

Annex I
List of nationally authorised veterinary medicinal products

Annex IA

List of nationally authorised veterinary medicinal products recommended for maintenance of the marketing authorisations

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Austria	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on Lösung zum Auftropfen auf die Haut für Hunde bis 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use
Austria	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on Lösung zum Auftropfen auf die Haut für Hunde über 4 kg bis 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use
Belgium	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Dog 40/200	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use
Belgium	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Dog 100/500	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Bulgaria	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on solution for dogs up to 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Bulgaria	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on solution for dogs over 4 up to 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Croatia	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on, otopina za nakapavanje, za pse do 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Croatia	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on, otopina za nakapavanje, za pse od 4 do 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Cyprus	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on διάλυμα για σκύλους έως 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use
Cyprus	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on διάλυμα για σκύλους από 4kg έως 10kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Czech Republic	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix roztok pro nakapání na kůži – spot- on pro psy do 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use
Czech Republic	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix roztok pro nakapání na kůži – spot- on pro psy od 4 do 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use
Denmark	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Bayvantic Vet. til hunde 4-10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use
Denmark	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Bayvantic Vet. til hunde op til 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Estonia	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use
Estonia	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Finland	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Bayvantic vet enintään 4 kg painaville koirille	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use
Finland	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Bayvantic vet koirille 4– 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use
France	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Advantix petit chien	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use
France	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Advantix très petit chien	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use
Germany	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Advantix Spot-on Lösung zum Auftropfen auf die Haut für Hunde bis 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Germany	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Advantix Spot-on Lösung zum Auftropfen auf die Haut für Hunde über 4 kg bis 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use
Greece	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use
Greece	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use
Hungary	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix spot on 4 kg alatti kutya'knak A.U.V.	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use
Hungary	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix spot on 4-10 kg közötti kutya'knak A.U.V.	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use
Ireland	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Advantix Spot-on solution for dogs up to 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use
Ireland	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Advantix Spot-on solution for dogs over 4 kg up to 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Advantix Spot-on per cani fino a 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Advantix Spot-on per cani oltre 4 kg fino a 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Petcuten soluzione spot- on per cani fino a 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Petcuten Spot-on per cani oltre 4 kg fino a 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Petsidill spot-on per cani fino ta 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on Solution	Dog (up to 4 kg)	Spot-on use
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Petsidill spot-on per cani oltre a 4 kg fino a 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on Solution	Dog (over 4 kg up to 10 kg)	Spot-on use
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Poli-Ecto soluzione spot- on per cani fino a 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Poli-Ecto soluzione spot- on per cani oltre 4 kg fino a 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use
Lithuania	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix, užlašinamasis tirpalas <= 4 kg svorio šunims	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use
Lithuania	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix, užlašinamasis tirpalas > 4-10 kg svorio šunims	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Luxembourg	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Dog 40/200	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use
Luxembourg	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Dog 100/500	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Netherlands	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix spot-on oplossing voor honden vanaf 4 kg tot 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use
Netherlands	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix spot-on oplossing voor honden tot 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Netherlands	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Petcuten spot-on oplossing voor honden tot en met 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use
Netherlands	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Petcuten spot-on oplossing voor honden van meer dan 4 kg tot en met 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use
Netherlands	Veterinaire Groothandel Wijchen B.V. Graafschap Hornelaan 137A 6001 AC Weert The Netherlands	Advantix 40/200 spot-on oplossing voor honden	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use
Netherlands	Veterinaire Groothandel Wijchen B.V. Graafschap Hornelaan 137A 6001 AC Weert The Netherlands	Advantix 100/500 spot- on oplossing voor honden	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use
Netherlands	Polymeds B.V. Osloweg 99A 9723BK Groningen The Netherlands	Advantix spot-on oplossing voor honden vanaf 4 kg tot 10 Kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use
Norway	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Bayvantic vet	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use
Norway	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Bayvantic vet	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Poland	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-On (100 mg + 500 mg)/1 ml; roztwór do nakrapiania	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Poland	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-On (40 mg + 200 mg)/0,4 ml; roztwór do nakrapiania	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Portugal	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix solução para unção punctiforme para cães até 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use
Portugal	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix solução para unção punctiforme para cães com mais de 4 kg até 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use
Romania	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix soluție spot-on pentru câini cu greutatea de la 4 kg până la 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Romania	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix soluție spot-on pentru câini cu greutatea până la 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use
Slovak Republic	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix spot-on roztok pre psy	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Slovenia	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix kožni nanos, raztopina za pse do 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use
Slovenia	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix kožni nanos, raztopina za pse od 4 do 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Spain	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix solucion spot- on para perros hasta 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use
Spain	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix solucion spot- on para perros de mas de 4 hasta 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use
Spain	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Poli-ecto solucion spot- on para perros hasta 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use
Spain	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Poli-ecto solucion spot- on para perros de mas de 4 hasta 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use
UK/Northern Ireland ¹	Elanco Europe Ltd. Form 2 Bartley Way Hook RG27 9XA United Kingdom	Advantix Spot-on solution for dogs over 4 kg up to 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use

¹ For the United Kingdom, as from 1 January 2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI.

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
UK/Northern Ireland ¹	Elanco Europe Ltd. Form 2 Bartley Way Hook RG27 9XA United Kingdom	Advantix Spot-on solution for dogs up to 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog (up to 4 kg)	Spot-on use

Annex IB

List of nationally authorised veterinary medicinal products recommended for variation of the marketing authorisations (quantitative NMP concentration and target animal safety warnings)

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Austria	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 1250 mg/250 mg lösung zum auftropfen für hunde von 10 kg bis 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Austria	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 200 mg/40 mg lösung zum auftropfen für hunde bis 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Austria	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 500 mg/100 mg lösung zum auftropfen für hunde von 4 kg bis 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Austria	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 0.4 ml spot-on solution for dogs up to 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Austria	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 1 ml spot-on solution for dogs over 4 kg up to 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Austria	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act Lösung zum Auftropfen für Hunde 2-5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Austria	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act Lösung zum Auftropfen für Hunde 5-10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Belgium	Dechra Veterinary Products Achterstenhoek 48 2275 Lille Belgium	Myorelax	Guaifenesin	100 mg/ml	Solution for infusion	Horse	Intravenous use
Belgium	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontline Protect voor honden 2-5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use
