	SP Veterinaria SA Ctra. Reus Vinyols km 4.1 43330 Riudoms Tarragona Spain	Кинофлокс 100 mg/ml инжекционен разтвор за говеда и свине	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Bulgaria	SP Veterinaria SA Ctra. Reus Vinyols km 4.1 43330 Riudoms Tarragona Spain	Колмик 100 мг/мл инжекционен разтвор за говеда и свине	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Cyprus	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 50 51368 Leverkusen Germany	Baytril 5%, Ενέσιμο διάλυμα για μόσχους, χοίρους και σκύλους	Enrofloxacin	50 mg/ml	Solution for injection	Calves, pigs, dogs
Czech Republic	Bayer s.r.o. Siemensova 2717/4 155 00 Praha 5 Czech Republic	BAYTRIL 2,5% (w/v) injekční roztok Přípravek s indikačním omezením	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats
Czech Republic	BAYER s.r.o. Siemensova 2717/4 155 00 Praha 5 Czech Republic	BAYTRIL 5% (w/v) injekční roztok Přípravek s indikačním omezením	Enrofloxacin	50 mg/ml	Solution for injection	Dogs, pigs, calves

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Czech Republic	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 25 mg/ml injekční roztok pro psy, kočky a exotická zvířata	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats exotic animals (small mammals, reptiles and birds)
Czech Republic	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 50 mg/ml injekční roztok pro skot, prasata, psy a kočky	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
Czech Republic	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 100 mg/ml injekční roztok pro skot a prasata	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Czech Republic	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 50 mg/ml injekční roztok	Enrofloxacin	50 mg/ml	Solution for injection	Dogs, pigs, calves
Czech Republic	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 100 mg/ml injekční roztok	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Czech Republic	Laboratorios Calier, S.A. c/ Barcelonès, 26 (Pla del Ramassà) 08520 Les Franqueses del Valles Barcelona Spain	ROXACIN 100 mg/ml injekční roztok	Enrofloxacin	100 mg/ml	Solution for injection	Pigs and calves
Denmark	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 50 51368 Leverkusen Germany	Baytril Vet	Enrofloxacin	50 mg/ml	Solution for injection	Dogs, cattle, poultry, cats, pigs
Denmark	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 50 51368 Leverkusen Germany	Baytril Vet	Enrofloxacin	100 mg/ml	Solution for injection	Dogs, cattle, poultry, cats, pigs
Denmark	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil	Enrofloxacin	50 mg/ml	Solution for injection	Dogs, cattle, poultry, cats, pigs
Estonia	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 25	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats, exotic animals (small mammals, reptiles and avian species)

Member State EU / EEA	Applicant / Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Estonia	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 50	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
Estonia	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 100	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Estonia	Industrial Veterinaria SA C/Esmeralda 19-21 08950 Esplugues de Llobregat Barcelona Spain	Ganadexil Enrofloxacina 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle (calves), pigs, dogs
Estonia	Laboratorios Hipra S.A. Avda. La Selva, 135 17170 Amer Girona Spain	Hipralona Enro-I	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs
Estonia	Vetoquinol Biowet Sp z o.o. 13/14 Kosynierów Gdyńskich St. 66-400 Gorzów Wlkp. Poland	Enrobioflox5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle (calves), pigs, dogs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Finland	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 50 51368 Leverkusen Germany	Baytril vet	Enrofloxacin	50 mg/ml	Solution for injection	Cats, dogs, sheep, cattle, pigs, goats
Finland	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Fenoflox vet	Enrofloxacin	50 mg/ml	Solution for injection	Cats, dogs, cattle, pigs
France	Animalcare Group plc. 10 Great North Way York Business Park Nether Poppleton York YO26 6RB United Kingdom	ENROCARE 25 MG/ML INJECTABLE POUR CHIENS CHATS ET NAC	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats, exotic animals
France	Animalcare Group plc. 10 Great North Way York Business Park Nether Poppleton York YO26 6RB United Kingdom	ENROCARE 50 MG/ML INJECTABLE POUR BOVINS PORCINS CHIENS ET CHATS	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
France	Animalcare Group plc. 10 Great North Way York Business Park Nether Poppleton York YO26 6RB United Kingdom	ENROCARE 100 MG/ML INJECTABLE POUR BOVINS ET PORCINS	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
France	Bayer Sante 220 Avenue de la Recherche 59120 LOOS France	BAYTRIL 2,5 % SOLUTION INJECTABLE	Enrofloxacin	25 mg/ml	Solution for injection	Cattle, pigs, dogs
France	Bayer Sante 220 Avenue de la Recherche 59120 LOOS France	BAYTRIL 5 % SOLUTION INJECTABLE	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs
France	Bayer Sante 220 Avenue de la Recherche 59120 LOOS France	BAYTRIL 10 % SOLUTION INJECTABLE	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
France	BIOLIS 21 Montee De La Garde 69340 Francheville France	QUINOTRYL 50 MG/ML SOLUTION INJECTABLE POUR BOVINS ET PORCIN S	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
France	BIOLIS 21 Montee De La Garde 69340 Francheville France	QUINOTRYL 100 MG/ML SOLUTION INJECTABLE POUR BOVINS ET PORCI NS	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
France	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	CHANENRO 50 MG/ML SOLUTION INJECTABLE POUR BOVINS, PORCINS, CHIENS ET CHATS	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
France	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	FLOXIBAC 50 MG/ML SOLUTION INJECTABLE POUR BOVINS, PORCINS, CHIENS ET CHATS	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
France	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	CHANENRO 100 MG/ML SOLUTION INJECTABLE POUR BOVINS ET PORCIN S	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
France	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	FLOXIBAC 100 MG/ML SOLUTION INJECTABLE POUR BOVINS ET PORCIN S	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Germany	Albrecht GmbH Hauptstr. 6-8 D-88326 Aulendorf Germany	Enro-Sleecol 50 mg/ml	Enrofloxacin	50 mg/ml	Solution for injection	Cattle (calves), pigs, dog
Germany	Albrecht GmbH Hauptstr. 6-8 D-88326 Aulendorf Germany	Enro-Sleecol 100 mg/ml	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Germany	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Enrotron 25	Enrofloxacin	25 mg/ml	Solution for injection	Pigs, rabbits, dogs, cats
Germany	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Enrotron 50	Enrofloxacin	50 mg/ml	Solution for injection	Cattle (calves), pigs, dog
Germany	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Enrotron 100	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Germany	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 50 51368 Leverkusen Germany	Baytril - Das Original - 2,5% Injektionslösung für Hunde, Katzen, Schweine und Kaninchen	Enrofloxacin	25 mg/ml	Solution for injection	Pigs, rabbits, dogs, cats

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Germany	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 50 51368 Leverkusen Germany	Baytril - Das Original - 5% Injektionslösung	Enrofloxacin	50 mg/ml	Solution for injection	Cattle (calves), pigs, dog
Germany	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 50 51368 Leverkusen Germany	Baytril - Das Original - 10% Injektionslösung für Rinder und Schweine	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Germany	Calluna Pharma bvba Treslong 34 B-2322 Hoogstraaten Belgium	Enrofloxacin 2,5% WDT, Injektionslösung	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats
Germany	Calluna Pharma bvba Treslong 34 B-2322 Hoogstraaten Belgium	Enrofloxacin 5% WDT, Injektionslösung	Enrofloxacin	50 mg/ml	Solution for injection	Cattle (calves), pigs, dog
Germany	Calluna Pharma bvba Treslong 34 B-2322 Hoogstraaten Belgium	Enrofloxacin 10% WDT, Injektionslösung	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Germany	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Fenoflox 50 mg/ml Injektionslösung für Rinder, Schweine, Hunde und Katzen	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Germany	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Floxibac 100 mg/ml	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Germany	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Fenoflox 100 mg/ml Injektionslösung für Rinder und Schweine	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Germany	Industrial Veterinaria SA C/Esmeralda 19-21 08950 Esplugues de Llobregat Barcelona Spain	Enrodexil 100 mg/ml Injektionslösung für Rinder und Schweine	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Germany	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 50 mg/ml Injektionslösung für Rinder (Kälber), Schweine und Hunde	Enrofloxacin	50 mg/ml	Solution for injection	Cattle (calves), pigs, dog
Germany	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 100 mg/ml Injektionslösung für Rinder und Schweine	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Germany	Laboratorios Calier, S.A. c/ Barcelonès, 26 (Pla del Ramassà) 08520 Les Franqueses del Valles Barcelona Spain	Roxacin 100 mg/ml	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Germany	Medistar Arzneimittel-Vertrieb GmbH Lüdinghauser Str. 23 D-59387 Ascheberg Germany	Enrostar 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle (calves), pigs, dog
Germany	Medistar Arzneimittel-Vertrieb GmbH Lüdinghauser Str. 23 D-59387 Ascheberg Germany	Enrostar 10%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Germany	Serumwerk Bernburg AG Hallesche Landstr. 105b D-06406 Bernburg Germany	Ursofloxacin 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle (calves), pigs, dog
Germany	Serumwerk Bernburg AG Hallesche Landstr. 105b D-06406 Bernburg Germany	Ursofloxacin 10%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Germany	SP Veterinaria SA Ctra. Reus Vinyols km 4.1 43330 Riudoms Tarragona Spain	Colmyc 100 mg/ml Inyectable	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Germany	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	Doraflox 100 mg/ml	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Germany	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	Unisol	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Germany	Virbac S.A. 1ére Avenue L.I.D. 2065m 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
Germany	Virbac S.A. 1ére Avenue L.I.D. 2065m 06516 Carros Cedex France	Powerflox 100 mg/ml Injektionslösung für Rinder und Schweine	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Greece	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 50 51368 Leverkusen Germany	Baytril 2,5%	Enrofloxacin	25 mg/ml	Solution for injection	Dogs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Greece	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 50 51368 Leverkusen Germany	Baytril 5%	Enrofloxacin	50 mg/ml	Solution for injection	Calves, pigs
Greece	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	FLOXIBAC 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
Greece	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	FLOXIBAC 10%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Greece	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	ENROFLOXACIN / HEALTHCARE	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats, exotic animals
Greece	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	ENROFLOXACIN / HEALTHCARE	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Greece	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	ENROFLOXACIN / HEALTHCARE	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Greece	Industrial Veterinaria SA C/Esmeralda 19-21 08950 Esplugues de Llobregat Barcelona Spain	ENRODEXIL	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Greece	SP Veterinaria SA Ctra. Reus Vinyols km 4.1 43330 Riudoms Tarragona Spain	COLMYC	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Greece	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	DORAFLOX	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Hungary	Bayer Hungária Kft. Alkotás u. 50. 1123 Budapest Hungary	Baytril 2,5% injekció A.U.V.	Enrofloxacin	25 mg/ml	Solution for injection	Pigs, rabbits, dogs, cats, exotic animals (mammals, birds, reptiles)

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Hungary	Bayer Hungária Kft. Alkotás u. 50. 1123 Budapest Hungary	Baytril 5% injekció A.U.V.	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs
Hungary	Bayer Hungária Kft. Alkotás u. 50. 1123 Budapest Hungary	Baytril 10% injekció A.U.V.	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Hungary	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Fenoflox 50 mg/ml injekció szarvasmarha, sertés, kutya és macska részére A.U.V.	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
Hungary	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Fenoflox 100 mg/ml injekció szarvasmarha és sertés részére A.U.V.	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Hungary	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 25 mg/ml injekció kutyák, macskák és egzotikus állatok részére A.U.V.	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats, exotic animals (small mammals, reptiles and avian species)

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Hungary	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 50 mg/ml injekció szarvasmarha, sertés,kutya és macska részére A.U.V.	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
Hungary	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 100 mg/ml injekció szarvasmarha és sertés részére A.U.V	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Hungary	Industrial Veterinaria SA C/Esmeralda 19-21 08950 Esplugues de Llobregat Barcelona Spain	ENRODEXIL 100 mg/ml injekció szarvasmarhák és sertések számára A.U.V.	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Hungary	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 5 % injekció A.U.V.	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, sheep, goats
Hungary	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 10% injekció A.U.V.	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Hungary	Laboratorios Syva S.A. Parroco Pablo Diez, 49-57 24010 Leon Spain	Syvaquinol 100 injekció A.U.V.	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Hungary	SP Veterinaria SA Ctra. Reus Vinyols km 4.1 43330 Riudoms Tarragona Spain	Colmyc 100 mg/ml injekció szarvasmarha és sertés részére A.U.V.	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Hungary	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	DORAFLOX 100 mg/ml injekció szarvasmarhák és sertések számára A.U.V.	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Hungary	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	LANFLOX 100 mg/ml injekció szarvasmarhák és sertések számára A.U.V.	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Iceland	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 50 51368 Leverkusen Germany	Baytril vet.	Enrofloxacin	50 mg/ml	Solution for injection	Calves, pigs, poultry dogs, cats
Iceland	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 50 51368 Leverkusen Germany	Baytril vet.	Enrofloxacin	100 mg/ml	Solution for injection	Calves, pigs, poultry dogs, cats

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Ireland	Animalcare Group plc. 10 Great North Way York Business Park Nether Poppleton York YO26 6RB United Kingdom	Enrocare 25 mg/ml Solution for Injection for Dogs, Cats and Exotic Animals	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats and exotic animals (small mammals, reptiles and avian species)
Ireland	Animalcare Group plc. 10 Great North Way York Business Park Nether Poppleton York YO26 6RB United Kingdom	Enrocare 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats.	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs weighing more than 25 kg, dogs, cats
Ireland	Animalcare Group plc. 10 Great North Way York Business Park Nether Poppleton York YO26 6RB United Kingdom	Enrocare 100 mg/ml Solution for Injection for Cattle and Pigs.	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs weighing more than 25 kg
Ireland	Bayer Limited The Atruim Blackthorn Road Dublin 18 Ireland	Baytril 2.5 % Solution for Injection	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats, exotic animals (small mammals, reptiles and avian species)

