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### Information and Notices

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## IV

(Notices)

## NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

## EUROPEAN COMMISSION

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

(published pursuant to Article 13 or 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council <sup>(1)</sup>)

(2014/C 91/01)

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

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
22.1.2014	Protaphane	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/234	24.1.2014
31.1.2014	Leflunomide Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/11/675	5.2.2014

<sup>(1)</sup> OJ L 136, 30.4.2004, p. 1.

**Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 to 28 February 2014**

*(published pursuant to Article 13 or 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council <sup>(1)</sup>)*

(2014/C 91/02)

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<sup>(1)</sup> OJ L 136, 30.4.2004, p. 1.

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

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
20.2.2014	Izba	travoprost	Alcon Laboratories (UK) Ltd. Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, United Kingdom	EU/1/13/905	Eye drops, solution	S01EE04	24.2.2014
20.2.2014	Neuraceq	florbetaben (18F)	Piramal Imaging GmbH Tegeler Strasse 6-7 13353 Berlin – Deutschland	EU/1/13/906	Solution for injection	V09AX06	24.2.2014
21.2.2014	Mirvaso	brimonidine	Galderma International Tour Europlaza, 20 avenue André Prothin, La Défense 4, La Défense Cedex 92927, France	EU/1/13/904	Gel	D11AX21	25.2.2014

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

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
6.2.2014	Cystadane	Orphan Europe S.A.R.L. Immeuble Le Wilson, 70 avenue du Général de Gaulle, F-92 800 Puteaux, France	EU/1/06/379	10.2.2014
6.2.2014	Humira	AbbVie Ltd M Maidenhead, SL6 4XE, United Kingdom	EU/1/03/256	10.2.2014
6.2.2014	Repso	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/11/674	11.2.2014
6.2.2014	Taxotere	Aventis Pharma S.A. 20 avenue Raymond Aron, F-92165 Antony CEDEX, France	EU/1/95/002	10.2.2014
11.2.2014	Pravafenix	LABORATOIRES SMB SA 26-28 rue de la Pastorale / 26-28 Herdersliedstraat, 1080 Brussel/Bruxelles, Belgique/België	EU/1/11/679	13.2.2014
11.2.2014	Sycrest	Organon N.V. Kloosterstraat 6, NL-5349 AB Oss, Nederland	EU/1/10/640	13.2.2014
11.2.2014	Temozolomide Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/09/606	14.2.2014
12.2.2014	Mozobil	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/09/537	13.2.2014
13.2.2014	Lyrica	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/04/279	17.2.2014
17.2.2014	Conbriza	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/09/511	19.2.2014
17.2.2014	Modigraf	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	EU/1/09/523	19.2.2014
17.2.2014	Victrelis	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/11/704	19.2.2014

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
20.2.2014	Betmiga	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	EU/1/12/809	24.2.2014
20.2.2014	Bosulif	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/13/818	24.2.2014
20.2.2014	Capecitabine Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/12/762	22.2.2014
20.2.2014	Capecitabine Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/12/761	25.2.2014
20.2.2014	Constella	Almirall, S.A. Ronda General Mitre, 151, E-08022 Barcelona, España	EU/1/12/801	24.2.2014
20.2.2014	Helixate NexGen	Bayer Pharma AG D-13342 Berlin, Deutschland	EU/1/00/144	24.2.2014
20.2.2014	KOGENATE Bayer	Bayer Pharma AG D-13342 Berlin, Deutschland	EU/1/00/143	24.2.2014
20.2.2014	Metalyse	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/00/169	24.2.2014
20.2.2014	Mycamine	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	EU/1/08/448	24.2.2014
20.2.2014	Nevirapine Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/09/598	25.2.2014
20.2.2014	Zoledronic acid Actavis	Actavis Group PTC ehf. Reykjavíkurvegur 76-78, 220 Hafnarfjörður, Iceland	EU/1/12/759	24.2.2014
20.2.2014	Zoledronic acid Mylan	Mylan S.A.S 117 allée des Parcs, F-69800 Saint Priest, France	EU/1/12/786	24.2.2014
21.2.2014	Celsentri	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/07/418	25.2.2014

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
21.2.2014	CONTROLOC Control	Takeda GmbH Byk-Gulden-Straße 2, D-78467 Konstanz, Deutschland	EU/1/09/515	25.2.2014
21.2.2014	Fertavid	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/09/510	25.2.2014
21.2.2014	NeuroBloc	Eisai Limited European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire AL10 9SN, United Kingdom	EU/1/00/166	25.2.2014
21.2.2014	NovoThirteen	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/12/775	25.2.2014
21.2.2014	PANTECTA Control	Takeda GmbH Byk-Gulden-Straße 2, D-78467 Konstanz, Deutschland	EU/1/09/518	25.2.2014
21.2.2014	PANTOLOC Control	Takeda GmbH Byk-Gulden-Straße 2, D-78467 Konstanz, Deutschland	EU/1/09/519	25.2.2014
21.2.2014	PANTOZOL Control	Takeda GmbH Byk-Gulden-Straße 2, D-78467 Konstanz, Deutschland	EU/1/09/517	25.2.2014
21.2.2014	SOMAC Control	Takeda GmbH Byk-Gulden-Straße 2, D-78467 Konstanz, Deutschland	EU/1/09/516	25.2.2014
21.2.2014	Stelara	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/08/494	25.2.2014
21.2.2014	Synflorix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/09/508	25.2.2014
21.2.2014	Vectibix	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/07/423	25.2.2014
28.2.2014	Adjupanrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/09/578	4.3.2014
28.2.2014	Capecitabine medac	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstr. 6, D-22880 Wedel, Deutschland	EU/1/12/802	4.3.2014



Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
28.2.2014	Effentora	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/08/441	5.3.2014
28.2.2014	Instanyl	Takeda Pharma A/S Langebjerg 1, DK-4000 Roskilde, Danmark	EU/1/09/531	4.3.2014
28.2.2014	Ixiaro	Valneva Austria GmbH Campus Vienna Biocenter 3, A-1030 Wien, Österreich	EU/1/08/501	4.3.2014
28.2.2014	Menveo	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/10/614	4.3.2014
28.2.2014	Mirapexin	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/97/051	4.3.2014
28.2.2014	PecFent	Archimedes Development Ltd Albert Einstein Centre, Nottingham Science and Technology Park, University Boulevard NG7 2 TN Nottingham, United Kingdom	EU/1/10/644	4.3.2014
28.2.2014	Prepandrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/08/453	4.3.2014
28.2.2014	Pumarix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/10/664	3.3.2014
28.2.2014	Rebif	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/98/063	4.3.2014
28.2.2014	Samsca	Otsuka Pharmaceutical Europe Ltd. Gallions, Wexham Springs, Framewood Road, Wexham, SL3 6PJ, United Kingdom	EU/1/09/539	4.3.2014
28.2.2014	Sifrol	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/97/050	4.3.2014
28.2.2014	Temozolomide Hospira	Hospira UK Limited Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, United Kingdom	EU/1/10/615	4.3.2014

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
28.2.2014	Xolair	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/05/319	4.3.2014

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

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
17.2.2014	Onduarp	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/11/729	19.2.2014

— **Lift of suspension of a marketing authorization (Article 20 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
21.2.2014	Luminity	Lantheus MI UK Limited Festival House, 39 Oxford Street, Newbury, Berkshire RG14 1JG, United Kingdom	EU/1/06/361	25.2.2014

**Issuing of a marketing authorization (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council <sup>(1)</sup>): Accepted**

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
11.2.2014	Bravecto	Fluralaner	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/13/158	Chewable tablet	QP53BX	13.2.2014
11.2.2014	NexGard	afoxolaner	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/13/159	Chewable tablet	QP53BX04	13.2.2014

<sup>(1)</sup> OJ L 136, 30.4.2004, p. 1.