Belgium	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontline Protect voor honden 5-10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Belgium	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontect voor honden 2-5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Belgium	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontect voor honden 5-10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Belgium	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 200 mg/40 mg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Belgium	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 500 mg/100 mg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Belgium	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 1250 mg/250 mg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Bulgaria	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 200 mg/40 mg spot-on solution for dogs up to 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Bulgaria	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 500 mg/100 mg spot-on solution for dogs over 4 kg up to 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Bulgaria	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 1250 mg/250 mg spot-on solution for dogs over 10 kg up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Bulgaria	DSM Denitrans Ltd. Razgrad, 11 Neofit Rilski str. Bulgaria	Neofenicol inj	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Bulgaria	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot- on solution for dogs 2-5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use
Bulgaria	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot- on solution for dogs 5-10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Croatia	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa, 200 mg/40 mg, otopina za nakapavanje, za pse do 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Croatia	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa, 500 mg/100 mg, otopina za nakapavanje, za pse od 4 kg do 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Croatia	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa, 1250 mg/250 mg, otopina za nakapavanje, za pse od 10 kg do 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Croatia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act, otopina za nakapavanje, za pse 2-5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use
Croatia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act, otopina za nakapavanje, za pse 5-10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Cyprus	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot- on διάλυμα επίχυσης για σκύλους 2-5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use
Cyprus	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot- on διάλυμα επίχυσης για σκύλους 5-10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Czech Republic	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 200 mg/40 mg roztok pro nakapání na kůži – spot-on pro psy do 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Czech Republic	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 500 mg/100 mg roztok pro nakapání na kůži – spot-on pro psy od 4 kg do 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Czech Republic	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 1250 mg/250 mg roztok pro nakapání na kůži – spot-on pro psy od 10 kg do 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Czech Republic	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act roztok pro nakapání na kůži - spot-on pro psy 2-5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use
Czech Republic	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act roztok pro nakapání na kůži - spot-on pro psy 5-10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Denmark	Boehringer Ingelheim Animal Health Nordics A/S Strødamvej 52 2100 Copenhagen Denmark	Frontect (til hunde 5- 10 kg)	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Cutaneous use
Denmark	Boehringer Ingelheim Animal Health Nordics A/S Strødamvej 52 2100 Copenhagen Denmark	Frontect (til hunde 2- 5 kg)	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Cutaneous use
Estonia	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Estonia	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Estonia	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Estonia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use
Estonia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Estonia	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Estonia	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Finland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa vet koirille, jotka painavat enintään 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Finland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa vet koirille, jotka painavat yli 4 kg-10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Finland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa vet koirille, jotka painavat yli 10 kg-25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Finland	Boehringer Ingelheim Animal Health Nordics A/S Strødamvej 52 2100 Copenhagen Denmark	Frontect 2–5 kg:n painoiselle koiralle	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Cutaneous use
Finland	Boehringer Ingelheim Animal Health Nordics A/S Strødamvej 52 2100 Copenhagen Denmark	Frontect 5–10 kg:n painoiselle koiralle	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Cutaneous use
France	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-act solution pour spot-on pour chiens 2 - 5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use
France	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-act solution pour spot-on pour chiens 5 - 10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
France	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontect solution pour spot-on pour chiens 2 - 5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Cutaneous use
France	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontect solution pour spot-on pour chiens 5 - 10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Cutaneous use
France	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 1250 mg/250 mg solution pour spot-on pour chiens de 10 kg a 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
France	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 200 mg/40 mg solution pour spot-on pour chiens jusqu'a 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
France	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 500 mg/100 mg solution pour spot-on pour chiens de 4 kg a 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
France	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Myorelax 100 mg/ml solution pour perfusion pour chevaux	Guaifenesin	100 mg/ml	Solution for infusion	Horse	Intravenous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
France	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Permetrix biocanina 1250 mg/250 mg solution pour spot-on pour chiens de 10 kg a 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
France	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Permetrix biocanina 200 mg/40 mg solution pour spot-on pour chiens jusqu'a 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use
France	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Permetrix biocanina 500 mg/100 mg solution pour spot-on pour chiens de 4 kg a 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
France	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 20 mg solution pour spot-on pour petits chats et chatons	Praziquantel	20 mg/0.5 ml	Spot-on solution	Cat	Spot-on use
France	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ridaworm 20 mg solution pour spot-on pour chats et chatons	Praziquantel	20 mg/0.5 ml	Spot-on solution	Cat	Spot-on use
Germany	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 1250 mg/250 mg lösung zum auftropfen für hunde von 10 kg bis 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Germany	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 200 mg/40 mg lösung zum auftropfen für hunde bis 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Germany	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 500 mg/100 mg lösung zum auftropfen für hunde von 4 kg bis 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Germany	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 1250 mg/250 mg lösung zum auftropfen für hunde über 10 kg bis 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Germany	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 200 mg/40 mg lösung zum auftropfen für hunde bis 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use
Germany	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 500 mg/100 mg lösung zum auftropfen für hunde über 4 kg bis 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Germany	Boehringer Ingelheim Vetmedica GmbH Binger Str. 173 55216 Ingelheim Germany	Frontline Tri-Act Lösung zum Auftropfen für Hunde 2-5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use
Germany	Boehringer Ingelheim Vetmedica GmbH Binger Str. 173 55216 Ingelheim Germany	Frontline Tri-Act Lösung zum Auftropfen für Hunde 5-10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Germany	CP-Pharma Handelsgesellschaft mbH Ostlandring 13 31303 Burgdorf Germany	My-50mg/ml	Guaifenesin	50 mg/ml	Solution for infusion	Horse	Intravenous use
Germany	CP-Pharma Handelsgesellschaft mbH Ostlandring 13 31303 Burgdorf Germany	Myolaxin 15%	Guaifenesin	15 mg/ml	Solution for infusion	Horse	Intravenous use
Germany	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Myorelax 100 mg/ml Infusionslösung für Pferde	Guaifenesin	100 mg/ml	Solution for infusion	Horse	Intravenous use
Germany	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 20 mg lösung zum auftropfen für katzen und katzenwelpen	Praziquantel	20 mg/0.5 ml	Spot-on solution	Cat	Spot-on use
Germany	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ridaworm 20 mg lösung zum auftropfen für katzen und katzenwelpen	Praziquantel	20 mg/0.5 ml	Spot-on solution	Cat	Spot-on use
Germany	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 0.4 ml spot-on solution for dogs up to 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Germany	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 1 ml spot-on solution for dogs over 4 kg up to 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Germany	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 100 mg/500 mg spot-on solution for dogs over 4 kg up to 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Germany	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 40 mg/200 mg spot-on solution for dogs up to 4kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Germany	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 0.4 ml spot-on solution for dogs up to 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Germany	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 1 ml spot-on solution for dogs over 4 kg up to 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Greece	Hellafarm AE 1st km Paiania- Markopoulou Avenue 19002, Paiania, Attiki, Athens Greece	Norodin 24	Trimethoprim Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig, dog, cat	Intramuscular, intravenous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Greece	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-act spot- on.so (33,8+252,4)mg/0,5 ml	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use