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Ireland	Bayer Limited The Atruim Blackthorn Road Dublin 18 Ireland	Baytril 5% Solution for Injection	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
Ireland	Bayer Limited The Atruim Blackthorn Road Dublin 18 Ireland	Baytril 10% Solution for Injection	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Ireland	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Floxibac 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats.	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
Ireland	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Fenoflox 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats.	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
Ireland	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Fenoflox 100 mg/ml Solution for Injection for Cattle and Pigs.	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Ireland	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Floxibac 100 mg/ml Solution for Injection for Cattle and Pigs	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Ireland	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 25 mg/ml Solution for injection for dogs, cats and exotic animals	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats, exotic animals (small mammals, reptiles and avian species)
Ireland	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 50 mg/ml Solution for injection for cattle, pigs, dogs and cats	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
Ireland	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 100 mg/ml Solution for injection for cattle and pigs	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Ireland	Global Vet Health SL c/Capcanes, n° 12-bajos Poligon Agro-Reus Reus 43206 Spain	Quinoflox 100 mg/ml solution for injection for cattle and pigs	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Ireland	Industrial Veterinaria SA C/Esmeralda 19-21 08950 Esplugues de Llobregat Barcelona Spain	ENRODEXIL 100 mg/ml solution for injection for cattle and pigs	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Ireland	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 50 mg/ml solution for injection for calves, pigs and dogs	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs
Ireland	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 100 mg/ml solution for injection for cattle and pigs	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Ireland	Laboratorios Calier, S.A. c/ Barcelonès, 26 (Pla del Ramassà) 08520 Les Franqueses del Valles Barcelona Spain	ROXACIN 100 mg/ml solution for injection for cattle and pig	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Ireland	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	Doraflox 100 mg/ml solution for injection for cattle and pigs	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Ireland	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	Unisol 100 mg/ml solution for injection for cattle and pigs	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Ireland	Virbac S.A. 1ére Avenue L.I.D. 2065m 06516 Carros Cedex France	Powerflox 50 mg/ml solution for injection for cattle, pigs, dogs and cats. Enrofloxacin.	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
Ireland	Virbac S.A. 1ére Avenue L.I.D. 2065m 06516 Carros Cedex France	Powerflox 100 mg/ml solution for injection for cattle and pigs Enrofloxacin	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Italy	Bayer SpA Viale Certosa, 130 20156 Milano Italy	Baytril	Enrofloxacin	25 mg/ml and 50 mg/ml	Solution for injection	Cattle, dogs, sheep, goats, cats, rabbits, pigs
Italy	Bayer SpA Viale Certosa, 130 20156 Milano Italy	Baytril 10%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs, sheep, goats
Italy	CEVA Salute Animale viale Colleoni, 15 20864 Agrate Brianza (MB) Italy	CEVAFLOX iniettabile, 100 mg/ml, soluzione iniettabile per bovini, ovini, suini.	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs, sheep

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Italy	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	GELLIFLOX 100mg/ml (or 50 mg/ml) soluzione iniettabile per bovini e suini	Enrofloxacin	100 mg/ml (or 50 mg/ml)	Solution for injection	Cattle, pigs
Italy	Drugs Italia s.r.l. Via G. Puecher, 8 20037 Paderno Dugnano (MI) Italy	EFLOXIN sluzione iniettabile	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, sheep
Italy	Fatro s.p.a. Via Emilia, 285 Ozzano Emilia (BO) Italy	VALEMAS 10 (or 5) 100 mg/ml (or 50 mg/ml) soluzione iniettabile per bovini, ovi-caprini e suini	Enrofloxacin	100 mg/ml (or 50 mg/ml)	Solution for injection	Cattle, pigs, sheep, goats
Italy	Friulchem via San Marco, 23 33099 Vivaro (PN) Italy	TENOTRIL 100mg/ml soluzione iniettabile epr bovini, suini, ovicaprini	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs, sheep, goats
Italy	Industrial Veterinaria SA C/Esmeralda 19-21 08950 Esplugues de Llobregat Barcelona Spain	ENRODEXIL 100mg/ml soluzione iniettabile per bovini e suini	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Italy	Laboratorios Calier, S.A. c/ Barcelonès, 26 (Pla del Ramassà) 08520 Les Franqueses del Valles Barcelona Spain	ROXACIN 100mg/ml soluzione iniettabile per bovini e suini	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Italy	SP Veterinaria SA Ctra. Reus Vinyols km 4.1 43330 Riudoms Tarragona Spain	COLMYC 100 mg/ml soluzione iniettabile	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Italy	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	LANFLOX 100mg/ml soluzione iniettabile per bovini e suini	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Latvia	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats, exotic animals
Latvia	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Latvia	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Lithuania	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	ENROTRON 25 mg/ml, injekcinis tirpalas šunims, katėms ir egzotiniams gyvūnams	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats, exotic animals (small mammals, reptiles and avian species)
Lithuania	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	ENROTRON 50 mg/ml, injekcinis tirpalas galvijams, kiaulėms, šunims ir katėms	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
Lithuania	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	ENROTRON 100 mg/ml, injekcinis tirpalas galvijams ir kiaulėms	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Lithuania	Vetoquinol Biowet Sp z o.o. 13/14 Kosynierów Gdyńskich St. 66-400 Gorzów Wlkp. Poland	ENROBIOFLOX 5 %, injekcinis tirpalas galvijams, kiaulėms ir šunims	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Luxembourg	Animalcare Group plc. 10 Great North Way York Business Park Nether Poppleton York YO26 6RB United Kingdom	Floxadil 25mg/ml Injektionsl!osung für Hunde, katzen und exotische Tiere	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats, exotic animals (small mammals, reptiles and birds)
Luxembourg	Animalcare Group plc. 10 Great North Way York Business Park Nether Poppleton York YO26 6RB United Kingdom	Floxadil 50mg/ml Injektionslösung fürRinder, Schweine, Hunde und Katzen	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs >25kg, dogs, cats
Luxembourg	Animalcare Group plc. 10 Great North Way York Business Park Nether Poppleton York YO26 6RB United Kingdom	Floxadil 100mg/ml Injektionslösung für Rinder und Schweine	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs >25kg
Luxembourg	Bayer SA-NV J.E. Mommaertslaan 14 1831 Diegem Machelen Belgium	Baytril piglet 25mg/ml	Enrofloxacin	25 mg/ml	Solution for injection	Pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Luxembourg	Bayer SA-NV J.E. Mommaertslaan 14 1831 Diegem Machelen Belgium	Baytril 2,5%	Enrofloxacin	25 mg/ml	Solution for injection	Cats, dogs
Luxembourg	Bayer SA-NV J.E. Mommaertslaan 14 1831 Diegem Machelen Belgium	Baytril 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs
Luxembourg	Bayer SA-NV J.E. Mommaertslaan 14 1831 Diegem Machelen Belgium	Baytril 10%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle
Luxembourg	Bayer SA-NV J.E. Mommaertslaan 14 1831 Diegem Machelen Belgium	Baytril Swine 100mg/ml	Enrofloxacin	100 mg/ml	Solution for injection	Pigs
Luxembourg	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Fenoflox 50mg/ml solution injectable pour bovins, porcins, chiens et chats	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Luxembourg	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Fenoflox 100mg/ml solution injectable pour bovins et porcins	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Luxembourg	SP Veterinaria SA Ctra. Reus Vinyols km 4.1 43330 Riudoms Tarragona Spain	Colmyc injectable Bovins Porcins	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Malta	Farmcare Ltd Florence A triq il Fran Qormi Malta	Baytril 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs
Malta	Industrial Veterinaria, S.A Esmeralda, 19, 08950 Esplugues de Llobreget Barcelona Spain	Ganadexil Enrofloxacino 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs
Malta	Laboratorios Calier, S.A. c/ Barcelonès, 26 (Pla del Ramassà) 08520 Les Franqueses del Valles Barcelona Spain	Roxacin injection	Enrofloxacin	100 mg/ml	Solution for injection	Pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Malta	Laboratorios Syva S.A. Parroco Pablo Diez, 49-57 24010 Leon Spain	Syvaquinol 25%	Enrofloxacin	25 mg/ml	Solution for injection	Calves, piglets, dogs
Malta	Laboratorios Syva S.A. Parroco Pablo Diez, 49-57 24010 Leon Spain	Syvaquinol 100%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Norway	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 50 51368 Leverkusen Germany	Baytril vet	Enrofloxacin	25 mg/ml	Solution for injection	Pigs, cattle, dogs, cats
Norway	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 50 51368 Leverkusen Germany	Baytril vet	Enrofloxacin	100 mg/ml	Solution for injection	Pigs, cattle, dogs, cats
Norway	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Fenoflox	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Poland	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 50 51368 Leverkusen Germany	Baytril 2,5% inj., 25 mg/ml roztwór do wstrzykiwań dla psów i kotów	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Poland	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 50 51368 Leverkusen Germany	Baytril 5% inj., enrofloksacyna 50 mg/ml, roztwór do wstrzykiwań dla bydła i świń	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs
Poland	Biowet Puławy Sp. z o.o. 2 Arciucha Str. 24-100 Puławy Poland	Enflocyna inj, 100 mg/ml, roztwór do wstrzykiwań dla bydła, świń, psów i kotów	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
Poland	Drwalewskie Zakłady Przemysłu Bioweterynaryjnego S.A. 6 Grójecka Str. 05-651 Drwalew Poland	Enrofloksacyna 10 % inj., 100 mg/ml roztwór do wstrzykiwań dla bydła	Enrofloxacin	100 mg/ml	Solution for injection	Cattle
Poland	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 25 mg/ml roztwór do wstrzykiwań dla psów, kotów i zwierząt egzotycznych	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats, exotic animals
Poland	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 50 mg roztwór do wstrzykiwań dla bydła, świń, psów i kotów	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Poland	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 100 mg/ml roztwór do wstrzykiwań dla bydła i świń	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Poland	Industrial Veterinaria SA C/Esmeralda 19-21 08950 Esplugues de Llobregat Barcelona Spain	Enrodexil, 100 mg/ml roztwór do wstrzykiwań dla bydła i świń	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Poland	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 5%	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs
Poland	Laboratorios Calier, S.A. c/ Barcelonès, 26 (Pla del Ramassà) 08520 Les Franqueses del Valles Barcelona Spain	Roxacin, 100 mg/ml roztwór do wstrzykiwań dla bydła i świń	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Poland	PFO "Vetos-Farma" Sp. z o.o. 21 Dzierżoniowska Str. 58-260 Bielawa Poland	Enrofloxacyna 5% iniekcja, enrofloxacyna 5g/100ml, roztwór dla bydła, świń, psów i kotów	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Poland	PFO "Vetos-Farma" Sp. z o.o. 21 Dzierżoniowska Str. 58-260 Bielawa Poland	Enrofloxacyna 10% iniekcja, enrofloksacyna 10 g/100 ml, roztwór do wstrzykiwań dla bydła, świń, psów i kotów	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
Poland	Pharmagal, s.r.o. Murgasova 5 949 01, Nitra Slovakia	Enrogal 50 mg/ml roztwór do wstrzykiwań	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs
Poland	Przedsiębiorstwo Wielobranżowe VET-AGRO Sp. z o.o. 32 Gliniana Str. 20-616 Lublin Poland	Enrocin 5% inj., enrofloksacyna 50 mg/ml, roztwór do wstrzykiwań dla bydła i świń	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs
Poland	SP Veterinaria SA Ctra. Reus Vinyols km 4.1 43330 Riudoms Tarragona Spain	Colmyc 100 mg/ml roztwór do wstrzykiwań dla bydła i świń	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Poland	Vetoquinol Biowet Sp z o.o. 13/14 Kosynierów Gdyńskich St. 66-400 Gorzów Wlkp. Poland	Enrobioflox 5% Injectio, 50 mg/ml roztwór do wstrzykiwań dla świń, bydła i psów	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Poland	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	Lanflox, 100 mg/ml roztwór do wstrzykiwań dla bydła i świń	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Portugal	Bayer PORTUGAL S.A. Rua Quinta do Pinheiro, 5 2794-003 Carnaxide Portugal	BAYTRIL 2,5% solução injectável	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats
Portugal	Bayer PORTUGAL S.A. Rua Quinta do Pinheiro, 5 2794-003 Carnaxide Portugal	Baytril 5% solução injectável	Enrofloxacin	50 mg/ml	Solution for injection	Dogs, cattle and pigs
Portugal	Bayer PORTUGAL S.A. Rua Quinta do Pinheiro, 5 2794-003 Carnaxide Portugal	Baytril 10% solução injectável	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Portugal	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Fenoflox 50 mg / ml solução injectável para bovinos, suínos, cães e gatos	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
Portugal	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Floxibac 50 mg/ml solução injetável para bovinos, suínos, cães e gatos	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Portugal	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Fenoflox 100 mg/ml solução injectável para bovinos e suínos	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Portugal	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Floxibac 100 mg/ml solução injectável para bovinos e suínos	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Portugal	ESTEVE FARMA, LDA Av. Do Forte, 3 Edifício Suécia II Piso 4A 2794-044 Carnaxide Portugal	ALSIR 25mg/ml solução injectável para Cães e Gatos	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats
Portugal	ESTEVE FARMA, LDA Av. Do Forte, 3 Edifício Suécia II Piso 4A 2794-044 Carnaxide Portugal	ALSIR 50Mmg/ml Solução Injectável	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs
Portugal	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 25 mg/ml Solução injectável para cães, gatos e animais exóticos	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats, exotic Animals (small mammals, reptiles and avian species)