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

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
6.2.2014	Melovem	Dopharma Research B.V. Zalmweg 24, NL-4941 VX Raamsdonksveer, Nederland	EU/2/09/098	10.2.2014
10.2.2014	Startvac	Laboratorios Hipra, S.A. Avda. La Selva, 135, E-17170- Amer (Girona), España	EU/2/08/092	12.2.2014
13.2.2014	Contacera	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-La-Neuve, Belgique	EU/2/12/144	17.2.2014
13.2.2014	Melosus	CP-Pharma Handelsgesellschaft mbH Ostlandring 13, D-31303 Burgdorf, Deutschland	EU/2/10/116	17.2.2014
20.2.2014	CaniLeish	VIRBAC S.A. 1ère Avenue - 2065 m - L.I.D., F-06516 Carros CEDEX, France	EU/2/11/121	24.2.2014

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

The European Medicines Agency  
7, Westferry Circus, Canary Wharf  
UK — LONDON E14 4H

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**Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 to 28 February 2014***(decisions taken pursuant to Article 34 of Directive 2001/83/EC <sup>(1)</sup> or Article 38 of Directive 2001/82/EC <sup>(2)</sup>)**(2014/C 91/03)***— Issuing, maintenance or modification of a national marketing authorization**

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorization	Member State concerned	Date of notification
20.2.2014	Acipimox	See Annex I	See Annex I	See Annex I	24.2.2014
28.2.2014	Nanotop	See Annex II	See Annex II	See Annex II	3.3.2014
28.2.2014	Enrofloxacin	See Annex III	See Annex III	See Annex III	4.3.2014
28.2.2014	Fentanyl	fentanyl (single substance-transmucosal formulations)	Not applicable	Not applicable	3.3.2014

<sup>(1)</sup> OJ L 311, 28.11.2001, p. 67.<sup>(2)</sup> OJ L 311, 28.11.2001, p. 1.

## ANNEX I

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

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Austria	Pfizer Corporation Austria GmbH Floridsdorfer Hauptstraße 1 1210 Vienna Austria	Acipimox	Olbetam - Kapseln	250 mg	capsule	oral use
Belgium	PFIZER S.A. Boulevard de la Plaine 17 1050 Ixelles Belgium	Acipimox	Olbetam	250 mg	capsule	oral use
Denmark	Pfizer ApS, Lautrupvang 8, 2750 Ballerup Denmark	Acipimox	Olbetam	250 mg	capsule, hard	oral use
Hungary	Pfizer Gyógyszerkereskedelmi Kft. Alkotás St 53 1123 Budapest Hungary	Acipimox	Olbetam 250 mg kemény kapszula	250 mg	capsule, hard	oral use
Italy	Pfizer Italia S.r.l. via Isonzo, 71 04100 Latina Italy	Acipimox	OLBETAM	250 mg	capsule, hard	oral use
Luxembourg	PFIZER S.A. Boulevard de la Plaine 17 1050 Ixelles Belgium	Acipimox	Olbetam	250 mg	capsule	oral use
The Netherlands	Pfizer B.V. Rivium Westlaan 142 2909 LD, Capelle a/d IJssel The Netherlands	Acipimox	Olbetam	250 mg	capsule	oral use
United Kingdom	Pfizer Limited Ramsgate Road Sandwich, Kent CT13 9NJ United Kingdom	Acipimox	Olbetam 250 mg Capsules	250 mg	capsule	oral use

**LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANTS/ MARKETING  
AUTHORISATION HOLDERS IN THE MEMBER STATES**

Member State EU/EEA	Marketing authorisation holder	Applicant	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Austria		ROTOP Pharmaka AG Bautzner Landstraße 400 D-01328 Dresden Germany	NANOTOP 0,5 mg Kit für ein radioaktives Arzneimittel	0,5 mg	Kit for radiopharmaceutical preparation	Subcutaneous use
Finland		ROTOP Pharmaka AG Bautzner Landstraße 400 01328 Dresden Germany	ROTOP-NanoHSA	0,5 mg	Kit for radiopharmaceutical preparation	Subcutaneous use
France		ROTOP Pharmaka AG Bautzner Landstraße 400 D-01328 Dresden Germany	ROTOP-NanoHSA 0,5 mg Trousse pour préparation radiophar- maceutique	0,5 mg	Kit for radiopharmaceutical preparation	Subcutaneous use
Germany	ROTOP Pharmaka AG Bautzner Landstraße 400 D-01328 Dresden Germany		NANOTOP	0,5 mg	Kit for radiopharmaceutical preparation	Subcutaneous use
Italy		ROTOP Pharmaka AG Bautzner Landstraße 400 D-01328 Dresden Germany	NANOTOP	0,5 mg	Kit for radiopharmaceutical preparation	Subcutaneous use
Norway		ROTOP Pharmaka AG Bautzner Landstraße 400 D-01328 Dresden Germany	Nanotop	0,5 mg	Kit for radiopharmaceutical preparation	Subcutaneous use
Portugal		ROTOP Pharmaka AG Bautzner Landstraße 400 D-01328 Dresden Germany	NANOTOP	0,5 mg	Kit for radiopharmaceutical preparation	Subcutaneous use or intravenous use
Spain		ROTOP Pharmaka AG Bautzner Landstraße 400 D-01328 Dresden Germany	ROTOP-NanoHSA 500 microgramos equipo de reactivos para preparación radiofarmacéutica	0,5 mg	Kit for radiopharmaceutical preparation	Subcutaneous use

Member State EU/EEA	Marketing authorisation holder	Applicant	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Sweden		ROTOP Pharmaka AG Bautzner Landstraße 400 D-01328 Dresden Germany	NanoHSA	0,5 mg	Kit for radiopharmaceutical preparation	Subcutaneous use
United Kingdom		ROTOP Pharmaka AG Bautzner Landstraße 400 D-01328 Dresden Germany	Nanotop	0,5 mg	Kit for radiopharmaceutical preparation	Subcutaneous use, Intravenous use



**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	Route of administration	Animal species
Austria	Bayer Austria GmbH, Lerchenfelder Guertel 9-11 1160 Wien Austria	Baytril 100 mg/ml - Lösung zum Eingeben für Hühner und Puten	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Austria	Krka d.d. Novo mesto, Šmarjeska cesta 6 8501 Novo Mesto Slovenia	Enrox 100 mg/ml Lösung zum Eingeben für Hühner und Puten	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens (broilers, broiler breeders, replacement chickens), turkeys
Austria	Pro Zoon Pharma GmbH, Karl Schoenherr Strasse 3 4600 Wels Austria	Enrozid TWS 100 mg/ml Lösung zum Eingeben für Hühner und Puten	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken and turkeys
Belgium	Bayer SA-NV J.E. Mommaertslaan 14 1831 Diegem (Machelen) Belgium	Baytril 10 %	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Belgium	Laboratorios Karizoo S.A., Pol. Ind. La Borda, Mas Pujades 11-12, 08140 Caldes de Montbui, Barcelona Spain	Enro-K 10 %	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Belgium	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel The Netherlands	Enroshort 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Belgium	Vetpharma Animal Health S.L., Les Corts 23, 08028 Barcelona Spain	Enroveto 100 mg/ml	Enrofloxacin	100 mg/ml	Concentrate for oral solution	Oral	Chickens and turkeys
Belgium	Krka d.d. Novo mesto, Šmarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys

Member State EU/EEA	Applicant/marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration	Animal species
Belgium	S.P. VETERINARIA, S.A. Ctra. Reus - Vinyols Km 4,1 Riudoms 43330 (Tarragona) Spain	Floxamax 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Belgium	Global Vet Health S.L. C/Capcanes, 12-bajos Poligono Agro-Reus 43206-Reus Tarragona Spain	Quinoflox 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and rabbits
Belgium	HIPRA LABORATORIOS Avda. La Selva 135, 17170 Amer (Girona) Spain	Spectron 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Belgium	Vetpharma Animal Health S.L., Les Corts 23, 08028 Barcelona Spain	Unisol 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Belgium	aniMedica GmbH, Im Südfeld 9, 48308 Senden-Bosensell Germany	Enrotron 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Bulgaria	VET - PARTNERS Ltd. 25 Ivan Asen II Str. 4270 Parvomay Bulgaria	Полистар Енро	Enrofloxacin	100 mg/ml	Oral solution	Oral	Poultry
Bulgaria	Ceva Santé Animale, 10 avenue de La Ballastière, 33500 Libourne France	Квиноекс -10	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Bulgaria	Ceva Santé Animale, 10 avenue de La Ballastière, 33500 Libourne France	Квинокол орален разтвор	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Bulgaria	Laboratorios Syva, s.a.u., Avenue Parroco Pablo Diez 49-57, 24010 Leon, Spain	Сиваквинол 10 % орал	Enrofloxacin	100 mg/ml	Oral solution	Oral	Broilers