Greece	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-act spot- on.so (67,6+504,8)mg/1ml	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Greece	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix spot-on.so	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Greece	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix spot-on.so	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Greece	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Greece	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Greece	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Greece	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Greece	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Greece	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Oxytetracycline L.A/Dopharma	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, calf, pig	Intramuscular use
Hungary	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 1250 mg/250 mg rácsepegtető oldat 10-25 kg-os kutyáknak A.U.V.	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Hungary	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 200 mg/40 mg rácsepegtető oldat 4kg alatti kutyáknak A.U.V.	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Hungary	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 500 mg/100 mg rácsepegtető oldat 4-10 kg-os kutyáknak A.U.V.	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Hungary	Merial 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act rácsepegtető oldat 2– 5 kg-os kutyáknak	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Hungary	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act rácsepegető oldat 5– 10 kg-os kutyáknak	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Ireland	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ridaworm 20 mg spot-on solution for small cats	Praziquantel	20 mg/0.5 ml	Spot-on solution	Cat	Spot-on use
Ireland	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 20 mg spot-on solution for small cats and kittens	Praziquantel	20 mg/0.5 ml	Spot-on solution	Cat	Spot-on use
Ireland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 1250 mg/250 mg spot-on solution for dogs over 10 kg up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Ireland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 200 mg/40 mg spot-on solution for dogs up to 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Ireland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 500 mg/100 mg spot-on solution for dogs over 4 kg up to 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Ireland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 200 mg/40 mg spot-on solution for dogs up to 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use
Ireland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 1250 mg/250 mg spot-on solution for dogs over 10 kg up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Ireland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 500 mg/100 mg spot-on solution for dogs over 4 kg up to 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Ireland	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 0.4 millilitre(s) spot-on solution	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Ireland	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 1.0 millilitre(s) spot-on solution	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Ireland	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 0.4 ml spot-on solution for dogs up to 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Ireland	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 1 ml spot-on solution for dogs over 4 kg up to 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Ireland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Daclotrix 200 mg/40 mg spot-on solution for dogs up to 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use
Ireland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Daclotrix 500 mg/100 mg spot-on solution for dogs over 4 kg up to 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Ireland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Daclotrix 1250 mg/250 mg spot-on solution for dogs over 10 kg up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Italy	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 200 mg/40 mg soluzione spot-on per cani fino a 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Italy	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 500 mg/100 mg soluzione spot-on per cani da 4 kg a 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Italy	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 1250 mg/250 mg soluzione spot-on per cani da 10 kg a 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Italy	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ridaworm 20 mg soluzione spot-on per gatti di taglia piccola.	Praziquantel	20 mg/0.5 ml	Spot-on solution	Cat	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 200 mg/40 mg soluzione spot-on per cani fino a 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use
Italy	Boehringer Ingelheim Animal Health Italia S.p.A. Via Lorenzini 8 20139 Milano Italy	Frontline Tri-Act soluzione spot-on per cani 2-5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog (2- 5 kg)	Spot-on use
Italy	Boehringer Ingelheim Animal Health Italia S.p.A. Via Lorenzini 8 20139 Milano Italy	Frontline Tri-Act soluzione spot-on per cani 5-10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog (5- 10 kg)	Spot-on use
Italy	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 20 mg soluzione spot-on per gatti di taglia piccola e gattini	Praziquantel	20 mg/0.5 ml	Spot-on solution	Cat	Spot-on use
Italy	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Preventix soluzione spot-on per cani fino a 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use
Italy	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Preventix soluzione spot-on per cani oltre 4 kg fino a 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix soluzione spot-on per cani fino a 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Italy	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix soluzione spot-on per cani oltre 4 kg fino a 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Italy	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Italy	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Italy	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Italy	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Latvia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act šķīdums pilināšanai uz ādas suņiem 2 – 5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog (2- 5 kg)	Spot-on use
Latvia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act šķīdums pilināšanai uz ādas suņiem 5 – 10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog (5- 10 kg)	Spot-on use
Latvia	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 500 mg/100 mg šķīdums pilināšanai uz ādas suņiem no 4 kg līdz 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog (over 4 kg up to 10 kg)	Spot-on use
Latvia	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 1250 mg/250 mg šķīdums pilināšanai uz ādas suņiem no 10 kg līdz 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog (over 10 kg up to 25 kg)	Spot-on use
Latvia	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 40 mg/200 mg šķīdums pilināšanai uz ādas suņiem līdz 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Latvia	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 100 mg/500 mg šķīdums pilināšanai uz ādas suņiem no 4 kg līdz 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Lithuania	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act, užlašnamasis tirpalas 2–5 kg šunims	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use
Lithuania	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act, užlašnamasis tirpalas 5-10 kg šunims	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Lithuania	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 500 mg/100 mg užlašnamasis tirpalas šunims, sveriantiems daugiau kaip 4 kg ir iki 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Lithuania	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 200 mg/40 mg užlašnamasis tirpalas šunims, sveriantiems iki 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Lithuania	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 1250 mg/250 mg užlašnamasis tirpalas šunims, sveriantiems daugiau kaip 10 kg ir iki 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Lithuania	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 40/200 spot- on solution for dogs up to 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Lithuania	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 100/500 spot-on solution for dogs over 4 up to 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Luxembourg	Dechra Veterinary Products Achterstenhoek 48 2275 Lille Belgium	Myorelax	Guaifenesin	100 mg/ml	Solution for infusion	Horse	Intravenous use
Luxembourg	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontline Protect voor honden 2-5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use
Luxembourg	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontline Protect voor honden 5-10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Luxembourg	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontect voor honden 2-5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Luxembourg	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontect voor honden 5-10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Luxembourg	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 200 mg/40 mg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Luxembourg	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 500 mg/100 mg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Luxembourg	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 1250 mg/250 mg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Malta	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Insectivex 50 mg/ml concentrate for emulsion and cutaneous application for bovine and non- food equine species	Cypermethrin	50 mg/ml	Concentrate for cutaneous spray, emulsion	Bovine species, horse	Cutaneous use
Malta	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot- on solution for dogs 2-5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Malta	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot- on solution for dogs 5 - 10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Netherlands	Alfasan Nederland B.V. Kuipersweg 9 3449 JA Woerden The Netherlands	Antipyranal, 200 mg/ml, oplossing voor injectie voor honden	Phenylbutazone	200 mg/ml	Solution for injection	Dog	Intramuscular use
Netherlands	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 200 mg/40 mg spot-on oplossing voor honden met een gewicht tot 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Netherlands	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 500 mg/100 mg spot-on oplossing voor honden met een gewicht van 4 kg tot 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Netherlands	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 1250 mg/250 mg spot-on oplossing voor honden met een gewicht van 10 kg tot 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Netherlands	Boehringer Ingelheim Animal Health Netherlands B.V. Comeniusstraat 6 1817 MS Alkmaar The Netherlands	Frontline Tri-act spot- on oplossing voor honden 2-5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Netherlands	Boehringer Ingelheim Animal Health Netherlands B.V. Comeniusstraat 6 1817 MS Alkmaar The Netherlands	Frontline Tri-act spot- on oplossing voor honden 5-10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Netherlands	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Gujatal 100 mg/ml oplossing voor infusie voor paarden	Guaifenesin	100 mg/ml	Solution for infusion	Horse	Intravenous use