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Portugal	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 50 mg/ml Solução injectável para bovinos, suínos, cães e gatos	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
Portugal	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 100 mg / ml solução injectável para bovinos e suínos	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Portugal	Global Vet Health SL c/Capcanes, n° 12-bajos Poligon Agro-Reus Reus 43206 Spain	Quinoflox 100 mg/ml solução injetável para bovinos e suínos	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Portugal	Laboratorios Calier, S.A. c/ Barcelonès, 26 (Pla del Ramassà) 08520 Les Franqueses del Valles Barcelona Spain	ROXACIN 100 mg/ml solução injectável para bovinos e suínos	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Portugal	SP Veterinaria SA Ctra. Reus Vinyols km 4.1 43330 Riudoms Tarragona Spain	Colmyc 100 mg/ml Solução injectável para bovinos e suínos	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Portugal	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	LANFLOX 100 mg/ml solução injectável para bovinos e suínos.	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Portugal	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	ENRODEXIL 100 mg/ml solução injectável para bovinos e suínos	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Romania	CENAVISA SA LABORATORIOS Cami Pedra Estela s/n 43205 REUS Spain	CENAMICINA 10 PLUS	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs, dogs
Romania	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	ENROTRON 25 mg/ml	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats, exotic animals
Romania	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	ENROTRON 50 mg/ml	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Romania	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	ENROTRON 100 mg/ml	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pig
Romania	Global Vet Health SL c/Capcanes, n° 12-bajos Poligon Agro-Reus Reus 43206 Spain	QUINOFLOX 100 mg/ml	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Romania	Industrial Veterinaria SA C/Esmeralda 19-21 08950 Esplugues de Llobregat Barcelona Spain	GANADEXIL ENROFLOXACINA 5 %	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs,
Romania	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	ENROXIL 50mg/ml	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, goats, sheep, dogs
Romania	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	ENROXIL 10%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Romania	Laboratorios Hipra S.A. Avda. La Selva, 135 17170 Amer Girona Spain	HIPRALONA ENRO I	Enrofloxacin	50 mg/ml	Solution for injection	Calves, pigs
Romania	Laboratorios Syva S.A. Parroco Pablo Diez, 49-57 24010 Leon Spain	SYVAQUINOL 100 injectable	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Romania	LABORATORIOS VELVIAN S.L C/Vitoria 9, 2 B 09004 Burgos Spain	ENRODEXIL 100 mg/ml	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Romania	PASTEUR Filiala Filipesti SRL Str. Principala nr. 944 Filipestii de Padure Jud. Prahova Romania	Enrofloxacina 5 % injectable solution	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, sheep, goats, pigs, dogs, cats
Romania	PASTEUR Filiala Filipesti SRL Str. Principala nr. 944 Filipestii de Padure Jud. Prahova Romania	Enrofloxacina 10 % injectable solution	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, sheep, goats, pigs, dogs, cats

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Romania	S.C. ROMVAC COMPANY S.A. Şos. Centurii, nr. 7 Voluntari Romania	Enrofloxarom 5 %	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, sheep, pigs, dogs
Romania	SP Veterinaria SA Ctra. Reus Vinyols km 4.1 43330 Riudoms Tarragona Spain	Colmyc 100 mg/ml inyectable solution	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Romania	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	DORAFLOX 100 mg/ml	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Slovakia	Bayer s.r.o. Litvínovská 609/3 190 21 Praha 9 Czech Republic	Baytril 2.5 % inj. ad us. vet.	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats
Slovakia	Bayer s.r.o. Litvínovská 609/3 190 21 Praha 9 Czech Republic	Baytril 5 % (w/v) injekčný roztok	Enrofloxacin	50 mg/ml	Solution for injection	Dogs, pigs, calves
Slovakia	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 25 mg/ml injekčný roztok pre psy , mačky a exotické živočíchy	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats, exotic animals

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Slovakia	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 50mg/ml injekčný roztok pre hovädzí dobytok, ošípané, psy a mačky	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
Slovakia	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 100 mg/ml injekčný roztok	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Slovakia	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 5 % inj. ad us. vet.	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, sheep, goats, pigs, dogs
Slovakia	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 10 % inj. ad us. vet.	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Slovakia	Laboratorios Hipra S.A. Avda. La Selva, 135 17170 Amer Girona Spain	Hipralona Enro - I 50 mg/ ml injekčný roztok	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Slovakia	Pharmagal, s.r.o. Murgasova 5 949 01, Nitra Slovakia	Enrogal 50 mg/ml injekčný roztok	Enrofloxacin	50 mg/ml	Solution for injection	Calves, pigs, dogs
Slovenia	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Enrotron 25, 25 mg/ml raztopina za injiciranje za pse, mačke, prašiče in kunce	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats, pigs, rabbits
Slovenia	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	ENROTRON 50, 50 mg/ml raztopina za injiciranje za govedo (teleta), prašiče in pse	Enrofloxacin	50 mg/ml	Solution for injection	Cattle (calves), pigs, dogs
Slovenia	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	ENROTRON 100, 100 mg/ml raztopina za injiciranje za govedo in prašiče	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Slovenia	Bayer d.o.o. Bravničarjeva 13 Ljubljana Slovenia	Baytril® 5 % raztopina za injiciranje	Enrofloxacin	50 mg/ml	Solution for injection	Calves, pigs, dogs
Slovenia	Bayer d.o.o. Bravničarjeva 13 Ljubljana Slovenia	Baytril® 10 % raztopina za injiciranje	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Slovenia	GENERA Slovenia d.o.o. Dunajska 51 1000 Ljubljana Slovenia	VETOFLOK 10 % raztopina za injiciranje	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Slovenia	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	ENROXIL 50 mg/ml raztopina za injiciranje za govedo, ovce, koze, prašiče in pse	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, sheep, goats, pigs, dogs
Slovenia	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	ENROX 100 mg/ml raztopina za injiciranje za govedo in prašiče	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Slovenia	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	ENROXIL 100 mg/ml raztopina za injiciranje za govedo in prašiče	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Spain	Hifarmax, Produtos e serviços veterinários, Lda Av. Marechal Craveiro Lopes nº96 R/C Dto 2775-696 Carcavelos Portugal	ENROCILL 50mg/ml solución inyectable para bovino, porcino y perros	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Spain	Industrial Veterinaria SA C/Esmeralda 19-21 08950 Esplugues de Llobregat Barcelona Spain	ENRODEXIL 100 mg/ml SOLUCION INYECTABLE PARA BOVINO Y PORCINO	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Spain	Laboratorios Calier, S.A. c/ Barcelonès, 26 (Pla del Ramassà) 08520 Les Franqueses del Valles Barcelona Spain	ROXACIN 100 mg/ml SOLUCION INYECTABLE	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Spain	Laboratorios Dr. Esteve, S.A. Avda. Mare de Déu de Montserrat, 221 08041 Barcelona Spain	ALSIR 2,5% SOLUCION INYECTABLE	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats
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
Spain	Laboratorios Dr. Esteve, S.A. Avda. Mare de Déu de Montserrat, 221 08041 Barcelona Spain	ALSIR 100 mg/ml SOLUCION INYECTABLE PARA BOVINO Y PORCINO	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Spain	SP Veterinaria SA Ctra. Reus Vinyols km 4.1 43330 Riudoms Tarragona Spain	QUINOLCEN 100 mg/ml SOLUCION INYECTABLE	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Spain	SP Veterinaria SA Ctra. Reus Vinyols km 4.1 43330 Riudoms Tarragona Spain	FLOXAVEX 100 mg/ml SOLUCION INYECTABLE	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Spain	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	LANFLOX 100 mg/ml SOLUCION INYECTABLE	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
Sweden	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 50 51368 Leverkusen Germany	Baytril® vet.	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, pigs, cattle, cats
Sweden	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 50 51368 Leverkusen Germany	Baytril® vet.	Enrofloxacin	100 mg/ml	Solution for injection	Dog, pigs, cattle, cats

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Sweden	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Fenoflox vet	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
The Netherlands	Animalcare Group plc. 10 Great North Way York Business Park Nether Poppleton York YO26 6RB United Kingdom	Floxadil 25 mg/ml, oplossing voor injectie voor honden, katten en exotische dieren	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats, exotic animals
The Netherlands	Animalcare Group plc. 10 Great North Way York Business Park Nether Poppleton York YO26 6RB United Kingdom	Floxadil 50mg/ml, oplossing voor injectie voor runderen, varkens, honden en katten	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
The Netherlands	Animalcare Group plc. 10 Great North Way York Business Park Nether Poppleton York YO26 6RB United Kingdom	Floxadil 100mg/ml, oplossing voor injectie voor runderen en varkens	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
The Netherlands	Bayer B.V. Energieweg 1 3641 RT Mijdrecht Netherlands	BAYTRIL 2,5% INJEKTIEVLOEISTOF	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats
The Netherlands	Bayer B.V. Energieweg 1 3641 RT Mijdrecht Netherlands	Baytril Piglet 25 mg/ml inspuitbare oplossing	Enrofloxacin	25 mg/ml	Solution for injection	Pigs
The Netherlands	Bayer B.V. Energieweg 1 3641 RT Mijdrecht Netherlands	BAYTRIL 5% INJEKTIEVLOEISTOF	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs
The Netherlands	Bayer B.V. Energieweg 1 3641 RT Mijdrecht Netherlands	BAYTRIL 5 % INJECTIEOPLOSSING	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, dogs, pigs
The Netherlands	Bayer B.V. Energieweg 1 3641 RT Mijdrecht Netherlands	BAYTRIL INJEKTIEVLOEISTOF 10%	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
The Netherlands	Bayer B.V. Energieweg 1 3641 RT Mijdrecht Netherlands	BAYTRIL 10 % INJECTIEOPLOSSING	Enrofloxacin	100 mg/ml	Solution for injection	Pigs, cattle

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
The Netherlands	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Fenoflox 50 mg/ml Oplossing voor injectie	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
The Netherlands	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Fenoflox 100 mg/ml Oplossing voor injectie voor runderen en varkens	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
The Netherlands	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 25 mg/ml, oplossing voor injectie	Enrofloxacin	25 mg/ml	Solution for injection	Dogs, cats, cage birds, reptiles
The Netherlands	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 50 mg/ml, oplossing voor injectie voor runderen, varkens, honden en katten	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
The Netherlands	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 100 mg/ml, oplossing voor injectie voor runderen en varkens	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
The Netherlands	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	ENROXIL Oplossing voor injectie 50 mg/ml voor kalveren, varkens en honden	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs
The Netherlands	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	ENROXIL 100 MG/ML SOLUTION FOR INJECTION	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
The Netherlands	Laboratorios Calier, S.A. c/ Barcelonès, 26 (Pla del Ramassà) 08520 Les Franqueses del Valles Barcelona Spain	Roxacin 100 mg/ml, oplossing voor injectie voor runderen en varkens	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
The Netherlands	Romikim Farma SL Gran Via Carlos III, 98,6 8027 Barcelona Spain	Enrodexil 100 mg/ml oplossing voor injectie voor runderen en varkens	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
The Netherlands	SP Veterinaria SA Ctra. Reus Vinyols km 4.1 43330 Riudoms Tarragona Spain	Colmyc 100 mg/ml injectieoplossing voor runderen en varkens	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
The Netherlands	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	Doraflox 100 mg/ml, oplossing voor injectie voor runderen en varkens	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
The Netherlands	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	Unisol 100 mg/ml, oplossing voor injectie voor runderen en varkens	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
The Netherlands	Virbac S.A. 1ére Avenue L.I.D. 2065m 06516 Carros Cedex France	Powerflox Oplossing voor injectie 50 mg/ml voor runderen, varkens, honden en katten	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, pigs, dogs, cats
The Netherlands	Virbac S.A. 1ére Avenue L.I.D. 2065m 06516 Carros Cedex France	Powerflox Oplossing voor injectie 100 mg/ml voor runderen en varkens	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
United Kingdom	Animalcare Ltd 10 Great North Way York Business Park Nether Poppleton York YO26 6RB United Kingdom	Enrocare 25 mg/ml Solution for Injection for Dogs, Cats and Exotic Animals	Enrofloxacin	25 mg/ml	Solution for injection	Cage birds, cats, dogs, exotic animals, reptiles, small mammals

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
United Kingdom	Animalcare Ltd 10 Great North Way York Business Park Nether Poppleton York YO26 6RB United Kingdom	Enrocare 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats	Enrofloxacin	50 mg/ml	Solution for injection	Cats, cattle, dogs, pigs
United Kingdom	Animalcare Ltd 10 Great North Way York Business Park Nether Poppleton York YO26 6RB United Kingdom	Enrocare 100 mg/ml Solution for Injection for Cattle and Pigs	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
United Kingdom	Bayer plc Animal Health Division Bayer House Strawberry Hill Newbury Berkshire RG14 1JA United Kingdom	Baytril 2.5% Solution for Injection	Enrofloxacin	25 mg/ml	Solution for injection	Cage birds, cats, dogs, exotic animals, reptiles, small mammals

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
United Kingdom	Bayer plc Animal Health Division Bayer House Strawberry Hill Newbury Berkshire RG14 1JA United Kingdom	Baytril 5% Solution for Injection	Enrofloxacin	50 mg/ml	Solution for injection	Cats, cattle, dogs, pigs
United Kingdom	Bayer plc Animal Health Division Bayer House Strawberry Hill Newbury Berkshire RG14 1JA United Kingdom	Baytril 10% Solution for Injection	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
United Kingdom	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Floxibac 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats	Enrofloxacin	50 mg/ml	Solution for injection	Cats, cattle, dogs, pigs
United Kingdom	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Fenoflox 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats	Enrofloxacin	50 mg/ml	Solution for injection	Cats, cattle, dogs, Pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
United Kingdom	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Floxibac 100 mg/ml Solution for Injection for Cattle and Pigs	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
United Kingdom	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland	Fenoflox 100 mg/ml Solution for Injection for Cattle and Pigs	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
United Kingdom	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 25 mg/ml Solution for Injection for Dogs, Cats and Exotic Animals	Enrofloxacin	25 mg/ml	Solution for injection	Cage birds, cats, dogs, exotic animals, reptiles, small mammals
United Kingdom	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats	Enrofloxacin	50 mg/ml	Solution for injection	Cats, cattle, dogs, pigs
United Kingdom	FORTE Healthcare Limited Cougar Lane Naul Co. Dublin Ireland	Enrotron 100 mg/ml Solution for Injection for Cattle and Pigs	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
United Kingdom	Global Vet Health SL c/Capcanes, n° 12-bajos Poligon Agro-Reus Reus 43206 Spain	Quinoflox 100 mg/ml Solution for Injection for Cattle and Pigs	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
United Kingdom	Industrial Veterinaria SA C/Esmeralda 19-21 08950 Esplugues de Llobregat Barcelona Spain	Enrodexil 100 mg/ml Solution for Injection for Cattle and Pigs	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
United Kingdom	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 50 mg/ml Solution for Injection for Calves, Pigs and Dogs	Enrofloxacin	50 mg/ml	Solution for injection	Cattle, dogs, pigs
United Kingdom	Krka d.d. Novo mesto Smarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 100 mg/ml Solution for Injection for Cattle and Pigs	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
United Kingdom	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	Doraflox 100 mg/ml Solution for Injection for Cattle and Pigs	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species
United Kingdom	Vetpharma Animal Health, S.L. Les Corts 23. 08028 Barcelona Spain	Unisol 100 mg/ml Solution for Injection for Cattle and Pigs	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs
United Kingdom	Virbac S.A. 1ére Avenue L.I.D. 2065m 06516 Carros Cedex France	Powerflox 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats Enrofloxacin	Enrofloxacin	50 mg/ml	Solution for injection	Cats, cattle, dogs, pigs
United Kingdom	Virbac S.A. 1ére Avenue L.I.D. 2065m 06516 Carros Cedex France	Powerflox 100 mg/ml Solution for Injection for Cattle and Pigs Enrofloxacin	Enrofloxacin	100 mg/ml	Solution for injection	Cattle, pigs

Annex II

Scientific conclusions and grounds for amendment of the summaries of product characteristics, labelling and package leaflets

Overall summary of the scientific evaluation of Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names, and related veterinary medicinal products authorised under Article 13 of Directive 2001/82/EC, as amended (see Annex I)

1. Introduction

Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names, and related veterinary medicinal products authorised under Article 13 of Directive 2001/82/EC, as amended are solutions for injection containing enrofloxacin at 25 mg/ml, 50 mg/ml and 100 mg/ml respectively. Enrofloxacin is a synthetic chemotherapeutic agent from the class of the fluoroquinolone carboxylic-acid derivatives. It has antibacterial activity against a broad spectrum of Gram-negative and Gram-positive bacteria. Enrofloxacin is for veterinary use only.