Member State EU/EEA	Applicant/marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration	Animal species
Bulgaria	Asklep Farma Lyulin 7, bl. 711, mag. 3 Sofia 1324 Bulgaria	Роксацин БГ орален	Enrofloxacin	100 mg/ml	Oral solution	Oral	Broilers
Bulgaria	Farma vet Ltd. 40 Otec Paisii Str. Shumen 9700 Bulgaria	Енрофлоксацин 10 % разтвор	Enrofloxacin	100 mg/ml	Oral solution	Oral	Broilers
Bulgaria	Bayer Animal Health GmbH, 51368 Leverkusen, Germany	Байтрил 10 % перорален разтвор	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Bulgaria	Global Vet Health S.L. C/Capcanes, 12-bajos Poligono Agro-Reus 43206-Reus Tarragona Spain	Флоксацин 100 mg/ml концентрат за орален разтвор за пилета и пуйки	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Bulgaria	Interchemie Werken De Adelaar BV Metaalweg 8 5804 CG Venray The Netherlands	Интерфлокс орален	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Cyprus	Bayer Animal Health GmbH 51368 Leverkusen Germany	Baytril oral solution 10 % for chickens (broilers and breeders) and turkeys	Enrofloxacin	10 %	Solution for oral use	Oral	Chickens (broilers and breeders), turkeys
Cyprus	Bayer Animal Health GmbH 51368 Leverkusen Germany	Baytril oral solution 0,5 %	Enrofloxacin	0,5 %	Solution for oral use	Oral	Broilers, rearing poultry, turkeys
Cyprus	Laboratorios Karizoo S.A., Pol. Ind. La Borda, Mas Pujades 11-12, 08140 Caldes de Montbui, Barcelona Spain	K-flox 100 mg/ml oral solution for broilers and rabbits	Enrofloxacin	100 mg/ml	Solution for oral use	Oral	Chickens and rabbits
Cyprus	Global Vet Health S.L. C/Capcanes, 12-bajos Poligono Agro-Reus 43206-Reus Tarragona Spain	Floxacin 100 mg concentrated solution for oral solution for chickens and turkeys	Enrofloxacin	100 mg/ml	Solution for oral use	Oral	Chickens and turkeys

Member State EU/EEA	Applicant/marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration	Animal species
Czech Republic	Laboratorios Karizoo S.A., Pol. Ind. La Borda, Mas Pujades 11-12, 08140 Caldes de Montbui, Barcelona Spain	Enro-K 10 % (w/v) perorální roztok	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken - broilers and turkey
Czech Republic	Vétoquinol s.r.o., Zámečnická 411, 288 02 Nymburk Czech Republic	ENROBIOFLOX 100 mg/ml perorální roztok	Enrofloxacin	100 mg/ml	Oral solution	Oral	Broiler chicken, non-rumi- nating calves and pigs
Czech Republic	INTERSIGN Pechačkova 5, 150 00 Prague 5 Czech Republic	ENROFLOXAN 100 mg/ml perorální roztok	Enrofloxacin	100 mg/ml	Oral solution	Oral	Broiler chicken, non-rumi- nating calves and pigs
Czech Republic	Pharmagal spol. s.r.o., Murgašova 5, 949 01 Nitra Slovak Republic	ENROGAL 100 mg/ml perorální roztok	Enrofloxacin	100 mg/ml	Oral solution	Oral	Pigs, calves, chicken (broilers), turkeys
Czech Republic	Krka d.d. Novo mesto, Šmarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 100 mg/ml, perorální roztok	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Czech Republic	Global Vet Health S.L. C/Capcanes, 12-bajos Poligono Agro-Reus 43206-Reus Tarragona Spain	FLOXACIN 100 mg/ml, koncentrát pro přípravu perorálního roztoku pro kura domácího a krůty	Enrofloxacin	100 mg/ml	Concentrate for oral solution	Oral	Chickens and turkeys
Czech Republic	Ceva Animal Health Slovakia, spol s.r.o., Račianska 77, 831 02 Bratislava, Slovak Republic	QUINOEX 100 mg/ml perorální roztok	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken broilers, turkey
Czech Republic	Laboratorios Calier S.A., C/Barcelones, 26 (Pla del Ramassa), 08520 Les Franqueses del Valles, Barcelona Spain	ROXACIN 100 mg/ml perorální roztok	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken broilers

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Czech Republic	Laboratorios Hipra S.A. Avda. La Selva 135, 17170 - Amer (Girona) Spain	SPECTRON 100 mg/ml roztok pro podání v pitné vodě pro kuřata a krůty	Enrofloxacin	100 mg/ml	Solution for use in drinking water	Oral	Chickens and turkeys
Czech Republic	Vetpharma Animal Health S.L., Les Corts 23, 08028 Barcelona Spain	UNISOL 100 mg/ml perorální roztok pro podání v pitné vodě pro kuřata a krůt	Enrofloxacin	100 mg/ml	Solution for use in drinking water	Oral	Chicken - broilers and turkey
Denmark	aniMedica GmbH, Im Südfeld 9, 48308 Senden-Bosensell Germany	Enrotron	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Denmark	Bayer Animal Health GmbH, 51368 Leverkusen, Germany	Baytril Vet	Enrofloxacin	100 mg/ml	Oral solution	Oral	Poultry, non egglayers
Estonia	Ceva Santé Animale, 10 avenue de La Ballastière, 33500 Libourne France	Quinoflox	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Estonia	Industrial Veterinaria S.A. Esmeralda, 19. 08950 Espluges de Llobregat, Barcelona Spain	Ganadexil Enrofloxacin	Enrofloxacin	100 mg/ml	Oral solution	Oral	Broiler
Estonia	Vetoquinol Biowet Sp. z.o.o., ul. Kosynierów Gdynskich 13-14, 66-400 Gorzów Wlkp., Poland	Enrobiofloxx 10 %	Enrofloxacin	100 mg/ml	Oral solution	Oral	Cattle (calves), pigs, chicken (broilers), cats, dogs
Estonia	Interchemie werken "De Adelaar" Eesti AS, Vanapere tee 14, Pringi 74001 Viimsi, Harjumaa, Estonia	Interfloxx Oral	Enrofloxacin	100 mg/ml	Oral solution	Oral	Poultry
France	Bayer Sante 220 Avenue de la Recherche 59120 Loos France	BAYTRIL 10 % solution buvable	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens, turkeys and rabbits

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France	Virbac 1ere Avenue 2065 M L I D 06516 Carros Cedex Spain	TENOTRYL 10 % solution buvable	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
France	Vetpharma Animal Health S.L., Les Corts 23, 08028 Barcelona Spain	LANFLOX 100 MG/ML solution pour utilisation dans l'eau de boisson pour poulets et dindes	Enrofloxacin	100 mg/ml	Solution for use in drinking water	Oral	Chickens and turkeys
France	Laboratorios Karizoo S.A., Pol. Ind. La Borda, Mas Pujades 11-12, 08140 Caldes de Montbui, Barcelona Spain	KARIFLOX 10 % solution buvable pour poulets et dindes	Enrofloxacin	100 mg/ml	Solution for use in drinking water	Oral	Chickens and turkeys
France	Ceva Santé Animale, 10 avenue de La Ballastière, 33500 Libourne France	QUINOFLOX 10 % solution buvable	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
France	Sogeval 200 Avenue De Mayenne Zone Industrielle Des Touches 53000 Laval France	ENROVAL 10 % solution buvable pour volailles	Enrofloxacin	100 mg/ml	Solution for use in drinking water	Oral	Chickens (broilers, replacement chickens, broiler breeders) and turkeys
France	Laboratorios Hipra S.A. Avda. La Selva 135, 17170 - Amer (Girona) Spain	SPECTRON 100 MG/ML solution pour utilisation dans l'eau de boisson pour poulets et dindes	Enrofloxacin	100 mg/ml	Solution for use in drinking water	Oral	Chickens and turkeys
France	Global Vet Health S.L. C/Capcanes, 12-bajos Poligono Agro-Reus 43206-Reus Tarragona Spain	NYOFLOX 100 MG/ML solution pour administration dans l'eau de boisson pour poulets et lapins	Enrofloxacin	100 mg/ml	Solution for use in drinking water	Oral	Chickens (broilers, replacement chickens, broiler breeders) and rabbits
Germany	Bayer Vital GmbH Kaiser-Wilhelm-Allee 51373 Leverkusen Germany	Baytril 10 %	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys

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Germany	Vetpharma Animal Health S.L., Les Corts 23, 08028 Barcelona Spain	Lanflox 100 mg/ml Lösung zum Eingeben über das Trinkwasser für Hühner und Puten	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Germany	aniMedica GmbH, Im Südfeld 9, 48308 Senden-Bosensell Germany	Enrotron 100 mg/ml oral solution for chicken and turkeys	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Germany	Laboratorios Hipra S.A. Avda. La Selva 135, 17170 - Amer (Girona) Spain	Spectron	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Germany	Global Vet Health S.L. C/Capcanes, 12-bajos Poligono Agro-Reus 43206-Reus Tarragona Spain	Quinoflox	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken (broilers, broiler parent animals, pullets), rabbit
Germany	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel The Netherlands	Enro-Sleecol	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Germany	Laboratorios Karizoo S.A., Pol. Ind. La Borda, Mas Pujades 11-12, 08140 Caldes de Montbui, Barcelona Spain	Enro-K 10 %	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Germany	Vetpharma Animal Health S.L., Les Corts 23, 08028 Barcelona Spain	Unisol 100 mg/ml Lösung zum Eingeben über das Trinkwasser für Hühner und Puten	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Germany	bioptivet Tierarzneimittel GmbH & Co. Im Landwehrwinkel 22 59073 Hamm Germany	Enrobioflox 100 mg/ml Lösung	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys

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Germany	bioptivet Tierarzneimittel GmbH & Co. Im Landwehrwinkel 22 59073 Hamm Germany	Enroflox 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Greece	Bayer Animal Health GmbH, 51368 Leverkusen, Germany	BAYTRIL 10 %	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken - broilers and turkey
Greece	Bayer Animal Health GmbH, 51368 Leverkusen, Germany	BAYTRIL 0,5	Enrofloxacin	5 mg/ml	Oral solution	Oral	Chicken - broilers and turkey
Greece	VIRBAC SA, 13e Rue LID BP 27 06511 Carros cedex France	FLOXATRIL	Enrofloxacin	100 mg/m	Oral solution	Oral	Chicken - broilers and turkey
Greece	S.P. VETERINARIA, S.A. Ctra. Reus - Vinyols Km 4,1 Riudoms 43330 (Tarragona) Spain	ENROFLOXACIN 10 %	Enrofloxacin	100 mg/m	Oral solution	Oral	Chicken - broilers and turkey
Greece	Laboratorios Karizoo S.A., Pol. Ind. La Borda, Mas Pujades 11-12, 08140 Caldes de Montbui, Barcelona Spain	FLEXIN	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken - broilers and turkey
Greece	Vetpharma Animal Health S.L., Les Corts 23, 08028 Barcelona Spain	LEVOFLOK	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken - broilers and rabbits
Greece	Laboratorios Karizoo S.A., Pol. Ind. La Borda, Mas Pujades 11-12, 08140 Caldes de Montbui, Barcelona Spain	AMIPLUS	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken - broilers and rabbits
Greece	Laboratorios Hipra S.A. Avda. La Selva 135, 17170 - Amer (Girona) Spain	SPECTRON	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken - broilers and turkey



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Greece	Laboratorios Maymo, S.A., Via Augusta 302, 08017 Barcelona Spain	QUIMIOCOLI	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken broiler
Hungary	Bayer Hungária Kft, Alkotás u. 50. 1123 Budapest Hungary	Baytril 10 % belsőleges oldat	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Hungary	Vetoquinol Biowet Sp. z.o.o., ul. Kosynierów Gdynskich 13-14, 66-400 Gorzów Wlkp., Poland	Enrobioflox 10 % belsőleges oldat	Enrofloxacin	100 mg/ml	Oral solution	Oral	Swine, cattle (calves), broiler chickens, dogs, cats
Hungary	Lavet Pharmaceuticals Ltd., Ottó u. 14., 1161 Budapest, Hungary	Enrocín 10 % oldat	Enrofloxacin	100 mg/ml	Concentrate for oral solution	Oral	Chickens and turkeys
Hungary	DIVASA - FARMAVIC, S.A. Ctra Sant Hipolit Km 71 08503 Gurb-Vic Barcelona Spain	Enrovét 10 % belsőleges oldat	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens
Hungary	VMD Állatgyógyászati Kft. Központ u. 22/b. 1093 Budapest Hungary	Enroveto-20 belsőleges oldat	Enrofloxacin	200 mg/ml	Concentrate for oral solution	Oral	Chickens, pigs and turkeys
Hungary	Krka d.d. Novo mesto, Šmarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 10 % belsőleges oldat	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Hungary	Global Vet Health S.L. C/Capcanes, 12-bajos Polígono Agro-Reus 43206-Reus Tarragona Spain	Floxacin 100 mg/ml koncentrátum belsőleges oldathoz házityúk és pulyka részére	Enrofloxacin	100 mg/ml	Concentrate for oral solution	Oral	Chickens and turkeys
Hungary	Dunavet-B Zrt. Dolgos u. 2., 1126 Budapest, Hungary	Ganadexil Enrofloxacin belsőleges oldat	Enrofloxacin	100 mg/ml	Oral solution	Oral	Broiler chickens

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Hungary	Laboratorios Karizoo S.A., Pol. Ind. La Borda, Mas Pujades 11-12, 08140 Caldes de Montbui, Barcelona Spain	Kariflox 10 % belsőleges oldat házityúk és pulyka részére	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Hungary	Vetpharma Animal Health S.L., Les Corts 23, 08028 Barcelona Spain	LANFLOX 100 mg/ml oldat ivóvízbe keveréshez házityúk és pulyka részére	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Hungary	TolnAgro Kft. Rákóczi u. 146. 7100 Szekszárd, Hungary	Neoflox 10 % belsőleges oldat házityúk (brojler csirke) és házinyúl számára	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken - broilers and rabbits
Hungary	Novimed Kft., Kiss Ernő u. 3. P+P Kereskedőház 1046 Budapest, Hungary	Novicen Flox belsőleges oldat	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens
Hungary	CEVA-Phylaxia Zrt. Szállás u. 5. 1107 Budapest, Hungary	Quinoex 10 belsőleges oldat	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Hungary	CEVA-Phylaxia Zrt. Szállás u. 5. 1107 Budapest, Hungary	QUINOFLOX 100 mg/ml belsőleges oldat	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Hungary	Laboratorios Hipra S.A. Avda. La Selva 135, 17170 - Amer (Girona) Spain	Spectron 100 mg/ml belsőleges oldat csirkék és pulykák részére	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Hungary	Laboratorios Syva, s.a.u., Avenue Parroco Pablo Diez 49-57, 24010 Leon, Spain	Syvaquinol 10 % belsőleges oldat	Enrofloxacin	100 mg/ml	Oral solution	Oral	Broiler chickens
Ireland	Bayer Limited, The Atrium, Blackthorn Road, Dublin 18 Ireland	Baytril 10 % Oral Solution	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys

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Ireland	Krka d.d. Novo mesto, Šmarjeska cesta 6 8501 Novo Mesto Slovenia	Enrox Oral Solution 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens (broilers, broiler breeders, replacement chickens), turkeys
Ireland	Universal Farma, S.L., Gran Via Carlos III, 98-7a, 08028 Barcelona Spain	Lanflox 100 mg/ml Oral Solution	Enrofloxacin	10 mg/ml	Oral solution	Oral	Chickens and turkeys
Ireland	Universal Farma, S.L., Gran Via Carlos III, 98-7a, 08028 Barcelona Spain	Unisol 10 % Oral Solution	Enrofloxacin	10 mg/ml	Oral solution	Oral	Chickens and turkeys
Ireland	Laboratorios Karizoo S.A., Pol. Ind. La Borda, Mas Pujades 11-12, 08140 Caldes de Montbui, Barcelona Spain	ENRO-K 10 % Oral Solution	Enrofloxacin	10 mg/ml	Oral solution	Oral	Chickens and turkeys
Ireland	Laboratorios Karizoo S.A., Pol. Ind. La Borda, Mas Pujades 11-12, 08140 Caldes de Montbui, Barcelona Spain	Kariflox 10 % Oral Solution for Chickens and Turkeys	Enrofloxacin	10 mg/ml	Oral solution	Oral	Chickens and turkeys
Ireland	S.P. VETERINARIA, S.A. Ctra. Reus - Vinyols Km 4,1 Riudoms 43330 (Tarragona) Spain	Floxamax Enrofloxacin 10 % Concentrate for Oral	Enrofloxacin	10 mg/ml	Oral solution	Oral	Chickens and turkeys
Ireland	Laboratorios Hipra S.A. Avda. La Selva 135, 17170 - Amer (Girona) Spain	Spectron 100 mg/ml Solution for use in Drinking Water for Chickens and Turkeys	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Ireland	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel The Netherlands	Enro-Sleecol 100 mg/ml oral solution for chickens and turkeys	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Ireland	aniMedica GmbH, Im Südfeld 9, 48308 Senden-Bosensell Germany	Enrotron	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys

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Ireland	HCS bvba, H. Kennisstraat 53, 2650 Edegem, Belgium	Enrofloxacin HCS 100 mg/ml oral solution for chickens and turkeys	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Italy	Laboratorios Hipra S.A. Avda. La Selva 135, 17170 - Amer (Girona) Spain	Spectron 100 mg/ml concentrate for oral solution	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Italy	Vetpharma Animal Health S.L., Les Corts 23, 08028 Barcelona Spain	Unisol 10 % oral solution	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Italy	Ceva Santé Animale, 10 avenue de La Ballastière, 33500 Libourne France	Cevaflox 100 mg/ml oral solution	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Italy	DOX-AL Italia S.p.A. Largo Donegani 2 20121 Milano Italy	Floxadox	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens, turkeys, guinea fowl, ducks, pheasant, quails, rabbits
Italy	Virbac SA Rue 13eme Rue 06511 Carros Cedex, France	Floxatril	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Italy	Global Vet Health S.L. C/Capcanes, 12-bajos Poligono Agro-Reus 43206-Reus Tarragona Spain	Quinoflox 100 mg/ml solution for use in drinking water, chicken and rabbits	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens, rabbits
Italy	Vetpharma Animal Health S.L., Les Corts 23, 08028 Barcelona Spain	Levoflok 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens, rabbits
Italy	Laboratorios Karizoo S.A., Pol. Ind. La Borda, Mas Pujades 11-12, 08140 Caldes de Montbui, Barcelona Spain	K-Flox oral solution for broilers and rabbits	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens, rabbits

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Italy	S.P. VETERINARIA, S.A. Ctra. Reus - Vinyols Km 4,1 Riudoms 43330 (Tarragona) Spain	Floxavex	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Italy	Bayer Viale Certosa 130 20156 Milano Italy	Baytril 10 % O.L.	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens, turkeys, rabbits
Latvia	Krka d.d. Novo mesto, Šmarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Latvia	Laboratorios Hipra S.A. Avda. La Selva 135, 17170 - Amer (Girona) Spain	Spectron	Enrofloxacin	100 mg/ml	Solution for use in drinking water	Oral	Chickens and turkeys
Latvia	Vet Line SIA Mazā Rānavas 2, Valdlauči, Ķekavas novads, Latvia	Interflox Oral	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Latvia	Ceva Santé Animale, 10 avenue de La Ballastière, 33500 Libourne France	Quinoflox	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Latvia	Laboratorios Calier S.A., C/Barcelones 26 (Pla del Ramassa), 08520 Les Franqueses del Valles, Barcelona Spain	Roxacin	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens
Latvia	Vetoquinol Biowet Sp. z.o.o., ul. Kosynierów Gdynskich 13-14, 66-400 Gorzów Wlkp., Poland	Enrobioflox 10 %	Enrofloxacin	100 mg/ml	Oral solution	Oral	Calves, pigs, dogs, cats, chickens (broilers), pigeons
Lithuania	CENAVISA, S.A., Cami Pedra Estela s/n, 43205 Reus (Tarragona) Spain	E-FLOX, geriamasis tirpalas	Enrofloxacin	100 mg/ml	Oral solution	Oral	Broiler chickens

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Lithuania	Vetoquinol Biowet Sp. z.o.o., ul. Kosynierów Gdynskich 13-14, 66-400 Gorzów Wlkp., Poland	ENROBIOFLOX 10 %, geriamasis tirpalas	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken, cattle, swine, pigeons, dogs and cats
Lithuania	Lavet Pharmaceuticals Ltd., Ottó u. 14., 1161 Budapest, Hungary	ENROCIN 10 %, geriamasis tirpalas	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Lithuania	PPHU "INEX" Partnership, ul. Białostocka 12, 11-500 Giżycko Poland	ENROFLOXAN 10 %, geriamasis tirpalas	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken, turkey, pigeons, cattle, swine, dogs and cats
Lithuania	Krka d.d. Novo mesto, Šmarjeska cesta 6 8501 Novo Mesto Slovenia	ENROXIL 100 mg/ml geriamasis tirpalas paukščiams	Enrofloxacin	100 mg/ml	Oral solution	Oral	Poultry
Lithuania	Ceva Santé Animale, 10 avenue de La Ballastière, 33500 Libourne France	QUINOFLOX 100 mg/ml geriamasis tirpalas	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Lithuania	Laboratorios Hipra S.A. Avda. La Selva 135, 17170 - Amer (Girona) Spain	SPECTRON 100 mg/ml tirpalas girdyti su geriamuoju vandeniu vištoms ir kalakutams	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Luxembourg	Bayer Belgium J.E. Mommaertslaan 14 B-1831 Diegem (Machelen) Belgium	Baytril 10 % solution orale	Enrofloxacin	10 g/100 ml	Oral solution	Oral	Chickens and turkeys
Luxembourg	Global Vet Health S.L. C/Capcanes, 12-bajos Poligono Agro-Reus 43206-Reus Tarragona Spain	Floxacin 100 mg/ml solution orale pour poulets et dindes	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Luxembourg	Krka d.d. Novo mesto, Šmarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 100 mg/ml pour poulets et dindes	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys

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Malta	Industrial Veterinaria S.A. Esmeralda, 19. 08950 Espluges de Llobregat, Barcelona Spain	Ganadexil Enrofloxacin	Enrofloxacin	100 mg/ml	Oral solution	Oral	Broilers
Malta	Laboratorios Syva, s.a.u, Avenue Parroco Pablo Diez 49-57, 24010 Leon, Spain	Syvaquinol 10 % oral	Enrofloxacin	100 mg/ml	Oral solution	Oral	Poultry
Malta	S.P. VETERINARIA, S.A. Ctra. Reus - Vinyols Km 4,1 Riudoms 43330 (Tarragona) Spain	Floxavex Oral solution	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Malta	Laboratorios Hipra S.A. Avda. La Selva 135, 17170 - Amer (Girona) Spain	Hipralona Enro-S	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Malta	Aerden L V.M.D Hoge Mauw 900 2370 Arendonk Belgium	Enroveto-20	Enrofloxacin	200 mg/ml	Oral solution	Oral	Chickens and turkeys
Malta	Romvac Co.S.A, 7 Soseaua Centurii, Voluntari, IF-077190 Romania	Enrofloxarom 10 % solution	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Malta	Pharmagal spol. s r.o., Murgašova 5, 949 01 Nitra, Slovakia	Enrogal oral solution	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Netherlands	Bayer B.V. Animal Health Division Energieweg 1 3641 RT Mijdrecht The Netherlands	Baytril 10 % orale oplossing	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Netherlands	Krka d.d. Novo mesto, Šmarjeska cesta 6 8501 Novo Mesto Slovenia	Enrox 100 mg/ml orale oplossing	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys

Member State EU/EEA	Applicant/marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration	Animal species
Netherlands	Laboratorios Karizoo S.A., Pol. Ind. La Borda, Mas Pujades 11-12, 08140 Caldes de Montbui, Barcelona Spain	Kariflox 10 % orale oplossing	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Netherlands	Vetpharma Animal Health S.L., Les Corts 23, 08028 Barcelona Spain	Lanflox 100 mg/ml orale oplossing	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Netherlands	S.P. VETERINARIA, S.A. Ctra. Reus - Vinyols Km 4,1 Riudoms 43330 (Tarragona) Spain	Floxamax 10 % orale oplossing	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Netherlands	aniMedica GmbH, Im Südfeld 9, 48308 Senden-Bosensell Germany	Enrotron 100 mg/ml orale oplossing	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Poland	Przedsiębiorstwo Farmaceutyczne Okoniewscy "Vetos-Farma" Sp. z o.o., ul. Dzierżonowska 21, 58-260 Bielawa Poland	Enrofloksacyna 10 % płyn, enro- floksacyna 100 mg/ml roztwór doustny dla kur i indyków	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Poland	Biowet Puławy Sp. z o.o. ul. Arciucha 2, 24-100 Puławy Poland	Enflocyna Sol, 50 mg/ml, roztwór doustny dla bydła, świń, psów, kur, indyków i gołębi	Enrofloxacin	50 mg/ml	Oral solution	Oral	Cattle, pig, dog, chicken, turkey and pigeon
Poland	Biofaktor Sp. z o.o., ul. Czysta 4, 96-100 Skierniewice, Poland	Enrofloxan 10 % roztwór, enro- floksacyna 100 mg/ml roztwór do podawania w wodzie do picia dla świń, kur i gołębi	Enrofloxacin	100 mg/ml	Oral solution for use in drinking water	Oral	Pig, chicken (broilers and laying hens) and pigeon
Poland	Laboratorios Calier S.A., C/Barcelones, 26 (Pla del Ramassa), 08520 Les Franqueses del Valles, Barcelona Spain	Roxacin 10 % oral solution, enro- floksacyna 100 mg/ml, roztwór doustny dla kur	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken



Member State EU/EEA	Applicant/marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration	Animal species
Poland	Przedsiębiorstwo Wielobranżowe VET-AGRO Sp. z o.o., ul. Gliniana 32, 20-616 Lublin, Poland	Enrocín 10 % Oral, enrofloksacyna 100 mg/ml, roztwór doustny dla kur i gołębi	Enrofloxacin	10 g/100 ml	Oral solution	Oral	Chicken and pigeon
Poland	Drwalewskie Zakłady Przemysłu Bioweterynaryjnego S.A. ul. Grójecka 6, 05-651 Drwalew, Poland	ENROFLOKSACYNA 10 %, enro- floksacyna 100 mg/ml roztwór doustny dla kur, indyków i gołębi	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken, turkey and pigeon
Poland	Vetoquinol Biowet Sp. z o.o., ul. Kosynierów Gdynskich 13-14, 66-400 Gorzów Wlkp., Poland	EnrobiofloX 10 %, 100 mg/ml, roztwór doustny dla kur, bydła, świń, psów, kotów i gołębi	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken, cattle, pig, dog, cat and pigeon
Poland	Scan Vet Poland Sp. z o.o. Skierszowo, ul. Kiszowska 9, 62-200 Gniezno Poland	Scanoflox 10 % Oral	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys (broilers); pigeons not intended for human consumption
Poland	Ceva Santé Animale, 10 avenue de La Ballastière, 33500 Libourne France	Quinoex-10, 100 mg/ml roztwór doustny dla kur i indyków	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Poland	Vetpharma Animal Health S.L., Les Corts 23, 08028 Barcelona Spain	Unisol 10 % roztwór doustny do podania w wodzie do picia dla kurcząt i indyków	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Poland	Laboratorios Karizoo S.A., Pol. Ind. La Borda, Mas Pujades 11-12, 08140 Caldes de Montbui, Barcelona Spain	ENRO-K roztwór doustny	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Poland	MEDIVET S.A., ul. Szkolna 17, 63-100 Śrem Poland	MEDOXIL ORAL 100 mg/ml roztwór doustny dla kur i królików	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and rabbits

Member State EU/EEA	Applicant/marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration	Animal species
Poland	Global Vet Health S.L. C/Capcanes, 12-bajos Poligono Agro-Reus 43206-Reus Tarragona Spain	Floxacin 100 mg/ml koncentrat do sporządzania roztworu doustnego dla kur i indyków	Enrofloxacin	100 mg/ml	Concentrate for oral solution	Oral	Chickens and turkeys
Poland	Laboratorios Hipra S.A. Avda. La Selva 135, 17170 - Amer (Girona) Spain	Spectron 100 mg/ml roztwór do podawania w wodzie do picia dla kurcząt i indyków	Enrofloxacin	100 mg/ml	Solution for use in drinking water	Oral	Chickens and turkeys
Poland	Global Vet Health S.L. C/Capcanes, 12-bajos Poligono Agro-Reus 43206-Reus Tarragona Spain	Quinoflox	Enrofloxacin	100 mg/ml	Solution for use in drinking water	Oral	Chicken (broilers, replacement chickens, broiler breeders), rabbit
Poland	Krka d.d. Novo mesto, Šmarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 10 % Oral	Enrofloxacin	100 mg/ml	Solution for use in drinking water	Oral	Chicken
Portugal	Global Vet Health S.L. C/Capcanes, 12-bajos Poligono Agro-Reus 43206-Reus Tarragona Spain	Quinoflox 100 mg/ml solução para administração na água de bebida para frangos e coelhos	Enrofloxacin	100 mg/ml	Concentrate for oral solution for use in drinking water	Oral	Chickens (broilers, replacement chickens, broiler breeders) and rabbits
Portugal	Vetpharma Animal Health S.L., Les Corts 23, 08028 Barcelona Spain	Levoflok 100 mg/ml solução oral para frangos de carne e coelhos (niflox)	Enrofloxacin	100 mg/ml	Oral solution to be administered in drinking water	Oral	Chicken - broilers and rabbits
Portugal	Laboratorios Karizoo S.A., Pol. Ind. La Borda, Mas Pujades 11-12, 08140 Caldes de Montbui, Barcelona Spain	K-Flok 100 mg/ml solução oral para frangos de carne e coelhos	Enrofloxacin	100 mg/ml	Oral solution to be administered in drinking water	Oral	Chicken - broilers and rabbits
Portugal	VETLIMA - Soc. distribuidora de produtos agro-pecuários, LDA Av. 5 de Outubro, 35-3º Esq. 1050-047 Lisboa Portugal	Vetaflox 100 mg/ml solução oral para frangos de engorda e coelhos	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken - broilers and rabbits