Netherlands	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Oxy L.A. INJ., 200 mg/ml oplossing voor injectie voor varkens en runderen	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Netherlands	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 20 mg spot-on oplossing voor kleine katten en kittens	Praziquantel	20 mg/0.5 ml	Spot-on solution	Cat	Spot-on use
Netherlands	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ridaworm 20 mg spot-on oplossing voor katten en kittens	Praziquantel	20 mg/0.5 ml	Spot-on solution	Cat	Spot-on use
Netherlands	Alfasan Nederland B.V. Kuipersweg 9 3449 JA Woerden The Netherlands	Sulfadimethoxine 20% Pro inj, 200 mg per ml, voor runderen en varkens	Sulfadimethoxine sodium	200 mg/ml	Solution for injection	Cattle, pig	Intramuscular, intravenous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Poland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Poland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Poland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Poland	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use
Poland	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Poland	ScanVet Poland Sp. z o.o. Gniezno, Skierszewo 62-200 Kiszowska 9 Poland	Sul-Tridin 24%	Trimethoprim Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intramuscular use
Poland	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 40/200 spot- on solution for dogs up to 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Poland	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 100/500 spot-on solution for dogs over 4 up to 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Poland	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 0.4 ml spot-on solution for dogs up to 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Poland	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 1 ml spot-on solution for dogs over 4 kg up to 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Poland	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 0.4 ml spot-on solution for dogs up to 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Poland	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 1 ml spot-on solution for dogs over 4 kg up to 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Portugal	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 200 mg/40 mg solução para unção punctiforme para cães até 4 Kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Portugal	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 500 mg/100 mg solução para unção punctiforme para cães com mais de 4 e até 10 Kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Portugal	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 1250 mg/250 mg solução para unção punctiforme para cães com mais de 10 e até 25 Kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Portugal	Boehringer Ingelheim Animal Health Portugal Unipessoal, Lda. Avenida de Pádua, 11 1800-294 Lisboa Portugal	Frontline Tri-Act Solução para unção punctiforme para cães 2-5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use
Portugal	Boehringer Ingelheim Animal Health Portugal Unipessoal, Lda. Avenida de Pádua, 11 1800-294 Lisboa Portugal	Frontline Tri-Act Solução para unção punctiforme para cães 5-10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Italy	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 500 mg/100 mg soluzione spot-on per cani oltre 4 kg fino a 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Italy	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 1250 mg/250 mg soluzione Spot-on per cani oltre 10 kg fino a 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Portugal	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 200 mg/40 mg solução para unção punctiforme para cães até 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use
Portugal	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 500 mg/100 mg solução para unção punctiforme para cães com mais de 4 e até 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Portugal	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 1250 mg/250 mg solução para unção punctiforme para cães com mais de 10 e até 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Romania	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 1250 mg/250 mg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Romania	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 500 mg/100 mg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Romania	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 200 mg/40mg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Romania	Belgica de Weerd B.V. Van de Reijtstraat 21 4814 NE Breda The Netherlands	Belgafox 200 mg/ml	Norfloxacin	200 mg/ml	Oral solution	Pigeons- not used for human consum ption	In drinking water use
Romania	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Oxy LA, inj, 200 mg/ml	Oxytetracycline	200 mg/ml	solution for injection	Cattle, pig	Intramuscular use
Romania	Belgica de Weerd B.V. Van de Reijtstraat 21 4814 NE Breda The Netherlands	Ornisol	Norfloxacin	120 mg/ml	Solution for use in drinking water	Pigeons- not used for human consum ption	Oral use
Romania	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use
Romania	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act soluție spot-on pentru câini de 5-10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Slovak Republic	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 200 mg/40 mg roztok na kvapkanie na kožu pre psov do 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Slovak Republic	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 500 mg/100 mg roztok na kvapkanie na kožu pre psov od 4 kg do 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Slovak Republic	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 1250 mg/250 mg roztok na kvapkanie na kožu pre psov od 10 kg do 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Slovak Republic	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot- on roztok na nakvapkanie na kožu pre psy 2-5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use
Slovak Republic	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot- on roztok na nakvapkanie na kožu pre psy 5-10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Slovenia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act kožni nanos, raztopina za pse 2 - 5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use
Slovenia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act kožni nanos, raztopina za pse 5 - 10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Slovenia	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 200 mg/40 mg, kožni nanos, raztopina za pse do 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Slovenia	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 500 mg/100 mg, kožni nanos, raztopina za pse nad 4 kg do 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Slovenia	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 1250 mg/250 mg, kožni nanos, raztopina za pse nad 10 kg do 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Slovenia	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 40/200 spot- on solution for dogs up to 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Slovenia	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 100/500 spot-on solution for dogs over 4 up to 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Spain	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ridaworm 20 mg solucion spot-on para gatos pequenos	Praziquantel	20 mg/0.5 ml	Spot-on solution	Cat	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Boehringer Ingelheim Animal Health España S.A.U. C/Prat de la Riba, 50 08174 Sant Cugat del Valles (Barcelona) Spain	Frontline Tri-act Solucion spot-on para perros 2 - 5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use
Spain	Boehringer Ingelheim Animal Health España S.A.U. C/Prat de la Riba, 50 08174 Sant Cugat del Valles (Barcelona) Spain	Frontline Tri-act Solucion spot-on para perros 5 - 10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use
Spain	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 40 mg/200 mg solución spot-on para perros de hasta 4 Kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Spain	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 100 mg/500 mg solución spot-on para perros de más de 4 kg hasta 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Spain	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Preventix 40 mg/200 mg solución spot-on para perros de hasta 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use
Spain	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Preventix 100 mg/500 mg solución spot-on para perros de más de 4 kg hasta 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 200 mg/40 mg solucion para unci3n dorsal puntual para perros de hasta 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Spain	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 500 mg/100 mg solucion para unci3n dorsal puntual para perros de m1s de 4 kg hasta 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Spain	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 1250 mg/250 mg solucion para unci3n dorsal puntual para perros de m1s de 10 kg hasta 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Spain	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 20 mg solucion spot-on para gatos y gatitos	Praziquantel	20 mg/0.5 ml	Spot-on solution	Cat	Spot-on use
Spain	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 200 mg/40 mg solucion para unci3n dorsal puntual para perros de hasta 4 Kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use
Spain	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 500 mg/100 mg solucion para unci3n dorsal puntual para perros de m1s de 4 kg hasta 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 1250 mg/250 mg solucion para unción dorsal puntual para perros de más de 10 kg hasta 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Spain	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 0,4 ml Solucion spot-on para perros de hasta 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Spain	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 1 ml Solucion spot-on para perros de mas de 4 kg hasta 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Spain	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 0,4 ml solucion spot-on para perros de hasta 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
Spain	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 1 ml solucion spot-on para perros de mas de 4 kg hasta 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use
Spain	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Daclotrix 200 mg/40 mg solucion para unción dorsal puntual para perros de hasta 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Daclotrix 500 mg/100 mg solucion para unción dorsal puntual para perros de más de 4 kg hasta 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
Spain	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Daclotrix 1250 mg/250 mg solucion para unción dorsal puntual para perros de más de 10 kg hasta 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Spain	Industrial Veterinaria, S.A. C/ Esmeralda, 19 08950 Esplugues de Llobregat (Barcelona) Spain	Oxitetraciclina Invesa 200 mg/ml L.A.	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, pig, sheep, goat	Intramuscular use
Spain	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Insectivex	Cipermethrin	50 mg/ml	Concentrate for cutaneous spray, emulsion	Cattle, horse (non- food- producin g)	Cutaneous use