Fluoroquinolones represent a class of antimicrobials which is critically important in the treatment of severe and invasive infections in humans and animals and are therefore of special interest for public and animal health. At the European level, different actions and activities are constantly taken in order to maintain the efficacy of fluoroquinolone-containing veterinary medicinal products.

On 22 April 2013, Spain presented to the European Medicines Agency (the Agency) a referral notification under Article 35 of Directive 2001/82/EC for Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names, and related veterinary medicinal products authorised under Article 13 of Directive 2001/82/EC, as amended.

It has been noted that the indications, posology and withdrawal periods approved by the Member States for Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names, and related veterinary medicinal products authorised under Article 13 of Directive 2001/82/EC are disharmonised across the Member States (EU/EEA).

The Committee for Medicinal Products for Veterinary Use (CVMP) was requested to consider what indications, dosage regimens, duration of treatments and withdrawal periods should be applied to the concerned products for each target species in order to ensure efficacious treatment, consumer safety as well as lower the risk of development of antimicrobial resistance to enrofloxacin taking into account the available data.

2. Discussion of the data available

Target species, indications and posology

Calves (50 mg/ml strength)

Cattle (100 mg/ml strength)

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of Pasteurella multocida, Mannheimia haemolytica, Mycoplasma spp. and Histophilus somni (50 mg/ml and 100 mg/ml strengths)

- *Dosage: 5 mg/kg body weight (bw), once daily for 3 to 5 days.*

The efficacy against *M. haemolytica* and *Mycoplasma bovis* has been justified with several experimental studies in which induced infection with *M. haemolytica* and *M. bovis* was produced. However, the provided results do not allow assessing the efficacy of the products for each one of these agents individually because only data about *M. haemolytica* have been provided. The results from the

pharmacokinetic/pharmacodynamic (PK/PD) analysis with *M. haemolytica* were not fully predictive of clinical efficacy. However, several experimental controlled studies were conducted employing both 2.5 and 5 mg/kg body weight (bw) parenteral doses, but more consistent data on the higher dose were presented. Confirmatory field trials showed clinical efficacy of the dose of 5 mg/kg bw/day rather than the lower dose.

Data regarding *Pasteurella* spp. are sparse. A dose-confirmation study and a field study showed clinical efficacy of the dose of 5 mg/kg bw/day against enzootic pneumonia caused by *M. haemolytica* and *P. multocida*. In addition, a PK/PD analysis was conducted with this pathogen, obtaining values considered as predictive of clinical efficacy.

As regards to *Mycoplasma bovis*, this microorganism is difficult to be identified and assessed since it is often involved in mixed infections. Several controlled experimental studies were conducted with induced infection (all of them together with *M. haemolytica*). The results of these trials demonstrated good clinical evolution of animals at the tested doses, but microbiological results were not provided or they indicated an incomplete elimination of the pathogen.

Taking into account all (clinical, PK/PD and antimicrobial resistance) data, the CVMP considered that this indication can be accepted.

Regarding *Histophilus somni*, only susceptibility data originated in Canada, USA and Europe were provided, showing the high susceptibility of the bacterium to enrofloxacin. However, clinical efficacy of the recommended dose for respiratory infection has not been demonstrated. Therefore the CVMP recommended the removal of the target pathogen *Histophilus somni* from the product information.

Treatment of infections of the alimentary tract and septicaemia caused by enrofloxacin susceptible strains of Escherichia coli (50 mg/ml and 100 mg/ml strengths)

- *Dosage: 5 mg/kg bw, once daily for 3 to 5 days.*

The results from an experimental study and a field study were provided. In these studies different doses were administered (overall range 1–6 mg/kg bw/day) and the study design did not allow evaluating the efficacy of each dose individually. In the field study, calves (from 15 kg to 150 kg bw) with naturally occurring gastrointestinal infections due to *E.coli*, were treated every day with enrofloxacin either orally, by a parenteral (intramuscular, subcutaneous or intravenous) route followed by oral, or only parenteral route. Cure or improvement was observed in 85% to 90% of animals treated by enrofloxacin, the best results being obtained when parenteral administration is followed by oral administration. From the results obtained, it was not possible to confirm whether the lower dose (2.5 mg/kg bw) produced cure or improvement in the animals. Therefore only the dose of 5 mg/kg bw for 3-5 days is supported.

Regarding the ‘septicaemia’ indication, this was present in the experimental study only. PK/PD and antimicrobial resistance data have been taken into account to justify this indication.

Taking into account all data, the CVMP considered that both indications can be accepted.

Arthritis caused by Mycoplasma bovis (50 mg/ml and 100 mg/ml strengths)

- *Dosage: 5 mg/kg bw, once daily for 5 days*

A field study compared 2 different durations of treatments (5 mg/kg bw for 3 or 5 days), but it did not compare the efficacy against an authorised product with a recognised efficacy for this indication. The overall recovery rate was 46.7%. The highest success rate was observed in calves ≤ 2 years old (71.4%), but it decreased in older animals. Taking into account all the documentation provided, the CVMP considered that this indication can be accepted, but in the 50 mg/ml strength it should be stated as “Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of

Mycoplasma bovis". In the 100 mg/ml strength, this indication should be restricted to cattle less than 2 years old.

Acute severe mastitis caused by Escherichia coli (100 mg/ml strength)

- *Dosage: 5 mg/kg bw, once daily for two consecutive days*

Regarding *E. coli*, a PK/PD study was conducted at the proposed dose. The critical PK parameters in milk were determined following intravenous administration of the 100 mg/ml strength and used to calculate the predictive PK/PD ratios together with MIC_{90} values for *E. coli*. These data are supported by published literature. Dose determination and dose confirmation studies demonstrated the efficacy of the recommended dose. A field study showed the efficacy of the proposed dose comparing it with a reference product containing cefquinome. Non-inferiority of the test product was demonstrated.

Taking into account all data, the CVMP considered that this indication can be accepted.

Acute severe mastitis caused by Staphylococcus aureus (100 mg/ml strength)

Taking into account the available data, the CVMP concluded that the poor bacteriological results obtained *in vivo* and the results from the PK/PD analysis do not sufficiently support this indication. The CVMP recommended the removal of the indication from the product information.

Piglets (25 mg/ml strength)

Pigs (50 mg/ml and 100 mg/ml strengths)

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of Actinobacillus pleuropneumoniae, Pasteurella multocida and Mycoplasma spp.

- *Dosage: 2.5 mg/kg bw, once daily for 3 days by intramuscular injection.*

A systematic review and meta-analysis of more than 50 studies showed a high efficacy of enrofloxacin in treating porcine respiratory disease complex although the etiological agents were no detailed. An enrofloxacin intramuscular injection at 2.5 mg/kg bw, administered once daily until the clinical signs of respiratory disease decreased, resulted in a 94.5% success rate. Additionally, the efficacy was demonstrated in several studies conducted in the USA with an arginin formulation of enrofloxacin at a 7.5 mg/kg bw dose.

Regarding *Pasteurella multocida*, no particular conclusion could be drawn from the documentation provided, in view of the lack of precise microbiological data and considering that extrapolation of data from other formulations is not justified in this case. Therefore PK/PD and resistance data were taken into account when considering the efficacy of enrofloxacin against *Pasteurella multocida*.

Similarly, for *Mycoplasma* spp. no particular conclusion could be drawn from the documentation provided, in view of the lack of precise microbiological data (not allowing to assess the efficacy of the product against each of the isolated microorganisms specifically) or the lack of complete elimination of *M. hyopneumoniae*. Therefore PK/PD and resistance data were taken into account when considering the efficacy of enrofloxacin against *Mycoplasma* spp.

In the case of *Actinobacillus pleuropneumoniae* several references were reviewed with experimental and field studies conducted in piglets and pigs. The provided data on efficacy are adequate to demonstrate efficacy against this bacteria.

Taking into account all data available (clinical, PK/PD and antimicrobial resistance data), the CVMP considered that this indication can be accepted.

Treatment of post-partum dysgalactiae syndrome (PDS), mastitis, metritis, agalactia (MMA syndrome) caused by enrofloxacin susceptible strains of Escherichia coli, Klebsiella spp. (100 mg/ml strength)

- *Dosage: 2.5 mg/kg bw, once daily for 3 days by intramuscular injection.*

Several publications and proprietary studies were reviewed. Clinical outcome was demonstrated on sows with MMA/PDS treated with enrofloxacin. The high efficacy of enrofloxacin in the MMA-syndrome therapy has been confirmed by meta-analysis and systematic review of 6 clinical and susceptibility studies on MMA/PDS and enrofloxacin from the period 1990 to 1998. In another study after five months at the end of the study, no enrofloxacin resistant bacteria could be isolated from the treated sows.

In conclusion, this indication in sows can be accepted for the 100 mg/ml strength, but not for the 50 mg/ml strength, as the administration of the lower strength product is not practicable in heavy animals. Moreover, the excessive volume of injection needed with the 50 mg/ml strength could lead to violation of allowed residues. Thus, the indication should be removed from the product information for the 50 mg/ml strength.

Treatment of infections of the urinary tract caused by enrofloxacin susceptible strains of Escherichia coli.

- *Dosage: 2.5 mg/kg bw, once daily for 3 days by intramuscular injection.*

A multi-centric comparative field trial in sows has been provided. The efficacy at the dosage of 2.5 mg/kg bw daily for 3 days was compared to the one of a trimetroprim-sulfamid fixed combination (30 mg/kg bw daily for 3 days). The bacteriological success was the first criteria of efficacy. The success rate was 76% on day 3 and 50% on day 10 in the test group *versus* 14.3% and 9.5%, respectively, for the same days, for the reference product. On the basis of the available data the CVMP considered that this indication can be accepted.

Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of Escherichia coli.

- *Dosage: 5 mg/kg bw, once daily for 3 days by intramuscular injection.*

The results of different well controlled studies with natural enteric infection were reviewed. The results of different field studies in piglets with enteritis were summarised. All animals were treated intramuscularly with enrofloxacin at 2.5 mg/kg bw once daily. The clinical response rate was 92%. Results of a dose-titration study with experimentally induced infection with enterotoxigenic *E. coli* in suckling piglets and weaners were also reported.

A second dose-titration trial was conducted in Japan with natural infection caused by *E. coli* in suckling piglets. Three different doses of enrofloxacin were administered: 1.25, 2.5 or 5 mg/kg bw/day for 3 days. A positive control group treated with oxytetracyclin and an untreated group were included. Enrofloxacin showed better clinical results than oxytetracyclin at all dose levels, with a more rapid decrease of total clinical scores and faecal consistency scores. Intestinal bacterial counts were significantly reduced by treatment with 2.5 mg/kg bw/day.

A field study was conducted to evaluate effect of enrofloxacin against pathogens related to the alimentary tract in suckling and weaning piglets with diarrhoea. The presence of bacteria including *E. coli* was determined. Enrofloxacin was administered at 2.5 and 5 mg/kg bw/day intramuscularly for 3 days and by oral route. An untreated group was included. Injectable enrofloxacin decreased diarrhoea incidence up to 70% in suckling piglets. Lower isolation index of *E. coli* in treated animals was observed.

In another study piglets were challenged with *E. coli* and displayed signs of diarrhoea and enterotoxaemia. The animals were split into four groups. A dose of 2.5 mg/kg bw/day intramuscularly for 1 or 3 days was tested comparing with oral administration. The results showed that all groups of medicated piglets increased in weight thus contrasting the control animals that were not treated with enrofloxacin. Treatment with enrofloxacin significantly reduced the incidence and severity of diarrhoea.

Intramuscular administration of enrofloxacin showed to be effective especially in cases of enterotoxaemia. No mortality was observed in the treatment groups.

However, taking into account the available PK/PD and resistance data it has been concluded that the dose for this indication can be accepted only at 5 mg of enrofloxacin per kg bw once daily for 3 days by intramuscular injection.

Treatment of septicaemia caused by enrofloxacin susceptible strains of E. coli.

- *Dosage: 5 mg/kg bw, once daily for 3 days by intramuscular injection.*

The available data does fully demonstrate the efficacy of this veterinary medicinal product for the treatment of septicaemia. Nevertheless, taking into account the available PK/PD and resistance data it has been concluded that the dose for this indication can be accepted only at 5 mg of enrofloxacin per kg bw once daily for 3 days by intramuscular injection.

Sheep and Goats (50 mg/ml and 100 mg/ml strengths)

Both strengths share the same indications, but differences exist in terms of target animal species i.e. in the 50 mg/ml strength the species were stated as dairy ewes/lambs and dairy goats/kids whereas in the 100 mg/ml strength the species were sheep and goats. The documentation provided was exactly the same, and both strengths (50 mg/ml and 100 mg/ml) have the same withdrawal periods. Thus, it was considered that for consistency the target animal species for both strengths should harmonised to “Sheep” and “Goats”. These terms will apply to all age ranges and physiological status, as well as for both meat and/or milk production animals.