Member State EU/EEA	Applicant/marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration	Animal species
Portugal	Prodivet-Zn, Nutrição e Comércio de Produtos Químicos, Farmacêuticos e Cosméticos, SA Av. Infante D. Henrique n° 333 H 3º Piso Esc. 41 1800-282 Lisboa Portugal	Prodirox 100 mg/ml solução oral para frangos e coelhos	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken - broilers and rabbits
Portugal	ESTEVE FARMA, LDA Av. Do Forte 3 - Edifício Suécia II, Piso 4A 2794-044 Carnaxide Portugal	ALSIR 100 mg/ml solução oral para frangos, galinhas e perus	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Portugal	Bayer Portugal S.A. Rua Quinta do Pinheiro 5 2794-003 Carnaxide Portugal	Baytril 10 % sol. oral	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens
Portugal	Calier Portugal, S.A Centro Empresarial Sintra Estoril II, Ed. C, R. Pé do Mouro Estrada de Albarraque 2710-335 Sintra Portugal	Roxacin oral, enrofloxacin 100 g/l solução oral	Enrofloxacin	100 g/ 1 L	Oral solution.	Oral	Chickens (broilers)
Portugal	Representagro – Representações LDA Estrada da Lapa 1, 2665-540 Venda do Pinheiro, Portugal	COLMYC-P solução oral 10 % para frangos de carne	Enrofloxacin	10 g/100 ml	Oral solution	Oral	Broilers
Portugal	CENAVISA, S.A., Cami Pedra Estela s/n, 43205 Reus (Tarragona) Spain	ACROLIN 10 solução oral para frangos de carne	Enrofloxacin	100 mg/ml	Oral solution	Oral	Broilers
Portugal	Global Vet Health S.L. C/Capcanes, 12-bajos Poligono Agro-Reus 43206-Reus Tarragona Spain	Floxacin 100 mg/ml concentrado para solução oral, para frangos e perús	Enrofloxacin	100 mg/ml	Concentrate for oral solution	Oral	Chickens and turkeys

Member State EU/EEA	Applicant/marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration	Animal species
Romania	INVESTA C/ Esmeralda 19-21 08950 Esplugues de Llobregat, Barcelona Spain	Ganadexil Enrofloxacin	Enrofloxacin	100 mg/ml	Oral solution	Oral	Poultry
Romania	S.C. Romvac Company S.A. Șos. Centurii, nr. 7, Voluntari Romania	Enrofloxarom 10 %	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Romania	S.C. CRIDA PHARM S.R.L. Str. Stadionului nr. 1, Oltenita Romania	Enroflox lich. 10 %	Enrofloxacin	100 mg/g	Oral solution	Oral	Poultry and pigs
Romania	Bayer Animal Health GmbH, 51368 Leverkusen, Germany	Baytril 10 %	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Romania	DIVASA - FARMAVIC, S.A. Ctra Sant Hipolit Km 71 08503 Gurb-Vic Barcelona Spain	Enrovet 10 %	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Romania	Krka d.d. Novo mesto, Šmarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 10 %	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Romania	Laboratorios Syva, s.a.u, Avenue Parroco Pablo Diez 49-57, 24010 Leon Spain	Syvaquinol 10 %	Enrofloxacin	100 mg/ml	Oral solution	Oral	Poultry
Romania	Lavet Pharmaceuticals Ltd., Ottó u. 14., 1161 Budapest, Hungary	Enrocine 10 %	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Romania	Hipra Laboratorios Avda. La Selva, 135, 17170 Amer (Girona) Spain	Hipralona Enro S	Enrofloxacin	100 mg/ml	Oral solution	Oral	Poultry (chicken)

Member State EU/EEA	Applicant/marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration	Animal species
Romania	S.C.MARAVET SRL 9 Europa, Baia Mare Romania	Anka-floxacin 10 %	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Romania	UNIVERSAL PHARMA Gran Via Carlos III 98-7a 08028-Barcelona Spain	Lanflox 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Romania	CEVA SANTE ANIMALE ZI Très le Bois - BP 372 22603 Loudeac Cedex France	Quinoex 10	Enrofloxacin	100 mg/ml	Oral solution	Oral	Poultry (broiler chickens, breeder hens, turkeys, breeder turkeys)
Romania	DELOS IMPEX' 96 SRL Str. Horia, Cloșca și Crișan, nr. 81, Otopeni, Jud. Ilfov, Romania	Enrodem 10 %	Enrofloxacin	100 mg/ml	Oral solution	Oral	Poultry, pigs
Romania	Global Vet Health S.L. C/Capcanes, 12-bajos Poligono Agro-Reus 43206-Reus Tarragona Spain	Quinoflox 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Oral	Poultry, rabbits
Romania	Vetoquinol Biowet Sp. z.o.o., ul. Kosynierów Gdynskich 13-14, 66-400 Gorzów Wlkp., Poland	Enrobioflox 10 %	Enrofloxacin	100 mg/ml	Oral solution	Oral	Poultry (broilers), bovine (calves), pigs
Romania	Pasteur - Filiala Filipești SRL Str. Principala nr. 944 Filipeștii de Pădure, Jud. Prahova, Romania	Enrofloxacină 10 %	Enrofloxacin	100 mg/ml	Oral solution	Oral	Calves, lambs, kids, piglets, poultry, dogs, cats
Romania	Global Vet Health S.L. C/Capcanes, 12-bajos Poligono Agro-Reus 43206-Reus Tarragona Spain	Floxacin 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys

Member State EU/EEA	Applicant/marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration	Animal species
Slovakia	Pharmagal spol. s r.o., Murgašova 5, 949 01 Nitra, Slovakia	Enrogal 100 mg/ml perorálny roztok	Enrofloxacin	100 mg/ml	Oral solution for use in drinking water	Oral	Pigs, calves, lambs, kids, poultry (chicken and turkey)
Slovakia	Krka d.d. Novo mesto, Šmarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 10 % sol. ad us.vet.	Enrofloxacin	100 mg/ml	Oral solution for use in drinking water	Oral	Chickens and turkeys
Slovakia	Ceva Animal Health Slovakia, spol s r.o., Račianska 77, 831 02 Bratislava, Slovakia	Quinoex 100 mg/ml perorálny roztok	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Slovakia	Laboratorios Calier S.A., C/Barcelones, 26 (Pla del Ramassa), 08520 Les Franqueses del Valles, Barcelona Spain	Roxacin 100 mg/ml perorálny roztok	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chicken
Slovakia	Laboratorios Hipra S.A. Avda. La Selva 135, 17170 - Amer (Girona) Spain	Spectron 100 mg/ml roytok na použitie v pitnej vode pre kurčatá a morkz	Enrofloxacin	100 mg/ml	Solution for use in drinking water	Oral	Chickens and turkeys
Slovakia	Vetpharma Animal Health S.L., Les Corts 23, 08028 Barcelona Spain	Unisol 100 mg/ml perorálny roztok na použitie v pitnej vode pre kurčatá a morky	Enrofloxacin	100 mg	Oral solution	Oral	Chickens and turkeys
Slovenia	Bayer d.o.o., Bravničarjeva 13 Ljubljana Slovenia	BAYTRIL 10 % peroralna raztopina	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Slovenia	Krka d.d. Novo mesto, Šmarjeska cesta 6 8501 Novo Mesto Slovenia	ENROX 100 mg/ml peroralna raztopina	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Slovenia	Krka d.d. Novo mesto, Šmarjeska cesta 6 8501 Novo Mesto Slovenia	ENROXIL 100 mg/ml peroralna raztopina za perutnino	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys

Member State EU/EEA	Applicant/marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration	Animal species
Slovenia	GENERA SI d.o.o., Dunajska 51, 1000 Ljubljana Slovenia	VETOFLOK 10 % peroralna raztopina	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Slovenia	Ceva Santé Animale, 10 avenue de La Ballastière, 33500 Libourne France	QUINOFLOX 100 mg/ml peroralna raztopina	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
Spain	Laboratorios Ovejero, S.A. Ctra León - Vilecha nº 30, 24192 León Spain	QUINOVET F	Enrofloxacin	100 mg/ml	Oral solution to be administered via drinking water	Oral	Chickens and turkeys
Spain	Labiana Life Sciences, S.A. C/ Venus, 26 Can Parellada Industrial 08228 Tarrassa Spain	KIN-O-FLOX	Enrofloxacin	100 g/l l	Oral solution	Oral	Poultry (broilers)
Spain	MEVET S.A.U. Polígono Industrial El Segre, P. 410. 25191 Lérida Spain	ENROVALL ORAL	Enrofloxacin	100 mg/ml	Oral solution to be administered via drinking water	Oral	Chickens (broilers)
Spain	Laboratorios Calier S.A., C/Barcelones, 26 (Pla del Ramassa), 08520 Les Franqueses del Valles, Barcelona Spain	ROXACIN SOLUCION ORAL	Enrofloxacin	100 mg/ml	Oral solution to be administered via drinking water	Oral	Chickens (broilers)
Spain	Laboratorio JAER. C/Barcelona 411. 08620 Sant Vicenc del Horts, Barcelona Spain	SORANOX	Enrofloxacin	100 mg/ml	Oral solution to be administered via drinking water	Oral	Chickens and turkeys
Spain	DIVASA - FARMAVIC, S.A. Ctra Sant Hipolit Km 71 08503 Gurb-Vic Barcelona Spain	ENROVET 10 %	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys

Member State EU/EEA	Applicant/marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration	Animal species
Spain	POLICHEM, S.A. Ctra Reus- Cambrils, Km 3. 43206 Reus. Tarragona Spain	POLISTAR	Enrofloxacin	100 g/l	Oral solution to be administered via drinking water	Oral	Chickens (broilers)
Spain	Industrial Veterinaria S.A. Esmeralda, 19. 08950 Espluges de Llobregat, Barcelona Spain	FENUTIN	Enrofloxacin	100 mg/ml	Oral solution to be administered via drinking water	Oral	Chickens (broilers)
Spain	CHEMO IBÉRICA, S.A. Gran Vía Carlos III 98 - 7a, 08028 Barcelona Spain	ENROFLOXACINO CHEMO 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution to be administered via drinking water	Oral	Chickens (broilers)
Spain	Laboratorios Karizoo S.A., Pol. Ind. La Borda, Mas Pujades, 11-12, 08140 Caldes de Montbui, Barcelona Spain	CONFLOX 100 mg/ml solucion oral para pollos	Enrofloxacin	100 mg/ml	Oral solution to be administered via drinking water	Oral	Chickens (broilers)
Spain	Industrial Veterinaria S.A. Esmeralda, 19 08950 Espluges de Llobregat, Barcelona Spain	Ganadexil enrofloxacinol solucion oral	Enrofloxacin	100 mg/ml	Oral solution to be administered via drinking water	Oral	Chicken - broilers and rabbits
Spain	Laboratorios Karizoo S.A., Pol. Ind. La Borda, Mas Pujades 11-12, 08140 Caldes de Montbui, Barcelona Spain	K-FLOX 100 mg/ml solucion oral para pollos y conejos	Enrofloxacin	100 mg/ml	Oral solution to be administered via drinking water	Oral	Chicken - broilers and rabbits
Spain	Universal Farma, S.L., Gran Vía Carlos III 98 - 7a, 08028 Barcelona Spain	Enrofloxacinol Universal 100 mg/ml solucion oral para pollos y conejos	Enrofloxacin	100 mg/ml	Oral solution to be administered via drinking water	Oral	Chicken - broilers and rabbits
Spain	S.P. VETERINARIA, S.A. Ctra. Reus - Vinyols Km 4,1 Riudoms 43330 (Tarragona) Spain	FLOXAVEX 100 mg/ml concentrado para solucion oral pollos y pavos	Enrofloxacin	10 % w/v	Concentrate for oral solution	Oral	Chickens and turkeys



Member State EU/EEA	Applicant/marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration	Animal species
Spain	Global Vet Health S.L. C/Capcanes, 12-bajos Poligono Agro-Reus 43206-Reus Tarragona Spain	FLOXACIN 100 mg/ml concentrado para solucion oral pollos y pavos	Enrofloxacin	100 mg/ml	Concentrate for oral solution	Oral	Chickens and turkeys
Spain	Global Vet Health S.L. C/Capcanes, 12-bajos Poligono Agro-Reus 43206-Reus Tarragona Spain	AQUAFLOX 100 mg/ml solucion para administracion en agua de bebida	Enrofloxacin	100 mg/ml	Solution for use in drinking water.	Oral	Chickens (broilers, replacement chickens, broiler breeders) and rabbits
Spain	Laboratorios Syva, s.a.u, Avenue Parroco Pablo Diez 49-57, 24010 Leon, Spain	SYVAQUINOL 10 % oral	Enrofloxacin	100 mg/ml	Oral solution	Oral	Poultry (broilers)
Spain	S.P. VETERINARIA, S.A. Ctra. Reus - Vinyols Km 4,1 Riudoms 43330 (Tarragona) Spain	COLMYC-C	Enrofloxacin	100 mg/ml	Oral solution to be administered via drinking water	Oral	Poultry (broilers and fattened turkeys), rabbits
Spain	Laboratorios Hipra S.A. Avda. La Selva 135, 17170 - Amer (Girona) Spain	HIPRALONA ENRO-S	Enrofloxacin	100 mg/ml	Oral solution to be administered via drinking water	Oral	Poultry (broilers and fattened turkeys), rabbits
Spain	Laboratorios Maymo, S.A., Via Augusta 302, 08017 Barcelona Spain	QUIMIUCOLI	Enrofloxacin	10 g/100 ml	Oral solution	Oral	Poultry (broilers)
Spain	LABORATORIOS E INDUSTRIAS IVEN, S.A. C/Luis I 56 28031 Madrid Spain	FLOXACIVEN	Enrofloxacin	10 g/100 ml	Oral solution	Oral	Poultry (broilers)
Spain	LABORATORIOS DR ESTEVE Avda. Madre de Déu de Montserrat 221 08041 Barcelona Spain	ALSIR 10 % solucion oral	Enrofloxacin	10 g/100 ml	Oral solution	Oral	Poultry (broilers, replacement chickens, broiler breeders and turkeys)

Member State EU/EEA	Applicant/marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration	Animal species
Spain	CENAVISA, S.A., Cami Pedra Estela s/n, 43205 Reus (Tarragona) Spain	FLOXICEN	Enrofloxacin	100 mg/ml	Oral solution	Oral	Poultry (broilers)
Spain	Laboratorios Serra Pamies, S.A. Crta de Castellvell, 24 43206 Reus (Tarragona) Spain	E-FLOX solucion oral	Enrofloxacin	100 mg/ml	Oral solution to be administered via drinking water	Oral	Poultry (broilers)
Spain	CEVA SALUD ANIMAL, Carabela La Niña 12, 5 <sup>a</sup> 08017 Barcelona Spain	QUINOEX-10	Enrofloxacin	100 mg/ml	Oral solution	Oral	Poultry (broilers and broiler breeders)
Sweden	Bayer Animal Health GmbH, 51368 Leverkusen, Germany	Baytril vet.	Enrofloxacin	100 mg/ml	Solution for use in water	Oral	Poultry
Sweden	aniMedica GmbH, Im Südfeld 9, 48308 Senden-Bosensell Germany	Enrotron	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
United Kingdom	Bayer plc Animal Health Division Bayer House Strawberry Hill Newbury RG14 1JA Berkshire United Kingdom	Baytril 10 % Oral Solution	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
United Kingdom	Krka d.d. Novo mesto, Šmarjeska cesta 6 8501 Novo Mesto Slovenia	Enroxil 100 mg/ml Oral Solution for Chickens and Turkeys	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys
United Kingdom	Vetpharma Animal Health S.L., Les Corts 23, 08028 Barcelona Spain	Lanflox 100 mg/ml Solution for Use in Drinking Water for Chickens and Turkeys	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys

Member State EU/EEA	Applicant/marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration	Animal species
United Kingdom	Global Vet Health S.L. C/Capcanes, 12-bajos Poligono Agro-Reus 43206-Reus Tarragona Spain	Quinoflox 100 mg/ml Solution for Use in Drinking Water, Chicken and Rabbits	Enrofloxacin	100 mg/ml	Oral solution	Oral	ChickensRabbits
United Kingdom	Vetpharma Animal Health S.L., Les Corts 23, 08028 Barcelona Spain	Unisol 100 mg/ml Oral Solution for use in Drinking Water for Chickens and Turkeys	Enrofloxacin	100 mg/ml	Oral solution	Oral	Chickens and turkeys











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