Sweden	Boehringer Ingelheim Animal Health Nordics A/S Strødamvej 52 2100 Copenhagen Denmark	Frontect 2-5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Sweden	Boehringer Ingelheim Animal Health Nordics A/S Strødamvej 52 2100 Copenhagen Denmark	Frontect 5-10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Cutaneous use
UK/Northern Ireland ¹	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 1250 mg/250 mg spot-on solution for dogs over 10 kg up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
UK/Northern Ireland ¹	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 200 mg/40 mg Spot-on Solution for Dogs up to 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
UK/Northern Ireland ¹	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 500 mg/100 mg spot-on solution for dogs over 4 kg up to 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Spot-on use
UK/Northern Ireland ¹	Boehringer Ingelheim Animal Health UK Limited Ellesfield Avenue Bracknell RG12 8YS United Kingdom	Frontline Tri-Act Spot- on Solution for Dogs 2-5 kg	Fipronil Permethrin	33.8 mg/0.5 ml 252.4 mg/0.5 ml	Spot-on solution	Dog	Spot-on use
UK/Northern Ireland ¹	Boehringer Ingelheim Animal Health UK Limited Ellesfield Avenue Bracknell RG12 8YS United Kingdom	Frontline Tri-Act Spot- on Solution for Dogs 5-10 kg	Fipronil Permethrin	67.6 mg/ml 504.8 mg/ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
UK/Northern Ireland ¹	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Myorelax 100 mg/ml solution for infusion for horses	Guaifenesin	100 mg/ml	Solution for infusion	Horse	Intravenous use
UK/Northern Ireland ¹	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 20 mg spot-on solution for small cats and kittens	Praziquantel	20 mg/0.5 ml	Spot-on solution	Cat	Spot-on use
UK/Northern Ireland ¹	Ceva Animal Health Ltd Unit 3, Anglo Office Park, White Lion Road Amersham HP7 9FB United Kingdom	Vectra 3D spot-on solution for dogs 1.5– 4 kg	Dinotefuran Pyriproxyfen Permethrin	44 mg/0.8 ml 3.9 mg/0.8 ml 317 mg/0.8 ml	Spot-on solution	Dog	Spot-on use
UK/Northern Ireland ¹	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 0.4 ml spot-on solution for dogs up to 4 kg	Imidacloprid Permethrin	40 mg/0.4 ml 200 mg/0.4 ml	Spot-on solution	Dog	Cutaneous use
UK/Northern Ireland ¹	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 1 ml spot-on solution for dogs over 4 kg up to 10 kg	Imidacloprid Permethrin	100 mg/ml 500 mg/ml	Spot-on solution	Dog	Cutaneous use

Annex IC

List of nationally authorised veterinary medicinal products recommended for variation of the marketing authorisations (quantitative NMP concentration, target animal safety warnings and user safety warnings during application)

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Austria	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on Lösung zum Auftropfen auf die Haut für Hunde über 10 kg bis 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Austria	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on Lösung zum Auftropfen auf die Haut für Hunde über 25 kg bis 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Austria	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on Lösung zum Auftropfen auf die Haut für Hunde über 40 kg bis 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use
Austria	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan, 20 mg/ml, Injektionslösung für Rinder, Schweine und Pferde	Meloxicam	20 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use
Austria	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan, 5 mg/ml, injektionslösung für hunde und katzen	Meloxicam	5 mg/ml	Solution for injection	Dog, cat	Intravenous, subcutaneous use
Austria	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 2000 mg/400 mg lösung zum auftropfen für hunde über 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Austria	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès Barcelona Spain	Cadorex 300 mg/ml Injektionslösung für Rinder, Schafe und Schweine	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Austria	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Cyclosol L.A. 200 mg/ml, Injektionslösung, für Rinder und Schweine	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Austria	Vana GmbH Wolfgang-Schmälzl-Gasse 6 1020 Wien Austria	Dexa "Vana" 2 mg/ml - Injektionslösung für Tiere	Dexamethasone	2 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intrabursal, intramuscular, intravenous, periarticular, subcutaneous use
Austria	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Diatrim 200 mg/ml + 40 mg/ml Injektionslösung	Trimethoprim Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Austria	Vétoquinol SA Magny-Vernois, B.P. 189 70204 Lure Cedex France	Droncit Spot-on 40 mg/ml Lösung zum Auftropfen auf die Haut für Katzen	Praziquantel	40 mg/ml	Spot-on solution	Cat	Spot-on use
Austria	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 2.5 ml spot-on solution for dogs over 10 kg up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Austria	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 4 ml spot-on solution for dogs over 25 kg up to 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Austria	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 6 ml spot-on solution for dogs over 40 kg up to 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Austria	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen 300 mg/ml Injektionslösung für Rinder und Schweine	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Austria	Laboratorios Calier, S.A. C/ Barcelonès, 26 08520 Les Franqueses del Vallès (Barcelona) Spain	Florinject 300 mg/ml Injektionslösung für Rinder und Schweine	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Austria	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act Lösung zum Auftropfen für Hunde 10-20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
Austria	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act Lösung zum Auftropfen für Hunde 20-40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use
Austria	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act Lösung zum Auftropfen für Hunde 40-60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Austria	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Metaxol 20/100 mg/ml lösung zum eingeben über das trinkwasser für schweine und hühner	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Austria	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Methoxasol-T 20/100 mg/ml lösung zum eingeben für schweine und hühner	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig, chicken	Oral use
Austria	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Nifencol 300 mg/ml Injektionslösung für Rinder und Schweine	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Austria	Intervet GesmbH Siemensstraße 107 1221 Vienna Austria	Nuflor 300 mg/ml Injektionslösung für Rinder und Schafe	Florfenicol	300 mg/ml	Solution for injection	Cattle, sheep	Intramuscular, subcutaneous use
Austria	Intervet GesmbH Siemensstraße 107 1221 Vienna Austria	Nuflor Schwein 300 mg/ml Injektionslösung	Florfenicol	300 mg/ml	Solution for injection	Pig	Intramuscular use
Austria	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate H18 W620 Monaghan Ireland	Prisulfan 24 % injektionslösung für tiere	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, sheep, dog	Intramuscular, intravenous, subcutaneous use
Austria	Intervet GesmbH Siemensstraße 107 1221 Vienna Austria	Resflor 300/16,5 mg/ml Injektionslösung für Rinder	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Austria	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Riketron N 200 mg/ml + 40 mg/ml - Injektionslösung für Pferde, Rinder und Schweine	Trimethopri m Sulfadimidin e	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Austria	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan 300 mg/ml Injektionslösung für Rinder und Schweine	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Belgium	Dechra Veterinary Products Achterstenhoek 48 2275 Lille Belgium	Cyclosol 200 Long Acting	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Belgium	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Dexa 0,2%	Dexamethasone	2 mg/ml	Solution for injection	Cattle	Intravenous use
Belgium	Emdoka John Lijssenstraat 16 2321 Hoogstraten Belgium	Emdotrim 10% SOL	Trimethoprim Sulfadiazine	16.7 mg/ml 83.3 mg/ml	Solution for use in drinking water	Chicken	Oral use
Belgium	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Oxy-Kel 20% Long Acting	Oxytetracycline	200 mg/ml	Solution for injection	Cattle	Intramuscular use
Belgium	V.M.D. n.v. Hoge Mauw 900 2370 Arendonk Belgium	Prednisolone 1%	Prednisolone	10 mg/ml	Solution for injection	Dog, cat	Intramuscular use
Belgium	V.M.D. n.v. Hoge Mauw 900 2370 Arendonk Belgium	Prednisolone 2,5%	Prednisolone	25 mg/ml	Solution for injection	Dog	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Belgium	V.M.D. n.v. Hoge Mauw 900 2370 Arendonk Belgium	Vetodexin 0,2%	Dexamethasone	2.64 mg/ml	Solution for injection	Cattle, dog	Intramuscular use
Belgium	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Dog 250/1250	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Belgium	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Dog 400/2000	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Belgium	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Dog 600/3000	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Spot-on use
Belgium	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontline Protect voor honden 10-20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
Belgium	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontline Protect voor honden 20-40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Belgium	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontline Protect voor honden 40-60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Belgium	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Ecomectin	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Pour-on use
Belgium	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Florfenikel	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Belgium	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Mycoflor	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Belgium	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor	Florfenicol	300 mg/ml	Solution for injection	Cattle, sheep	Intramuscular, subcutaneous use
Belgium	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor Minidose	Florfenicol	450 mg/ml	Solution for injection	Cattle	Intramuscular, subcutaneous use
Belgium	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor swine	Florfenicol	300 mg/ml	Solution for injection	Pig	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Belgium	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxtmeer Netherlands	Resflor 300	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Belgium	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Belgium	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Belgium	Laboratorios Calier, S.A. C/ Barcelonès, 26 08520 Les Franqueses del Vallès (Barcelona) Spain	Florinject	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Belgium	Dechra Regulatory B.V. Handelsweg 25 5531 AE Bladel Netherlands	Methoxasol	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig, chicken (broiler)	In drinking water use
Belgium	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontect voor honden 10- 20 kg	Fipronil Permethrin	135.2 mg/ 2 ml 1009.6 mg /2 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Belgium	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontect voor honden 20- 40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use