Sheep (50 mg/ml and 100 mg/ml strengths)

Treatment of mastitis caused by enrofloxacin susceptible strains of Staphylococcus aureus, Escherichia coli.

- *Dosage: 5 mg/kg bw, once daily for 3 days by subcutaneous administration.*

The efficacy of enrofloxacin for the treatment of acute mastitis was investigated in a field trial in sheep with clinical signs of acute mastitis. In the milk samples the pathogens *Staph. aureus* and *E. coli* were identified. Two different enrofloxacin treatment schemes were investigated: 5 mg/kg bw for 3 days and 2.5 mg/kg for 5 days. All treated animals showed a rapid improvement in mammary gland functions, and no clinical differences were found between the two treatment schedules. Clinical and bacteriological cure were obtained.

In another study the efficacy against *Staph. aureus* in commercial dairy herds was investigated. Two different doses were examined: 2.5 mg/kg bw and 5 mg/kg bw, twice daily for 3 consecutive days. The clinical parameters improved. The percentage of bacteriological cure (*Staph. aureus*) was 39.5% in the 2.5 mg/kg group and 82% in the 5 mg/kg group.

On the basis of the available data the CVMP considered that this indication can be accepted.

Treatment of Escherichia coli infections of the alimentary tract or septicaemia caused by enrofloxacin susceptible strains of Escherichia coli.

- *Dosage: 5 mg/kg bw, once daily for 3 days by subcutaneous administration.*

Two field studies were provided to demonstrate the efficacy of enrofloxacin in the treatment of infections of the alimentary tract caused by *E.coli* and septicaemia caused by *E.coli*.

In the first study two groups of lambs suffering from coli-enteritis were treated intramuscularly with enrofloxacin, at the dosage of 2.5 mg/kg bw for 5 days or 5 mg/kg bw for 4 days. Most of the animals recovered within 2-3 days.

In the second study, lambs with septicaemia caused by *E. coli* and *Cl. perfringens* were treated intramuscularly at the dosage of 5 mg/kg bw for 5 days. Better clinical results were observed in 3-4 weeks old animals compared to 1-2 weeks old animals.

On the basis of the available data the CVMP considered that these indications can be accepted.

Goats (50 mg/ml and 100 mg/ml strengths)

The CVMP position paper regarding availability of products for minor uses and minor species (EMEA/CVMP/477/03)[1] establishes that cattle (dairy and meat animals) and sheep (meat animals) are considered as major food-producing species. Sheep intended for milk production and goats do not fall into the category of major species, are by default are classified as minor species and, thus, assessed in the context of the CVMP guideline on efficacy and target animal safety data requirements for veterinary medicinal products intended for minor uses or minor species (EMEA/CVMP/EWP/117899/2004)[2].

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of Pasteurella multocida and *Mannheimia haemolytica.*
Treatment of mastitis caused by enrofloxacin susceptible strains of Staphylococcus aureus and *Escherichia coli.*
Treatment of Escherichia coli infections of the alimentary tract or septicaemia caused by enrofloxacin susceptible strains of Escherichia coli.

- *Dosage: 5 mg/kg bw, once daily for 3 days by subcutaneous administration.*

In a study the pharmacokinetics of enrofloxacin were compared in Desert sheep and Nubian goats after intravenous and intramuscular administration at 5 mg/kg bw dose. The study results indicate that the pharmacokinetics of enrofloxacin did not differ significantly between sheep and goats.

No field studies were submitted to support the indications in goats. The respiratory indications were extrapolated from the ones existing in cattle. The remaining indications i.e. mastitis, alimentary tract infections and septicaemia were extrapolated from sheep. These extrapolations were considered acceptable as goats are considered as minor species.

Data on the MIC of different isolates of *M.haemolytica* confirms the high susceptibility of this pathogen to enrofloxacin, as well as a very low resistance rate.

Although limited data were available the percentage of resistance of *Staph. aureus* isolated from goat mastitis was also very low.

The 2012 RESAPATH annual report indicated that more than 90% of *Pasteurella* in goats are sensitive to enrofloxacin.

In view of above the CVMP considered that these indications can be accepted.

Dogs and Cats (25 mg/ml and 50 mg/ml strengths)

Dogs: *Treatment of infections of the alimentary, respiratory and urogenital tracts (including prostatitis, adjunctive antibiotic therapy for pyometra), skin and wound infections, otitis caused by susceptible strains of: Staphylococcus spp., Escherichia coli, Pasteurella spp., Klebsiella spp., Bordetella spp., Pseudomonas spp., Proteus spp.*

Cats: *Treatment of infections of the alimentary, respiratory and urogenital tracts (as adjunctive antibiotic therapy for pyometra), skin and wound infections, caused by susceptible strains of:*

[1] CVMP position paper regarding availability of products for minor uses and minor species (EMEA/CVMP/477/03) - http://www.ema.europa.eu/docs/en_GB/document_library/Position_statement/2009/10/WC500005163.pdf
[2] CVMP guideline on efficacy and target animal safety data requirements for veterinary medicinal products intended for minor uses or minor species (EMEA/CVMP/EWP/117899/2004) - http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004678.pdf

Staphylococcus spp., Escherichia coli, Pasteurella spp., Klebsiella spp., Bordetella spp., Pseudomonas spp., Proteus spp.

- *Dosage: 5 mg/kg bw, once daily by subcutaneous injection for up to 5 days.*

Several proprietary studies and numerous scientific publications, documenting the efficacy of enrofloxacin, either by injectable and/or oral route of administration, were provided to demonstrate the efficacy against the above specified bacteria for the intended indications in both dogs and cats

The data provided consist of studies performed with several posology regimens where the more frequent dose of 5 mg/kg bw was used. In other cases, a combination of parenteral and oral administration or the parenteral route alone was used. However, the analysis of the results did not allow differentiating the efficacy data and attribute to a particular posology regimen. In support of the efficacy data, published literature was provided, but, generally, lacking specific data and employing variable posology regimens. Therefore for the justification of the posology, a PK/PD were taken into account. The PK/PD analysis shows that the PK/PD ratios are largely exceeded for Gram-negative pathogens. The C_{max}/MIC and AUC/MIC ratios for *Staphylococcus* spp. are also appropriate for Gram-positive infection in both species as well.

Therefore the CVMP considered that these indications can be accepted for dogs and cats, when taking into account that the PK/PD data shown are theoretically predictive of good clinical efficacy in the treatment of the bacterial infections for which the products are intended, and the efficacy of the products has been confirmed by field studies and good clinical experience since more than two decades.

Rabbits (25 mg/ml strength)

Treatment of infections of the alimentary and respiratory tracts caused by enrofloxacin susceptible strains of: Escherichia coli, Pasteurella multocida and Staphylococcus spp.

Treatment of skin and wound infections caused by enrofloxacin susceptible strains of: Staphylococcus aureus.

- Dosage: 10 mg/kg bw, once daily for 5 to 10 consecutive days by subcutaneous administration.

Rabbits are classified as minor species and thus the available data is assessed in the context of the CVMP guideline on efficacy and target animal safety data requirements for veterinary medicinal products intended for minor uses or minor species (EMEA/CVMP/EWP/117899/2004).

The available data showed that enrofloxacin is one of the most commonly used antimicrobials in lagomorphs to manage many different bacterial diseases because of its efficacy and safety.

Documentation that describes the uses of the injectable veterinary medicinal product in the treatment of infections of both the alimentary and respiratory tract, as well as for the treatment of skin and wound infections was provided. All available clinical data referred to pet rabbits only.

Enrofloxacin is also authorised for administration by oral route in farm rabbits all over Europe, and therefore CVMP considered that the use of an injectable solution could lead to a lesser exposure than the oral route as it can be individually administered to sick animals (with more precise dosage based on individual weights of animals) and can prevent the use in mass treatment.

Thus, the indications in farm rabbits should be considered as an extrapolation from other data (oral route for farm rabbits and/or pet rabbits with the injectable route).

The documentation provided was considered acceptable to support the efficacy of enrofloxacin against infections of the alimentary and respiratory tracts *caused by Escherichia coli, Pasteurella multocida* and *Staphylococcus* spp.

Regarding the indication for treatment of skin and wound infections caused by *Staphylococcus aureus*, the available data were suggestive of a non-complete bacteriological cure, and no PK/PD data were available.

The Committee is aware that (i) the use of enrofloxacin in rabbit production could lead to an increase in *Staph. aureus* resistance, (ii) isolates of *Staph. aureus* multi-resistant to several types of antimicrobials are currently documented and (iii) that there can be a transfer of resistant bacteria from animals to humans, involving both consumers and handlers of rabbits.

The following information addressing the concern of the risk to public health (consumers and handlers) due to the potential for selection of antibiotic resistant strains of *Staph. aureus* following use of the product in food rabbits was considered:

- In a study 4.2% of 71 isolates of *Staph. aureus* collected between 2006-2007 in Germany were resistant to enrofloxacin.
- In another study 56 *Staph. aureus* strains were isolated from commercial rabbit farms in different Member States and tested for resistance. The authors concluded that resistance to antimicrobial agents in *Staph. aureus* isolates originating from rabbits is relatively rare compared to resistance in *Staph. aureus* isolates originating from other animals and humans.
- In another referral for an enrofloxacin oral solution (Hipralona Enro-S (EMEA/V/A/79))[3] the Committee concluded that the risk is likely to be minor, in rabbits, in comparison with the other species due to the size of rabbit's production and no measures have been deemed necessary to minimize the risk for spread of *methicillin resistant Staphylococcus aureus* (MRSA) from those. The risk on individual level might be increased for rabbit as compared to other species. Rabbits are raised in continuous systems where resistant bacteria might be persistent over time, however the overall risk would remain low due to the low consumption of rabbit meat.
- A study, conducted in intensive rabbit farms in Spain, has demonstrated a high prevalence of *Staph. aureus* strains, 17.2% of which were found to be methicillin-resistant[4]. The study also unveiled very high resistance to quinolones (around 38% for ciprofloxacin).
- A study described the first case of livestock-associated methicillin-resistant *Staph. aureus* LA-MRSA (ST398, spa types t034 and t5210) occurring in rabbits raised intensively for meat production and involving farm workers or their family members[5].

As stated in CVMP reflection paper on the use of fluoroquinolones in food producing animals - Precautions for use in the SPC regarding prudent use guidance[6], 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.
For some serious animal indications, fluoroquinolones could be the only alternative available (EMEA/CVMP/SAGAM/184651/2005)[7]. In the case of dermatitis caused by *Staph. aureus* in rabbits, no other veterinary medicinal products are authorised for this indication in this animal species in the EU.

[3] http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/referrals/Hipralona_Enro-S/vet_referral_000067.jsp&mid=WC0b01ac05805c5170
[4] Ortega et al. Characterisation and public health risks of antimicrobial resistance in *Staphylococcus aureus* in intensive rabbit breeding. Rev Sci Tech Off Int Epiz 2009;28:1119-1128
[5] Agnoletti et al. First reporting of methicillin-resistant *Staphylococcus aureus* (MRSA) ST398 in an industrial rabbit holding and in farm-related people. Vet Microbiol 2014;170:172-177
[6] CVMP 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) - http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500005173.pdf
[7] CVMP public statement on the use of (fluoro)quinolones in food-producing animals in the European Union: development of resistance and impact on human and animal health (2007) (EMEA/CVMP/SAGAM/184651/2005) - http://www.ema.europa.eu/docs/en_GB/document_library/Public_statement/2009/10/WC500005152.pdf

Although the scientific justification for this indication is not as robust as desirable, a clinical cure (response to treatment) of 87.5% was obtained in infections involving *Staph. aureus*, together with a bacteriological cure of 66.67%.

In view of the lack of therapeutic alternatives, if this indication was not accepted, this product as well as many other antimicrobial products, could be used off-label (under the so-called cascade). Off-label use, leaves the decision on the posology of use to the veterinary practitioner and bears a potential risk of misuse, thus it could increase the risk for developing antimicrobial resistance. Furthermore, the veterinary practitioner will be left without an authorised product for the treatment of skin and wound infections caused by *Staph. aureus* in rabbits. This might potentially lead to problems of animal welfare. It is expected that the use of these products for this indication may not be high, as the product is to be administered parenterally to rabbits with a frequency of daily injection for a period of 5 to 10 days.

In conclusion the Committee can accept this indication considering that it is an injectable formulation, and that necessary restrictions provided in the SPC, together with the withdrawal period, would be in favour of a more adequate use of the veterinary medicinal product in rabbits compared to the use under the cascade.

Rodents, reptiles and ornamental birds (25 mg/ml strength)

Treatment of infections of the alimentary and respiratory tracts where clinical experience, if possible supported by sensitive testing of the causal organism, indicates enrofloxacin as the substance of choice.

- *Dosage for rodents: 10 mg/kg bw, once daily by subcutaneous injection for 5–10 consecutive days*
- *Dosage for reptiles: 5-10 mg/kg bw, once daily by intramuscular injection for 5 consecutive days.*
- *Dosage for ornamental birds: 20 mg/kg bw, once daily by intramuscular injection for 5-10 consecutive days.*

Supporting literature for use of enrofloxacin was provided in rodents (e.g. hamsters, gerbils, guinea pigs), in reptiles (snakes, lizards and chelonia) and in ornamental birds.

The CVMP considered the target species and associated indications and dosages can be accepted because all species are considered as minor species, and no concern on safety or on efficacy has been reported in the Member States where these target species are authorised.

Contraindications

Enrofloxacin is reported to have deleterious effect on articular cartilage in growing horses. Although horses are not authorised as target species the Committee considered that a contraindication for use in growing horses should be included in the product information for the 50 mg/ml and 100 mg/ml strengths.

Special warnings and precautions

Warning sentences have been included in sections 4.5 and 4.6 of the SPC regarding the potential articular cartilage damage in growing cattle and lambs, based on the available literature. Different tolerance studies were conducted in calves with oral administration of enrofloxacin. Degenerative changes of articular cartilage were observed with doses of 30 mg enrofloxacin/kg bw/day during 14 days. The use of enrofloxacin in growing lambs at the recommended dose for 15 days caused histological changes in the articular cartilage, not associated to clinical signs.

Antimicrobial resistance in target pathogens

Data on resistance to enrofloxacin in target pathogens have been provided for cattle, pigs, sheep, goats, dogs and cats. These data come from different bibliographic publications as well as publicly available reports from European monitoring programs and cover the period between 1998 and 2009. The data show that, in general, high susceptibility to enrofloxacin is observed among the majority of strains of bovine and porcine respiratory pathogens as well as non-enteric *E. coli*.

However, there are concerns regarding the moderate to high resistance rates observed in enteric *E. coli* isolated from cattle and pigs. From the overall data provided by the MAHs (efficacy data, PK/PD and target pathogens resistance), it can be concluded that the dose of 2.5 mg/kg bw/day (even showing a relatively good clinical response in some cases) may not allow complete elimination of bacteria and it could lead to resistance development against *E. coli*.

On the other hand, no resistance or very low resistance rates were observed for bacteria causing mastitis in ruminants (*E. coli*, *Staph. aureus*, coagulase-negative staphylococci).

Regarding target species dog and cat, data submitted show an increase in resistance rates of non enteric *E. coli* and *Staphylococcus* spp. from the period 2004-2006 until the period 2008-2009 in the isolates tested in Germany. No data from other European countries/regions have been submitted, so it could not been evaluated if this situation is representative of the whole EU.

Antimicrobial resistance in food borne bacteria

Only few data have been submitted by the MAHs regarding resistance in food borne bacteria.

Low to moderate (8% to 20%) resistance rates to ciprofloxacin have been observed in indicator isolates of *E. coli* for the different target species in different European countries. Data show low resistance rates to enrofloxacin/ciprofloxacin in *Salmonella* spp. isolates from cattle and pigs.

Moderate to high resistance rates to ciprofloxacin were found for *Campylobacter* spp. in the last years: bovine: 45 to 86%; porcine: 4% to 27%. It is not clear whether quinolone resistant *Campylobacter* infection is associated with adverse human health consequences.

Finally, resistance to ciprofloxacin in *Enterococcus* bacteria varied from 0 to 29% in cattle and from 0 to 33% in pigs. No resistance was found in samples from sheep and goats.

Withdrawal periods

The Committte considered that the differences in excipients, as well as the different concentrations of active substance in the products concerned by this referral, do not affect residue depletion from the administration site in such a manner as would require different withdrawal periods for each formulation. The results of the studies provided show that the variation in the residue profile due to sources of variation associated with the injectable use of these products (e.g. sampling procedure) was much higher than the variation due to formulation effect. It is therefore appropriate to derive a single harmonised withdrawal period based on the totality of residue data from all formulation groups.

Cattle (intravenous)

Meat and offal (50 mg/ml and 100 mg/ml strengths): Data were available from two studies, one performed with a dose of 2.5 mg/kg bw/day for 5 days and one with a dose of 5 mg/kg bw/day for 5 days. At the recommended dose residues in all tissues were below the MRLs at day 1 post-administration. However, at the lower dose, residues were above the MRLs at day 1 but below the MRLs by the second time point (day 4 after administration). The MAH proposed a withdrawal period of

5 days. Using the alternative approach[8] this represents an unusually high safety span in relation to the data generated with the recommended dose but a reasonable safety span (20%) in relation to the lower dose study. A harmonised withdrawal period of 5 days can be accepted for cattle meat and offal when animals are treated at the recommended dose of 5 mg/kg bw with either the 50 mg/ml strength or the 100 mg/ml strengths administered intravenously.

Milk (100 mg/ml strength): Only one residue depletion study in cattle milk was considered adequate for the purpose of setting a withdrawal period in milk. The study was conducted with only 12 animals and therefore a statistical analysis[8] of the data could not be performed and consequently a withdrawal period was derived using the alternative approach. The first time point at which all residues fell below the MRL was 60 hours. A 20% safety span was considered appropriate to compensate for the small number of animals used in the study. Thus a withdrawal period of 72 hours (3 days) is recommended for milk from cattle treated at the recommended dose of 5 mg/kg bw/day with the 100 mg/ml strength intravenously.

Cattle (subcutaneous)

Meat and offal (50 mg/ml and 100 mg/ml strengths): Four studies were considered adequate for use in deriving the withdrawal period: two complete residue depletion studies performed with the proposed dose and two limited studies focused on the injection site, which was the withdrawal period determining tissue. Due to the variability of the data the statistical method was not considered appropriate and a withdrawal period was derived using the alternative approach. It was considered appropriate to derive a single harmonised withdrawal period based on the combined data from the 4 studies. The first time point at which all residue values fell below the MRL was 9 days. In order to compensate for the biological uncertainties and the variability of the data, a safety span of 30% was used, resulting in a withdrawal period of 12 days. This is recommended as the withdrawal period for cattle meat and offal for animals treated at the recommended dose of 5 mg/kg bw/day for 5 days with either the 50 mg/ml or 100 mg/ml strenghts and administered subcutaneously. This withdrawal period should be applied to all the concerned products. It represents a practical approach in line with the aims of this procedure and is appropriate for the protection of consumer safety.

Milk (100 mg/ml strength):

Data were available from two studies. Neither was appropriate for analysis using the statistical method. It was considered appropriate to derive a single withdrawal period based on the combined data from these 2 studies using the alternative approach. In both studies the first time point at which residues in milk from all animals were below the MRL was 72 hours. To compensate for deficiencies in the studies a safety span of 20% was considered appropriate, resulting in a withdrawal period of 96 hours (4 days). This is recommended as the withdrawal period for milk from cattle treated at the recommended dose of 5 mg/kg bw with the 100 mg/ml strength subcutaneously.

Sheep

Meat and offal (50 mg/ml and 100 mg/ml strengths): Two residue depletion studies were provided with sheep treated at 5 mg/kg bw for 5 days. Due to deficiencies in the data provided a withdrawal period could not be derived using the statistical approach. The withdrawal period was derived from the first study, but also bearing in mind the results of the second (confirmatory) study. The first time point where all residues were below the MRLs, in both studies, was 3 days post-treatment. A safety span of 30% was used to compensate for the deficiencies in the studies. Thus, a withdrawal period of 4 days is recommended for sheep meat and offal for animals treated at the recommended dose of 5 mg/kg bw with the 50 mg/ml and 100 mg/ml strengths by subcutaneous injection.

[8] CVMP note for guidance on the approach towards harmonisation of withdrawal periods (EMEA/CVMP/036/95) - http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004428.pdf

Milk (50 mg/ml and 100 mg/ml strengths): One residue depletion studies was provided with animals treated at 5 mg/kg bw for 5 days. All residues were below the MRL on the 4th milking (48 hours). The withdrawal period was statistically calculated by means of the TTSC method (i.e. where residues in all animals fall below the level considered safe within the time span for which data are available) resulting in 5.6 milkings / 3 days. A withdrawal period of 72 hours (3 days) is recommended for sheep milk for animals treated at the recommended dose of 5 mg/kg bw with the 50 mg/ml and 100 mg/ml strengths by subcutaneous injection.

Goats

Meat and offal (50 mg/ml and 100 mg/ml strengths): In line with the CVMP guideline on safety and residue data requirements for veterinary medicinal products intended for minor uses or minor species (EMEA/CVMP/SWP/66781/2005)[9], in relation to identical products the withdrawal period established for a major ruminant species may be extrapolated to a minor ruminant species applying a safety span of 1.5 where there is the potential for local residues. Consequently, based on the recommended withdrawal period of 4 days for sheep meat and offal and applying a safety span of 1.5, a withdrawal period of 6 days can be recommended for goat meat and offal when animals are treated at the recommended dose of 5 mg/kg bw with the 50 mg/ml and 100 mg/ml strenghts by subcutaneous injection.

Milk (50 mg/ml and 100 mg/ml strengths): As the relevant products will not leave local residues in milk, the withdrawal period established for the major species can be directly extrapolated to the minor species without the need to apply a safety span. Consequently, the recommended withdrawal period of 4 days for cattle milk can be directly extrapolated to goat's milk when animals are treated at the recommended dose of 5 mg/kg bw with the 50 mg/ml and 100 mg/ml strengths by subcutaneous injection.

Pigs

Meat and offal (25 mg/ml, 50 mg/ml and 100 mg/ml strengths): Four studies were considered adequate for use in deriving the withdrawal period: one complete study performed with the recommended dose and three limited studies focused on the injection site, which was the withdrawal period determining tissue. Due to variability of the data the statistical method was not considered appropriate and a withdrawal period was derived using the alternative approach. It was considered appropriate to derive a single harmonised withdrawal period based on the combined data from the four studies. The first time point at which all residue values fell below the MRL was 10 days. In order to compensate for the biological uncertainties and the variability of the data, a safety span of 30% was used, resulting in a withdrawal period of 13 days. This is recommended as the withdrawal period for pig meat and offal for animals treated at the recommended dose of 5 mg/kg bw/day for 3 days with either the 25 mg/ml, 50 mg/ml or 100 mg/ml strenghts administered by intramuscular injection. The withdrawal period should be applied to all the concerned products. It represents a practical approach in line with the aims of this procedure and is appropriate for the protection of consumer safety.

Rabbits

Meat and offal (25 mg/ml strength): Two residue depletion studies were provided, but only in one of the studies were the animals treated at the recommended dose of 10 mg/kg bw for up to 10 days. A statistical analysis of the data could not be undertaken and consequently the withdrawal period was derived using the alternative approach. All residues were below the MRLs at 5 days. Applying a safety

[9] CVMP guideline on safety and residue data requirements for veterinary medicinal products intended for minor uses or minor species (EMEA/CVMP/SWP/66781/2005) - http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004581.pdf

span of 20% to compensate for deficiencies in the study results in a withdrawal period of 6 days recommended for rabbit meat and offal for animals treated at the recommended dose of 10 mg/kg bw with the 25 mg/ml strength by subcutaneous injection.

3. Benefit-risk assessment

The indications assessed are considered to be aligned with the principles of responsible use of fluoroquinolones in animals.

In order to optimise the dosage and to avoid development of resistance it has been concluded that the dose rate of 2.5 mg/kg bw/day should be deleted for all the indications in cattle. The latter also applies for alimentary tract infections and septicaemia caused by *E. coli* in pigs.

The withdrawal periods should be amended as proposed to provide assurance for consumer safety.

Further to the assessment of the available data several contraindications and warning sentences are recommended to ensure the safe use of the products.

The overall benefit-risk balance of the products under this procedure was deemed positive subject to the recommended changes in the product information (see Annex III).

Grounds for amendment of the summaries of product characteristics, labelling and package leaflets

Whereas:

- on the basis of the available data, the CVMP considered that indications as provided in Annex III were justified;
- on the basis of the available data, the CVMP considered that the dose rate of 2.5 mg/kg bw/day should be deleted for all the indications in cattle.
- on the basis of the available data, the CVMP considered that the dose rate of 2.5 mg/kg bw/day should be deleted for alimentary tract infections and septicaemia due to *E. coli* in pigs;
- on the basis of the available residue depletion data in cattle, pigs, sheep, goats and rabbits chickens and turkeys, the CVMP considered that withdrawal periods should be aligned to provide assurance for consumer safety;
- the CVMP considered that the overall benefit-risk balance is positive for the veterinary medicinal products(see annex I), subject to amendments in the product information;

the CVMP recommended variations of the marketing authorisations for Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names, and related veterinary medicinal products authorised under Article 13 of Directive 2001/82/EC, as amended, as referred in Annex I, in order to amend the summaries of product characteristics, labelling and package leaflets as set out in Annex III.

Annex III

Amendments in the relevant sections of the summaries of product characteristics, labelling and package leaflets

A. For products listed in Annex I containing 25 mg enrofloxacin per ml

Summary of product characteristics

Where the following target species have already been approved, the wording below relating to the relevant species should be used:

4.2 Indications for use, specifying the target species

Dogs

Treatment of infections of the alimentary, respiratory and urogenital tracts (including prostatitis, adjunctive antibiotic therapy for pyometra), skin and wound infections, otitis (externa/media) caused by enrofloxacin susceptible strains of: *Staphylococcus* spp., *Escherichia coli, Pasteurella* spp., *Klebsiella* spp., *Bordetella* spp., *Pseudomonas* spp. and *Proteus* spp.

Cats

Treatment of infections of the alimentary, respiratory and urogenital tracts (as adjunctive antibiotic therapy for pyometra), skin and wound infections, caused by enrofloxacin susceptible strains of: *Staphylococcus* spp., *Escherichia coli, Pasteurella* spp., *Klebsiella* spp., *Bordetella* spp., *Pseudomonas* spp. and *Proteus* spp.

Pigs (piglets)

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of: *Pasteurella multocida, Mycoplasma* spp. and *Actinobacillus pleuropneumoniae*.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli.*
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.

Rabbits

Treatment of infections of the alimentary and respiratory tracts caused by enrofloxacin susceptible strains of: *Escherichia coli*, *Pasteurella multocida* and *Staphylococcus* spp.
Treatment of skin and wound infections caused by enrofloxacin susceptible strains of *Staphylococcus aureus.*

Rodents, reptiles and ornamental birds

Treatment of infections of the alimentary and respiratory tracts where clinical experience, if possible, supported by susceptibility testing of the causal organism, indicates enrofloxacin as the substance of choice.

Add, to all products:

4.8 Interaction with other medicinal products and other forms of interaction

Care should be taken during the concomitant use of flunixin and enrofloxacin in dogs to avoid adverse drug reactions. The decrease in drug clearances as a result of co-administration of flunixin and enrofloxacin indicates that these substances interact during the elimination phase. Thus, in dogs, the co-administration of enrofloxacin and flunixin increased the AUC and the elimination half-life of flunixin and increased the elimination half-life and reduced the C_{max} of enrofloxacin.

Where the following target species have already been approved, the wording below relating to the relevant species should be used:

4.9 Amounts to be administered and administration route

Subcutaneous or intramuscular use.

Repeated injections should be made at different injection sites.
To ensure a correct dosage, body weight (bw) should be determined as accurately as possible to avoid underdosing.