Belgium	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontect voor honden 40- 60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Belgium	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 2000 mg/400 mg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Belgium	Dechra Regulatory B.V. Handelsweg 25 5531 AE Bladel Netherlands	Metaxol	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Belgium	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	T.S. Sol	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Belgium	Dechra Regulatory B.V. Handelsweg 25 5531 AE Bladel Netherlands	Diatrim	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig, dog, cat	Intramuscular, intravenous, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Belgium	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès (Barcelona) Spain	Flodoex	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Belgium	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Nifencol	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Belgium	Laboratorios Syva, S.A.U. Avda. Párroco Pablo Díez, 49-57 24010 León Spain	Florfenis	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Bulgaria	Kepro B.V., Maagdenburgstraat 17 7421 ZA Deventer The Netherlands	Florum 20% oral	Florfenicol	200 mg/ml	Solution for use in drinking water	Pig, chicken	In drinking water use
Bulgaria	Crida Pharm S.R.L. Str. Intrarea Vagonetului, 2, 47 Bucureşti Romania	Florcid 10 % - BG	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Bulgaria	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Florfenikel 300 mg/ml solution for injection for cattle and pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Bulgaria	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen 300 mg/ml solution for injection for cattle and pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Bulgaria	Sudachim, Ltd str. Jordan Stubel 10A 1700 Sofia Bulgaria	Florfenil 10 %	Florfenicol	100 mg/ml	Solution for use in drinking water	Pig, chicken	In drinking water use
Bulgaria	Farma Vet Ltd. Shumen, 40 Otec Paisii str. Bulgaria	Bisulvet	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig, broiler	In drinking water use
Bulgaria	Zavet JSC 7330 Zavet, 5, Kiril and Metodii str. Bulgaria	Florfenicol 10% solution	Florfenicol	100 mg/ml	Oral solution	Pig, chicken	In drinking water use
Bulgaria	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	FlorFlu 300/16.5 mg/ml solution for injection for cattle	Florfenicol Flunixin	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Bulgaria	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on solution for dogs over 10 up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Bulgaria	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on solution for dogs over 25 up to 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Bulgaria	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on solution for dogs over 40 kg up to 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Bulgaria	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan, 20 mg/ml, solution for injection for cattle, pigs and horses	Meloxicam	20 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use
Bulgaria	Kepro B.V., Maagdenburgstraat 17 7421 ZA Deventer The Netherlands	Kepcox 2.5% oral	Toltrazuril	25 mg/ml	Oral solution	Chicken, turkey	In drinking water use
Bulgaria	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès (Barcelona) Spain	Cadorex 300 mg/ml solution for injection for cattle, sheep and pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Bulgaria	Interchemie Werken De Adelaar BV Metalweeg 8 5804 CG Venray The Netherlands	Intertrim LA	Trimethopri m Sulfadoxine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use
Bulgaria	Interchemie Werken De Adelaar BV Metalweeg 8 5804 CG Venray The Netherlands	Introflor-100 oral	Florfenicol	100 mg/ml	Oral solution	Pig, chicken	In drinking water use
Bulgaria	Asklep-Pharma Ltd Lyulin 7, bl. 711A, shop. 3, Sofia Bulgaria	Norotrim Injection solution for injection for cattle, swine, horses, dogs and cats	Trimethopri m Sulfadoxine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intramuscular, intravenous, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Bulgaria	Asklep-Pharma Ltd Lyulin 7, bl. 711A, shop. 3, Sofia Bulgaria	Norodine 24 injectable solution	Trimethopri m Sulfadoxine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Bulgaria	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 2000 mg/400 mg spot-on solution for dogs over 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Bulgaria	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Mycoflor, 300 mg/ml solution for injection for cattle and pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Bulgaria	MSD Animal Health, Lda. Edifício Vasco da Gama, 19 Quinta da Fonte, Porto Salvo 2770-192 Paço de Arcos Portugal	Resflor 300/16.5 mg/mL solution for injection for cattle	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Bulgaria	Industrial Veterinaria, S.A. C/ Esmeralda, 19 08950 Esplugues de Llobregat (Barcelona) Spain	Promectine	Ivermectin	10 mg/ml	Solution for injection	Cattle, pig	Subcutaneous use
Bulgaria	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan 300 mg/ml solution for injection for cattle and swine	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Bulgaria	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	T.S.-Sol	Trimethopri m Sulfamethox azole	20 mg/ml 80 mg/ml	Oral solution	Pig, chicken	In drinking water use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Bulgaria	Vetprom AD 2400, Radomir, 26 Otetc Paisii str. Bulgaria	Thiamphenicol – 20% solutio pro injectionibus 100 ml	Thiamphenic ol Procain Hydrochlorid e	200 000 IU/ml 0.01 g/ml	Solution for injection	Cattle, chicken	Intramuscular, oral use
Bulgaria	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot-on solution for dogs 10-20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
Bulgaria	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot-on solution for dogs 20-40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use
Bulgaria	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot-on solution for dogs 40-60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Bulgaria	Vet Pro Komers Ltd 4000 Plovdiv, JK Trakia, bl. 189, vh. B, app. 2 Bulgaria	Inspector Quadro K	Fipronil Praziquantel Pyriproxyfen Moxidectin	107 mg/ml 42.8 mg/ml 21.4 mg/ml 10.7 mg/ml	Spot-on solution	Cat	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Bulgaria	Vet Pro Komers Ltd 4000 Plovdiv, JK Trakia, bl. 189, vh. B, app. 2 Bulgaria	Inspector Quadro C	Fipronil Praziquantel Pyriproxyfen Moxidectin	107 mg/ml 42.8 mg/ml 21.4 mg/ml 10.7 mg/ml	Spot-on solution	Dog	Cutaneous use
Croatia	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on, otopina za nakapavanje, za pse od 10 do 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Croatia	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on, otopina za nakapavanje, za pse od 25 do 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Croatia	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on, otopina za nakapavanje, za pse od 40 do 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Spot-on use
Croatia	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa, 2000 mg/400 mg, otopina za nakapavanje, za pse od 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Croatia	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès (Barcelona) Spain	Cadorex, 300 mg/mL, otopina za injekciju, za goveda, ovce i svinje	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Croatia	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Diatrim 200 mg/mL + 40 mg/mL, otopina za injekciju	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Croatia	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen, 300 mg/mL, otopina za injekciju, za goveda i svinje	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Croatia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act, otopina za nakapavanje, za pse 10-20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
Croatia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act, otopina za nakapavanje, za pse 20-40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use
Croatia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act, otopina za nakapavanje, za pse 40-60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Croatia	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Nifencol, 300 mg/mL, otopina za injekciju, za goveda i svinje	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Croatia	Intervet International B.V. Podružnica u RH Ivana Lučića 2a 10000 Zagreb Croatia	Resflor, otopina za injekciju, za goveda	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Croatia	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Riketron N, 200 mg/mL + 40 mg/mL, otopina za injekciju za goveda, konje i svinje	Trimethopri m Sulfadimidin e	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous use
Croatia	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan 300 mg/mL, otopina za injekciju, za goveda i svinje	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Croatia	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	T.S.-sol, 20/100 mg/mL, otopina za primjenu u vodi za piće, za svinje i kokoši	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Cyprus	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Resflor 300/16,5 mg/ml ενέσιμο διάλυμα για βοοειδή	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Cyprus	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor swine injectable solution 300 mg/ml	Florfenicol	300 mg/ml	Solution for injection	Pig	Intramuscular use
Cyprus	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Tallaght, Dublin 24 Ireland	Tetroxy LA 200 mg/ml solution for injection	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Cyprus	Σπύρος Σταυρινίδης Κέμικαλς Λτδ Λεωφ. Στασίνου 28, 1060 Λευκωσία, Κύπρος Τηλ. 22 447464	Norodine 24 Ενέσιμο Διάλυμα	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Cyprus	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on διάλυμα για σκύλους από 25kg έως 40kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Cyprus	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on διάλυμα για σκύλους από 10kg έως 25kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Cyprus	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-on διάλυμα για σκύλους άνω των 40 kg έως 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use
Cyprus	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot-on διάλυμα επίχυσης για σκύλους 10-20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
Cyprus	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot-on διάλυμα επίχυσης για σκύλους 20-40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Cyprus	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot-on διάλυμα επιχύσης για σκύλους 40-60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Cyprus	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan, 20 mg/ml, ενέσιμο διάλυμα για βοοειδή, χοίρους και άλογα	Meloxicam	20 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use
Cyprus	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Florfenikel 300 mg/ml ενέσιμο διάλυμα για βοοειδή και χοίρους	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Cyprus	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès (Barcelona) Spain	Cadorex 300 mg/ml, ενέσιμο διάλυμα για βοοειδή, πρόβατα και χοίρους	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Cyprus	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Mycoflor 300mg/ml ενέσιμο διάλυμα για βοοειδή και χοίρους	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Cyprus	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan 300 mg/ml, ενέσιμο διάλυμα για βοοειδή και χοίρους	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Czech Republic	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix roztok pro nakapání na kůži – spot-on pro psy od 40 kg do 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Czech Republic	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix roztok pro nakapání na kůži – spot-on pro psy od 10 do 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Czech Republic	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix roztok pro nakapání na kůži – spot-on pro psy od 25 kg do 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Czech Republic	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan, 20 mg/ml, injekční roztok pro skot, prasata a koně	Meloxicam	20 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use