Dogs and cats
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/5 kg bw, daily by subcutaneous injection for up to 5 days.
Treatment may be initiated with injectable product and maintained with enrofloxacin tablets. Duration of treatment should be based on the duration of treatment approved for the appropriate indication in the product information of the tablet product.

Pigs (piglets)
2.5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily by intramuscular injection for 3 days.

Alimentary tract infection or septicaemia caused by *Escherichia coli*: 5 mg of enrofloxacin/kg of bw, corresponding to 2 ml/10 kg bw, once daily by intramuscular injection for 3 days.

In pigs, the injection should be made in the neck at the ear base.
Not more than 3 ml should be administered at one intramuscular injection site.

Rabbits
10 mg/kg bw, corresponding to 2 ml/5 kg bw, once daily by subcutaneous injection for 5 to 10 consecutive days.

Rodents
10 mg/kg bw, corresponding to 0.4 ml/kg bw, once daily by subcutaneous injection for 5 to 10 consecutive days. If necessary, depending on the severity of clinical signs, this dosage can be doubled.

Reptiles
Reptiles are ectothermic, relying on external heat sources to maintain their body temperature at the optimum level for correct function of all body systems. Metabolism of substances and activity of the immune system are, thus, critically dependent on the body temperature. Therefore, the veterinarian must be aware of the correct temperature requirements of the respective reptile species and the hydration status of the individual patient. Furthermore, it has to be considered that large differences exist in the pharmacokinetic behaviour of enrofloxacin among different species, which additionally will influence the decision about the correct dosage of *“product name (to be completed nationally)”*. Therefore, the recommendations made here can only be used as a starting point for individual dose setting.

5–10 mg/kg bw, corresponding to 0.2–0.4 ml/kg bw, once daily by intramuscular injection for 5 consecutive days.
An extension of the treatment interval to 48 hours may be necessary in individual cases. In complicated infections, higher dosages and longer treatment courses may be necessary. The presence of the renal portal system in reptiles means it is prudent to administer substances in the front half of the body wherever possible.

Ornamental birds
20 mg/kg bw, corresponding to 0.8 ml/kg bw**,** once daily by intramuscular injection for 5 to 10 consecutive days. In case of complicated infections higher doses may be necessary.

Where the following target species have already been approved, the following withdrawal periods apply:

4.11 Withdrawal period(s)

Pigs:
Meat and offal: 13 days.

Rabbits:
Meat and offal: 6 days.

Do not use in birds intended for human consumption.

Add, to all products and delete the existing text:

5.1. Pharmacodynamic properties

Mode of action
Two enzymes essential in DNA replication and transcription, DNA gyrase and topoisomerase IV, have been identified as the molecular targets of fluoroquinolones. Target inhibition is caused by non-covalent binding of fluoroquinolone molecules to these enzymes. Replication forks and translational complexes cannot proceed beyond such enzyme-DNA-fluoroquinolone complexes, and inhibition of DNA and mRNA synthesis triggers events resulting in a rapid, drug concentration-dependent killing of pathogenic bacteria. The mode of action of enrofloxacin is bactericidal and bactericidal activity is concentration dependent.

Antibacterial spectrum
Enrofloxacin is active against many Gram-negative bacteria such as *Escherichia coli*, *Klebsiella* spp., *Actinobacillus pleuropneumoniae*, *Pasteurella* spp. (e.g. *Pasteurella multocida*), *Bordetella* spp., *Proteus* spp., *Pseudomonas* spp., against Gram-positive bacteria such as *Staphylococcus* spp. (e.g. *Staphylococcus aureus*) and against *Mycoplasma* spp. at the recommended therapeutic doses.

Types and mechanisms of resistance
Resistance to fluoroquinolones has been reported to arise from five sources, (i) point mutations in the genes encoding for DNA gyrase and/or topoisomerase IV leading to alterations of the respective enzyme, (ii) alterations of drug permeability in Gram-negative bacteria, (iii) efflux mechanisms, (iv) plasmid mediated resistance and (v) gyrase protecting proteins. All mechanisms lead to a reduced susceptibility of the bacteria to fluoroquinolones. Cross-resistance within the fluoroquinolone class of antimicrobials is common.

Labelling:

Where the following target species have already been approved, the following withdrawal periods apply:

8. WITHDRAWAL PERIOD

Pigs:
Meat and offal: 13 days.

Rabbits:
Meat and offal: 6 days.

Do not use in birds intended for human consumption.

Package leaflet:

Where the following target species have already been approved, the wording below relating to the relevant species should be used:

4. INDICATIONS

Dogs

Treatment of infections of the alimentary, respiratory and urogenital tracts (including prostatitis, adjunctive antibiotic therapy for pyometra), skin and wound infections, otitis (externa/media) caused by enrofloxacin susceptible strains of: *Staphylococcus* spp., *Escherichia coli, Pasteurella* spp., *Klebsiella* spp., *Bordetella* spp., *Pseudomonas* spp. and *Proteus* spp.

Cats

Treatment of infections of the alimentary, respiratory and urogenital tracts (as adjunctive antibiotic therapy for pyometra), skin and wound infections, caused by enrofloxacin susceptible strains of: *Staphylococcus* spp., *Escherichia coli, Pasteurella* spp., *Klebsiella* spp., *Bordetella* spp., *Pseudomonas* spp. and *Proteus* spp.

Pigs (piglets)

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of: *Pasteurella multocida, Mycoplasma* spp. and *Actinobacillus pleuropneumoniae*.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli.*
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.

Rabbits

Treatment of infections of the alimentary and respiratory tracts caused by enrofloxacin susceptible strains of: *Escherichia coli*, *Pasteurella multocida* and *Staphylococcus* spp.
Treatment of skin and wound infections caused by enrofloxacin susceptible strains of *Staphylococcus aureus.*

Rodents, reptiles and ornamental birds

Treatment of infections of the alimentary and respiratory tracts where clinical experience, if possible, supported by susceptibility testing of the causal organism, indicates enrofloxacin as the substance of choice.

Where the following target species have already been approved, the wording below relating to the relevant species should be used:

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Subcutaneous or intramuscular use.
Repeated injections should be made at different injection sites.

Dogs and cats

5 mg of enrofloxacin/kg body weight (bw), corresponding to 1 ml/5 kg bw, once daily by subcutaneous injection for up to 5 days.
Treatment may be initiated with injectable product and maintained with enrofloxacin tablets. Duration of treatment should be based on the duration of treatment approved for the appropriate indication in the product information of the tablet product.

Pigs (piglets)

2.5 mg of enrofloxacin/kg bw corresponding to 1 ml/10 kg bw, once daily by intramuscular injection for 3 days.

Alimentary tract infection or septicaemia caused by *Escherichia coli*: 5 mg of enrofloxacin/kg bw, corresponding to 2 ml/10 kg bw, once daily by intramuscular injection for 3 days.

In pigs, the injection should be made in the neck at the ear base.

Not more than 3 ml should be administered at one intramuscular injection site.

Rabbits

10 mg/kg bw, corresponding to 2 ml/5 kg bw, once daily by subcutaneous injection for 5 to 10 consecutive days.

Rodents

10 mg/kg bw, corresponding to 0.4 ml/kg bw, once daily by subcutaneous injection for 5 to 10 consecutive days. If necessary, depending on the severity of clinical signs, this dosage can be doubled.

Reptiles

Reptiles are ectothermic, relying on external heat sources to maintain their body temperature at the optimum level for correct function of all body systems. Metabolism of substances and activity of the immune system are, thus, critically dependent on the body temperature. Therefore, the veterinarian must be aware of the correct temperature requirements of the respective reptile species and the hydration status of the individual patient. Furthermore, it has to be considered that large differences exist in the pharmacokinetic behaviour of enrofloxacin among different species, which additionally will influence the decision about the correct dosage of *"product name (to be completed nationally)"*. Therefore, the recommendations made here can only be used as a starting point for individual dose setting.

5–10 mg/kg bw, corresponding to 0.2–0.4 ml/kg bw, once daily by intramuscular injection for 5 consecutive days.

An extension of the treatment interval to 48 hours may be necessary in individual cases. In complicated infections, higher dosages and longer treatment courses may be necessary. The presence of the renal portal system in reptiles means it is prudent to administer substances in the front half of the body wherever possible.

Ornamental birds

20 mg/kg bw, corresponding to 0.8 ml/kg bw, once daily by intramuscular injection for 5 to 10 consecutive days. In case of complicated infections higher doses may be necessary.

Add, to all products:

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

Where the following target species have already been approved, the following withdrawal periods apply:

10. WITHDRAWAL PERIOD

Pigs:

Meat and offal: 13 days.

Rabbits:

Meat and offal: 6 days.

Do not use in birds intended for human consumption.

Add, to all products:

12. SPECIAL WARNINGS

Interaction with other medicinal products and other forms of interaction:

Care should be taken during the concomitant use of flunixin and enrofloxacin in dogs to avoid adverse drug reactions. The decrease in drug clearances as a result of co-administration of flunixin and enrofloxacin indicates that these substances interact during the elimination phase. Thus, in dogs, the co-administration of enrofloxacin and flunixin increased the AUC and the elimination half-life of flunixin and increased the elimination half-life and reduced the C_{max} of enrofloxacin.

B. For products listed in Annex I containing 50 mg enrofloxacin per ml

Summary of product characteristics

Where the following target species have already been approved, the wording below relating to the relevant species should be used:

4.1 Target species

The terms 'Sheep and Goats' should be used instead of 'Dairy ewes/lambs' and 'Dairy goats/kids'.
The term 'young stock' should be replaced with 'Cattle (calves)'.

Where the following target species have already been approved, the wording below relating to the relevant species should be used:

4.2 Indications for use, specifying the target species

Calves

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma* spp.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis*.

Sheep

Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of mastitis caused by enrofloxacin susceptible strains of *Staphylococcus aureus* and *Escherichia coli*.

Goats

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida* and *Mannheimia haemolytica*.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of mastitis caused by enrofloxacin susceptible strains of *Staphylococcus aureus* and *Escherichia coli*.

Pigs

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mycoplasma* spp. and *Actinobacillus pleuropneumoniae*.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli.*

Dogs

Treatment of infections of the alimentary, respiratory and urogenital tracts (including prostatitis, adjunctive antibiotic therapy for pyometra), skin and wound infections, otitis (externa/media) caused

by enrofloxacin susceptible strains of *Staphylococcus* spp., *Escherichia coli, Pasteurella* spp., *Klebsiella* spp., *Bordetella* spp., *Pseudomonas* spp. and *Proteus* spp.

Cats

Treatment of infections of the alimentary, respiratory and urogenital tracts (as adjunctive antibiotic therapy for pyometra), skin and wound infections, caused by enrofloxacin susceptible strains of, e.g.: *Staphylococcus* spp., *Escherichia coli, Pasteurella* spp., *Klebsiella* spp., *Bordetella* spp., *Pseudomonas* spp. and *Proteus* spp.

Add, to all products:

4.3 Contraindications

Do not use in growing horses because of possible deleterious damage on articular cartilage.

Add, to all products:

4.5 Special precautions for use

Special precautions for use in animals

Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg bw during 14 days.

The use of enrofloxacin in growing lambs at the recommended dose for 15 days caused histological changes in the articular cartilage, not associated with clinical signs.

Add, to all products:

4.8 Interaction with other medicinal products and other forms of interaction

Care should be taken during the concomitant use of flunixin and enrofloxacin in dogs to avoid adverse drug reactions. The decrease in drug clearances as a result of co-administration of flunixin and enrofloxacin indicates that these substances interact during the elimination phase. Thus, in dogs, the co-administration of enrofloxacin and flunixin increased the AUC and the elimination half-life of flunixin and increased the elimination half-life and reduced the C_{max} of enrofloxacin.

Where the following target species have already been approved, the wording below relating to the relevant species should be used:

4.9 Amounts to be administered and administration route

Intravenous, subcutaneous or intramuscular use.
Repeated injections should be made at different injection sites.
To ensure a correct dosage, body weight (bw) should be determined as accurately as possible to avoid underdosing.

Calves

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 3-5 days.
Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis:* 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 5 days.
The product can be administered by slow intravenous or subcutaneous administration.
Not more than 10 ml should be administered at one subcutaneous injection site.

Sheep and goats

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily by subcutaneous injection for 3 days.
Not more than 6 ml should be administered at one subcutaneous injection site.

Pigs

2.5 mg of enrofloxacin/kg bw, corresponding to 0.5 ml/10 kg bw, once daily by intramuscular injection for 3 days.

Alimentary tract infection or septicaemia caused by *Escherichia coli*: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily by intramuscular injection for 3 days.

In pigs, the injection should be made in the neck at the ear base.

Not more than 3 ml should be administered at one intramuscular injection site.

Dogs and cats

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, daily by subcutaneous injection for up to 5 days.

Treatment may be initiated with injectable product and maintained with enrofloxacin tablets. Duration of treatment should be based on the duration of treatment approved for the appropriate indication in the SPC of the tablet product.

Where the following target species have already been approved, the following withdrawal periods apply:

4.11 Withdrawal period(s)

Calves:
Following intravenous injection: Meat and offal: 5 days.
Following subcutaneous injection: Meat and offal: 12 days.
Not authorised for use in animals producing milk for human consumption.

Sheep:
Meat and offal: 4 days.
Milk: 3 days.

Goats:
Meat and offal: 6 days.
Milk: 4 days.

Pigs:
Meat and offal: 13 days.

Add, to all products and delete the existing text:

5.1. Pharmacodynamic properties

Mode of action

Two enzymes essential in DNA replication and transcription, DNA gyrase and topoisomerase IV, have been identified as the molecular targets of fluoroquinolones. Target inhibition is caused by non-covalent binding of fluoroquinolone molecules to these enzymes. Replication forks and translational complexes cannot proceed beyond such enzyme-DNA-fluoroquinolone complexes, and inhibition of DNA and mRNA synthesis triggers events resulting in a rapid, drug concentration-dependent killing of pathogenic bacteria. The mode of action of enrofloxacin is bactericidal and bactericidal activity is concentration dependent.

Antibacterial spectrum

Enrofloxacin is active against many Gram-negative bacteria such as *Escherichia coli*, *Klebsiella* spp., *Actinobacillus pleuropneumoniae*, *Mannheimia haemolytica*, *Pasteurella* spp. (e.g. *Pasteurella multocida*), *Bordetella* spp., *Proteus* spp., *Pseudomonas* spp., against Gram-positive bacteria such as *Staphylococcus* spp. (e.g. *Staphylococcus aureus*) and against *Mycoplasma* spp. at the recommended therapeutic doses.

Types and mechanisms of resistance

Resistance to fluoroquinolones has been reported to arise from five sources, (i) point mutations in the genes encoding for DNA gyrase and/or topoisomerase IV leading to alterations of the respective enzyme, (ii) alterations of drug permeability in Gram-negative bacteria, (iii) efflux mechanisms, (iv) plasmid mediated resistance and (v) gyrase protecting proteins. All mechanisms lead to a reduced susceptibility of the bacteria to fluoroquinolones. Cross-resistance within the fluoroquinolone class of antimicrobials is common.

Labelling:

Where the following target species have already been approved, the following withdrawal periods apply:

8. WITHDRAWAL PERIOD

Calves:
IV: Meat and offal: 5 days.
SC: Meat and offal: 12 days.
Not authorised for use in animals producing milk for human consumption.

Sheep:
Meat and offal: 4 days.
Milk: 3 days.

Goats:
Meat and offal: 6 days.
Milk: 4 days.

Pigs:
Meat and offal: 13 days.

Package leaflet:

Where the following target species have already been approved, the wording below relating to the relevant species should be used:

4. INDICATIONS

Calves

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma* spp.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis*.

Sheep

Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of mastitis caused by enrofloxacin susceptible strains of *Staphylococcus aureus* and *Escherichia coli*.

Goats

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida* and *Mannheimia haemolytica*.

Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of mastitis caused by enrofloxacin susceptible strains of *Staphylococcus aureus* and *Escherichia coli*.

Pigs

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mycoplasma* spp. and *Actinobacillus pleuropneumoniae*.

Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli.*

Dogs

Treatment of infections of the alimentary, respiratory and urogenital tracts (including prostatitis, adjunctive antibiotic therapy for pyometra), skin and wound infections, otitis (externa/media) caused by enrofloxacin susceptible strains of *Staphylococcus* spp*., Escherichia coli, Pasteurella* spp*., Klebsiella* spp*., Bordetella* spp*., Pseudomonas* spp*.* and *Proteus* spp*.*

Cats

Treatment of infections of the alimentary, respiratory and urogenital tracts (as adjunctive antibiotic therapy for pyometra), skin and wound infections, caused by enrofloxacin susceptible strains of, e.g.: *Staphylococcus* spp*., Escherichia coli, Pasteurella* spp*., Klebsiella* spp*., Bordetella* spp*., Pseudomonas* spp*.* and *Proteus* spp*.*

Add, to all products:

5. CONTRAINDICATIONS

……..

Do not use in growing horses because of possible deleterious damage on articular cartilage.

Where the following target species have already been approved, the wording below relating to the relevant species should be used:

7. TARGET SPECIES

The terms ‘Sheep and Goats’ should be used instead of ‘Dairy ewes / lambs’ and ‘Dairy goats/kids’.

The term ‘young stock’ should be replaced with ‘Cattle (calves)’.

Where the following target species have already been approved, the wording below relating to the relevant species should be used:

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intravenous, subcutaneous or intramuscular use.

Repeated injections should be made at different injection sites.

Calves

5 mg of enrofloxacin/kg body weight (bw), corresponding to 1 ml/10 kg bw, once daily for 3-5 days.

Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis:* 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 5 days.

The product can be administered by slow intravenous or subcutaneous administration.

Not more than 10 ml should be administered at one subcutaneous injection site.

Sheep and goats

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily by subcutaneous injection for 3 days.
Not more than 6 ml should be administered at one subcutaneous injection site.

Pigs

2.5 mg of enrofloxacin/kg bw, corresponding to 0.5 ml/10 kg bw, once daily by intramuscular injection for 3 days.
Alimentary tract infection or septicaemia caused by *Escherichia coli*: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily by intramuscular injection for 3 days.
In pigs, the injection should be made in the neck at the ear base.
Not more than 3 ml should be administered at one intramuscular injection site.

Dogs and cats

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily by subcutaneous injection for up to 5 days.
Treatment may be initiated with injectable product and maintained with enrofloxacin tablets. Duration of treatment should be based on the duration of treatment approved for the appropriate indication in the SPC of the tablet product.

Add, to all products:

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

Where the following target species have already been approved, the following withdrawal periods apply:

10. WITHDRAWAL PERIOD

Calves:
Following intravenous injection: Meat and offal: 5 days.
Following subcutaneous injection: Meat and offal: 12 days.
Not authorised for use in animals producing milk for human consumption.

Sheep:
Meat and offal: 4 days.
Milk: 3 days.

Goats:
Meat and offal: 6 days.
Milk: 4 days.

Pigs:
Meat and offal: 13 days.

Add, to all products:

12. SPECIAL WARNINGS

Special precautions for use in animals:

Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg bw during 14 days.

The use of enrofloxacin in growing lambs at the recommended dose for 15 days caused histological changes in the articular cartilage, not associated with clinical signs.

…….

Interaction with other medicinal products and other forms of interaction:

Care should be taken during the concomitant use of flunixin and enrofloxacin in dogs to avoid adverse drug reactions. The decrease in drug clearances as a result of co-administration of flunixin and enrofloxacin indicates that these substances interact during the elimination phase. Thus, in dogs, the co-administration of enrofloxacin and flunixin increased the AUC and the elimination half-life of flunixin and increased the elimination half-life and reduced the C_{max} of enrofloxacin.

C. For products listed in Annex I containing 100 mg enrofloxacin per ml

Summary of product characteristics

Where the following target species have already been approved, the wording below relating to the relevant species should be used:

4.1 Target species

The terms 'Sheep and Goats' should be used instead of 'Dairy ewes/lambs' and 'Dairy goats/kids'.

Where the following target species have already been approved, the wording below relating to the relevant species should be used:

4.2 Indications for use, specifying the target species

Cattle

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma* spp.
Treatment of acute severe mastitis caused by enrofloxacin susceptible strains of *Escherichia coli.*
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis* in cattle less than 2 years old.

Sheep

Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of mastitis caused by enrofloxacin susceptible strains of *Staphylococcus aureus* and *Escherichia coli*.

Goats

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida* and *Mannheimia haemolytica.*
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of mastitis caused by enrofloxacin susceptible strains of *Staphylococcus aureus* and *Escherichia coli*.

Pigs

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mycoplasma* spp. and *Actinobacillus pleuropneumoniae.*
Treatment of infections of the urinary tract caused by enrofloxacin susceptible strains of *Escherichia coli.*
Treatment of post-partum dysgalactiae syndrome, PDS (MMA syndrome) caused by enrofloxacin susceptible strains of *Escherichia coli* and *Klebsiella* spp.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.

Add, to all products:

4.3 Contraindications

Do not use in growing horses because of possible deleterious damage on articular cartilage.

Add, to all products:

4.5 Special precautions for use

Special precautions for use in animals

Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg bw during 14 days.

The use of enrofloxacin in growing lambs at the recommended dose for 15 days caused histological changes in the articular cartilage, not associated with clinical signs.

Where the following target species have already been approved, the wording below relating to the relevant species should be used:

4.9 Amounts to be administered and administration route

Intravenous, subcutaneous or intramuscular use.

Repeated injections should be made at different injection sites.

To ensure a correct dosage, body weight (bw) should be determined as accurately as possible to avoid underdosing.

Cattle

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily for 3-5 days.

Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis* in cattle less than 2 years old: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily for 5 days.

The product can be administered by slow intravenous or subcutaneous administration.

Acute mastitis caused by *Escherichia coli*: 5 mg enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, by slow intravenous injection once daily for two consecutive days.

The second dose may be administered by the subcutaneous route. In this case, the withdrawal period following subcutaneous injection applies.

Not more than 10 ml should be administered at one subcutaneous injection site.

Sheep and goats

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily by subcutaneous injection for 3 days.

Not more than 6 ml should be administered at one subcutaneous injection site.

Pigs

2.5 mg of enrofloxacin/kg bw, corresponding to 0.5 ml/20 kg bw, once daily by intramuscular injection for 3 days.

Alimentary tract infection or septicaemia caused by *Escherichia coli*: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily by intramuscular injection for 3 days.

In pigs, the injection should be made in the neck at the ear base.

Not more than 3 ml should be administered at one intramuscular injection site.

Where the following target species have already been approved, the following withdrawal periods apply:

4.11 Withdrawal period(s)

Cattle:
Following intravenous injection:
Meat and offal: 5 days.
Milk: 3 days.

Following subcutaneous injection:
Meat and offal: 12 days.
Milk: 4 days.

Sheep:
Meat and offal: 4 days.
Milk: 3 days.

Goats:
Meat and offal: 6 days.
Milk: 4 days.

Pigs:
Meat and offal: 13 days.

Add, to all products and delete the existing text:

5.1 Pharmacodynamic properties

Mode of action

Two enzymes essential in DNA replication and transcription, DNA gyrase and topoisomerase IV, have been identified as the molecular targets of fluoroquinolones. Target inhibition is caused by non-covalent binding of fluoroquinolone molecules to these enzymes. Replication forks and translational complexes cannot proceed beyond such enzyme-DNA-fluoroquinolone complexes, and inhibition of DNA and mRNA synthesis triggers events resulting in a rapid, drug concentration-dependent killing of pathogenic bacteria. The mode of action of enrofloxacin is bactericidal and bactericidal activity is concentration dependent.

Antibacterial spectrum

Enrofloxacin is active against many Gram-negative bacteria such as *Escherichia coli*, *Klebsiella* spp., *Actinobacillus pleuropneumoniae*, *Mannheimia haemolytica*, *Pasteurella* spp. (e.g. *Pasteurella multocida*), against Gram-positive bacteria such as *Staphylococcus* spp. (e.g. *Staphylococcus aureus*) and against *Mycoplasma* spp. at the recommended therapeutic doses.

Types and mechanisms of resistance

Resistance to fluoroquinolones has been reported to arise from five sources, (i) point mutations in the genes encoding for DNA gyrase and/or topoisomerase IV leading to alterations of the respective enzyme, (ii) alterations of drug permeability in Gram-negative bacteria, (iii) efflux mechanisms, (iv) plasmid mediated resistance and (v) gyrase protecting proteins. All mechanisms lead to a reduced susceptibility of the bacteria to fluoroquinolones. Cross-resistance within the fluoroquinolone class of antimicrobials is common.

Labelling:

Where the following target species have already been approved, the following withdrawal periods apply:

8. WITHDRAWAL PERIOD

Cattle:
IV: Meat and offal: 5 days.
Milk: 3 days.
SC: Meat and offal: 12 days.
Milk: 4 days.

Sheep:
Meat and offal: 4 days.
Milk: 3 days.

Goats:
Meat and offal: 6 days.
Milk: 4 days.

Pigs:
Meat and offal: 13 days

Package leaflet:

4. INDICATIONS

Where the following target species have already been approved, the wording below relating to the relevant species should be used:

Cattle

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma* spp.
Treatment of acute severe mastitis caused by enrofloxacin susceptible strains of *Escherichia coli.*
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis* in cattle less than 2 years old.

Sheep

Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of mastitis caused by enrofloxacin susceptible strains of *Staphylococcus aureus* and *Escherichia coli*.

Goats

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida* and *Mannheimia haemolytica.*
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of mastitis caused by enrofloxacin susceptible strains of *Staphylococcus aureus* and *Escherichia coli*.

Pigs

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mycoplasma* spp. and *Actinobacillus pleuropneumoniae.*

Treatment of infections of the urinary tract caused by enrofloxacin susceptible strains of *Escherichia coli.*

Treatment of post-partum dysgalactiae syndrome, PDS (MMA syndrome) caused by enrofloxacin susceptible strains of *Escherichia coli* and *Klebsiella* spp.

Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.

Add, to all products:

5. CONTRAINDICATIONS

Do not use in growing horses because of possible deleterious damage on articular cartilage.

Where the following target species have already been approved, the wording below relating to the relevant species should be used:

7. TARGET SPECIES

The terms 'Sheep and Goats' should be used instead of 'Dairy ewes/lambs' and 'Dairy goats/kids'.

Where the following target species have already been approved, the wording below relating to the relevant species should be used:

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intravenous, subcutaneous or intramuscular use.

Repeated injections should be made at different injection sites.

Cattle

5 mg of enrofloxacin/kg body weight (bw), corresponding to 1 ml/20 kg bw, once daily for 3-5 days.

Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis* in cattle less than 2 years old*:* 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily for 5 days.

The product can be administered by slow intravenous or subcutaneous administration.

Acute mastitis caused by *Escherichia coli*: 5 mg enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, by slow intravenous injection once daily for two consecutive days.

The second dose may be administered by the subcutaneous route. In this case, the withdrawal period following subcutaneous injection applies.

Not more than 10 ml should be administered at one subcutaneous injection site.

Sheep and goats

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily by subcutaneous injection for 3 days.

Not more than 6 ml should be administered at one subcutaneous injection site.

Pigs

2.5 mg of enrofloxacin/kg bw, corresponding to 0.5 ml/20 kg bw, once daily by intramuscular injection for 3 days.

Alimentary tract infection or septicaemia caused by *Escherichia coli*: 5 mg of enrofloxacin/kg bw, corresponding to 1.0 ml/20 kg bw, once daily by intramuscular injection for 3 days.

In pigs, the injection should be made in the neck at the ear base.

Not more than 3 ml should be administered at one intramuscular injection site.

Add, to all products:

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

Where the following target species have already been approved, the following withdrawal periods apply:

10. WITHDRAWAL PERIOD

Cattle:
Following intravenous injection: Meat and offal: 5 days.
Milk: 3 days.

Following subcutaneous injection: Meat and offal: 12 days.
Milk: 4 days.

Sheep:
Meat and offal: 4 days.
Milk: 3 days.

Goats:
Meat and offal: 6 days.
Milk: 4 days.

Pigs:
Meat and offal: 13 days.

Add, to all products:

12. SPECIAL WARNINGS

Special precautions for use in animals:

Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg bw during 14 days.

The use of enrofloxacin in growing lambs at the recommended dose for 15 days caused histological changes in the articular cartilage, not associated with clinical signs.