Czech Republic	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 2000 mg/400 mg roztok pro nakapání na kůži – spot-on pro psy nad 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Czech Republic	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès (Barcelona) Spain	Cadorex 300 mg/ml injekční roztok pro skot, ovce a prasata	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Czech Republic	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen 300 mg/ml injekční roztok pro skot a prasata	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Czech Republic	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Florfenikel 300 mg/ml injekční roztok pro skot a prasata	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Czech Republic	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act roztok pro nakapání na kůži - spot-on pro psy 10-20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
Czech Republic	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act roztok pro nakapání na kůži - spot-on pro psy 20-40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use
Czech Republic	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act roztok pro nakapání na kůži - spot-on pro psy 40-60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Czech Republic	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Metaxol 20/100 mg/ml roztok pro podání v pitné vodě pro prasata a kura domácího	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Czech Republic	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Methoxasol 20/100 mg/ml roztok pro podání v pitné vodě pro prasata a kura domácího	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig, chicken (broiler)	In drinking water use
Czech Republic	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Mycoflor 300 mg/ml injekční roztok pro skot a prasata	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Czech Republic	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Nifencol 300 mg/ml, injekční roztok pro skot a prasata	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Czech Republic	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate H18 W620 Monaghan Ireland	Norodine 40/200 mg/ml injekční roztok	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Czech Republic	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor Minidose 450 mg/ml injekční roztok pro skot	Florfenicol	450 mg/ml	Solution for injection	Cattle	Intramuscular, subcutaneous use
Czech Republic	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor 300 mg/ml injekční roztok	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Czech Republic	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Resflor 300/16,5 mg/ml injekční roztok pro skot	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Czech Republic	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan 300 mg/ml injekční roztok pro skot a prasata	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Czech Republic	Virbac S.A. 1ere Avenue 2065 M L.I.D. 06516 Carros France	Terralon 200 mg/ml LA injekční roztok	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Czech Republic	V.M.D. n.v. Hoge Mauw 900 2370 Arendonk Belgium	Vetodexin 2 mg/ml injekční roztok	Dexamethasone	2 mg/ml	Solution for injection	Dog, cat	Intramuscular use
Denmark	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Bayvantic Vet.	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use
Denmark	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Bayvantic Vet. til hunde 10-25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Denmark	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Bayvantic Vet. til hunde 25-40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Denmark	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès (Barcelona) Spain	Cadorex Vet.	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Denmark	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Ecomectin pour-on vet.	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Pour-on use
Denmark	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Denmark	Laboratorios Syva, S.A.U. Avda. Párroco Pablo Díez, 49-57 24010 León Spain	Florfenis	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Denmark	Boehringer Ingelheim Animal Health Nordics A/S Strødamvej 52 2100 Copenhagen Denmark	Frontect (til hunde 20-40 kg)	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Denmark	Boehringer Ingelheim Animal Health Nordics A/S Strødamvej 52 2100 Copenhagen Denmark	Frontect (til hunde 10-20 kg)	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Cutaneous use
Denmark	Boehringer Ingelheim Animal Health Nordics A/S Strødamvej 52 2100 Copenhagen Denmark	Frontect (til hunde 40-60 kg)	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Cutaneous use
Denmark	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Kelaflor	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Denmark	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Mycoflor	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Denmark	ScanVet Animal Health A/S Kongevejen 66 3480 Fredensborg Denmark	Norodine Vet.	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Denmark	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor Minidose	Florfenicol	450 mg/ml	Solution for injection	Cattle	Intramuscular, subcutaneous use
Denmark	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor Vet.	Florfenicol	300 mg/ml	Solution for injection	Cattle, sheep	Intramuscular, subcutaneous use
Denmark	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Resflor Vet.	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Denmark	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Denmark	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Suprim Vet	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig, chicken (broiler)	In drinking water use
Denmark	Virbac S.A. 1ere Avenue 2065 M L.I.D. 06516 Carros France	Terralon Prolongatum Vet.	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Denmark	Bimeda Animal Health Limited Broomhill Road Dublin 24 Ireland	Tetroxy Prolongatum Vet.	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular use
Denmark	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Veticyclin Pronlongatum Vet.	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular use
Estonia	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Estonia	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Estonia	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Spot-on use
Estonia	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan	Meloxicam	20 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use
Estonia	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Estonia	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès (Barcelona) Spain	Cadorex	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Estonia	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Estonia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
Estonia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use
Estonia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Estonia	Interchemie Werken De Adelaar Eesti AS Vanapere tee 14 Viimsi 74013 Harjumaa Estonia	Introflor-300	Florfenicol	300 mg/ml	Solution for injection	Cattle, sheep	Intramuscular, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Estonia	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel The Netherlands	Metaxol	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Estonia	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate H18 W620 Monaghan Ireland	Norodine 24	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Estonia	Intervet International B.V. Wim de Kôverstraat 35 5831 AN Boxtmeer Netherlands	Resflor	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Estonia	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Estonia	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Tallaght, Dublin 24 Ireland	Tetroxy L.A.	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular use
Estonia	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Estonia	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Finland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa vet koirille, jotka painavat yli 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Finland	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Bayvantic vet koirille 10– 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Finland	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Bayvantic vet koirille 25– 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Finland	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Bayvantic vet koirille 40– 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use
Finland	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès Barcelona Spain	Cadorex Vet.	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Finland	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Florselect Vet.	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Finland	Boehringer Ingelheim Animal Health Nordics A/S Strødamvej 52 2100 Copenhagen Denmark	Frontect 10–20 kg:n painoiselle koiralle	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Finland	Boehringer Ingelheim Animal Health Nordics A/S Strødamvej 52 2100 Copenhagen Denmark	Frontect 20–40 kg:n painoiselle koiralle	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Finland	Boehringer Ingelheim Animal Health Nordics A/S Strødamvej 52 2100 Copenhagen Denmark	Frontect 40–60 kg:n painoiselle koiralle	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Cutaneous use
Finland	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor vet Minidose	Florfenicol	450 mg/ml	Solution for injection	Cattle	Intramuscular, subcutaneous use
Finland	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Resflor vet.	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
France	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Cyclosol 200 LA	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
France	Virbac S.A. 1ere Avenue 2065 M L.I.D. 06516 Carros France	Terralon 20 % LA	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
France	Virbac S.A. 1ere Avenue 2065 M L.I.D. 06516 Carros France	Panadia	Tetracyclin (as hydrochlorid e) Procain (as hydrochlorid e)	80 mg/mL 17.30 mg/ml	Powder and solvent for solution for injection	Cattle	Intramuscular use
France	Vétoquinol SA Magny-Vernois, B.P. 189 70204 Lure Cedex France	Longicine	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
France	Dopharma France 23 Rue du Prieure 44150 Vair sur Loire France	Remacycline L.A.	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
France	Intervet Rue Olivier de Serres 49071 Beaucouze Cedex France	Resflor solution injectable	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
France	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Floron 450 mg/ml solution injectable pour bovins	Florfenicol	450 mg/ml	Solution for injection	Cattle	Subcutaneous use
France	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-act solution pour spot-on pour chiens 10 - 20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
France	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-act solution pour spot-on pour chiens 20 - 40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use
France	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-act solution pour spot-on pour chiens 40 - 60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
France	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontect solution pour spot-on pour chiens 10 - 20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Cutaneous use
France	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontect solution pour spot-on pour chiens 20 - 40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Cutaneous use
France	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontect solution pour spot-on pour chiens 40 - 60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Cutaneous use
France	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Advantix chien moyen	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
France	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Advantix grand chien	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
France	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 2000 mg/400 mg solution pour spot-on pour chiens de plus de 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
France	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès (Barcelona) Spain	Cadorex 300 mg/ml solution injectable pour bovins ovins et porcins	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
France	Laboratorios Calier, S.A. C/ Barcelonès, 26 08520 Les Franqueses del Vallès (Barcelona) Spain	Calflor 300 mg/ml solution injectable pour bovins et porcins	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
France	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Diatrim 200 mg/ml + 40 mg/ml solution injectable	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
France	Eco Animal Health Europe Limited 6th Floor, South Bank House, Barrow Street Dublin 4, D04 TR29 Ireland	Divamectin pour-on	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Pour-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
France	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Endectine Pour-on	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Pour-on use
France	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen 300 mg/ml solution injectable pour bovins et porcins	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
France	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Florfenikel 300 mg/ml solution injectable pour bovins et porcins	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
France	Laboratorios Syva, S.A.U. Avda. Párroco Pablo Díez, 49-57 24010 León Spain	Florfenis 300 mg/ml solution injectable pour bovins	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
France	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Florflu 300/16,5 mg/ml solution injectable pour bovins	Florfenicol Flunixin	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
France	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Methoxasol 20/100 mg/ml, solution pour utilisation dans l'eau de boisson pour porcs et poulets	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig, chicken (broiler)	In drinking water use
France	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Mycoflor 300 mg/ml solution injectable pour bovins et porcins	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
France	Intervet Rue Olivier de Serres 49071 Beaucouze Cedex France	Nuflor 300 mg/ml solution injectable pour bovins et ovins	Florfenicol	300 mg/ml	Solution for injection	Cattle, sheep	Intramuscular, subcutaneous use
France	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor 450 solution injectable pour bovins	Florfenicol	450 mg/ml	Solution for injection	Cattle	Intramuscular, subcutaneous use
France	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Permetrix biocanina 2000 mg/400 mg solution pour spot-on pour chiens de plus de 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
France	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 60 mg solution pour spot-on pour chats de grande taille	Praziquantel	60 mg/1.5 ml	Spot-on solution	Cat	Spot-on use
France	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Qualimec pour-on	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Topical use
France	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ridaworm 40 mg solution pour spot-on pour chats moyens	Praziquantel	40 mg/ml	Spot-on solution	Cat	Spot-on use
France	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ridaworm 60 mg solution pour spot-on pour grands chats	Praziquantel	60 mg/1.5 ml	Spot-on solution	Cat	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
France	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
France	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer The Netherlands	T.s.-sol 20/100 mg/ml solution pour administration dans l'eau de boisson pour porcs et poulets	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Germany	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Advantix Spot-on Lösung zum Auftropfen auf die Haut für Hunde über 10 kg bis 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Germany	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Advantix Spot-on Lösung zum Auftropfen auf die Haut für Hunde über 25 kg bis 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Germany	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Advantix Spot-on Lösung zum Auftropfen auf die Haut für Hunde über 40 kg bis 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use
Germany	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan, 20 mg/ml	Meloxicam	20 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use
Germany	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan, 5 mg/ml	Meloxicam	5 mg/ml	Solution for injection	Dog, cat	Intravenous, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Germany	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 2000 mg/400 mg lösung zum auftropfen für hunde über 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Germany	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Bigram	Trimethopri m Sulfadimidin e	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous use
Germany	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès Barcelona Spain	Cadorex 300 mg/ml Injektionslösung für Rinder, Schafe und Schweine	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Germany	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 2000 mg/400 mg lösung zum auftropfen für hunde über 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Germany	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel The Netherlands	Diatrim 200 mg/ml + 40 mg/ml Injektionslösung	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Germany	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Dophamec 5 mg/ml rind pour-on	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Pour-on use
Germany	Vétoquinol SA Magny-Vernois, B.P. 189 70204 Lure Cedex France	Droncit Spot-on 40 mg/ml	Praziquantel	40 mg/ml	Spot-on solution	Cat	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Germany	Ceva Tiergesundheit GmbH Kanzlerstr. 4 40472 Düsseldorf Germany	Fletic spot on Maxi	Permethrin	744 mg/ml	Spot-on solution	Dog	Spot-on use
Germany	Ceva Tiergesundheit GmbH Kanzlerstr. 4 40472 Düsseldorf Germany	Fletic spot on Mini	Permethrin	744 mg/ml	Spot-on solution	Dog	Spot-on use
Germany	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen 300 mg/ml Injektionslösung für Rinder und Schweine	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Germany	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Florfenikel 300 mg/ml Injektionslösung für Rinder und Schweine	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Germany	Laboratorios Syva, S.A.U. Avda. Párroco Pablo Díez, 49-57 24010 León Spain	Florfenis 300 mg/ml Injektionslösung für Rinder, Schafe und Schweine	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Germany	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	FlorFlu	Florfenicol Flunixin	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Germany	Laboratorios Calier, S.A. C/ Barcelonès, 26 08520 Les Franqueses del Vallès (Barcelona) Spain	Florinject 300 mg/ml Injektionslösung für Rinder und Schweine	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Germany	Boehringer Ingelheim Vetmedica GmbH Binger Str. 173 55216 Ingelheim Germany	Frontline Tri-Act Lösung zum Auftropfen für Hunde 10-20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
Germany	Boehringer Ingelheim Vetmedica GmbH Binger Str. 173 55216 Ingelheim Germany	Frontline Tri-Act Lösung zum Auftropfen für Hunde 20-40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use
Germany	Boehringer Ingelheim Vetmedica GmbH Binger Str. 173 55216 Ingelheim Germany	Frontline Tri-Act Lösung zum Auftropfen für Hunde 40-60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Germany	Bremer Pharma GmbH Werkstrasse 42 34414 Warburg Germany	Hefrotrim	Trimethopri m Sulfadimidin e sodium	40 mg/ml 215.8 mg/ml	Solution for injection	Cattle, pig	Intramuscular, intravenous use
Germany	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Metaxol 20/100 mg/ml lösung zum eingeben über das trinkwasser für schweine und hühner	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Germany	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Mycoflor 300 mg/ml Injektionslösung für Rinder und Schweine	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Germany	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Nifencol 300 mg/ml Injektionslösung für Rinder und Schweine	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Germany	Intervet Deutschland GmbH Feldstr. 1a 85716 Unterschleißheim Germany	Nuflor Minidose	Florfenicol	450 mg/ml	Solution for injection	Cattle	Intramuscular, subcutaneous use
Germany	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 60 mg lösung zum auftropfen für große katzen	Praziquantel	60 mg/1.5 ml	Spot-on solution	Cat	Spot-on use
Germany	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Qualimec Rind Pour-on	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Topical use
Germany	Intervet Deutschland GmbH Feldstr. 1a 85716 Unterschleißheim Germany	Resflor	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Germany	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ridaworm 40 mg lösung zum auftropfen für mittelgroße katzen	Praziquantel	40 mg/ml	Spot-on solution	Cat	Spot-on use
Germany	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ridaworm 60 mg Lösung zum Auftropfen für große Katzen	Praziquantel	60 mg/1.5 ml	Spot-on solution	Cat	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Germany	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Riketron N Injektionslösung	Trimethopri m Sulfadimidin e sodium	40 mg/ml 215.8 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous use
Germany	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan 300 mg/ml Injektionslösung für Rinder und Schweine	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Germany	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	T.S.Sol 20/100 mg/ml	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Germany	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	TMPS oral	Trimethopri m Sulfamethox azole	20 mg/ml 80 mg/ml	Solution for use in drinking water	Chicken	Oral use
Germany	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Trimethosel	Trimethopri m Sulfadimidin e sodium	40 mg/ml 215.8 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous use
Germany	CP-Pharma Handelsgesellschaft mbH Ostlandring 13 31303 Burgdorf Germany	Vitamin D3 1.000.000 I.E. ad us. vet.	Colecalciferol	25 mg/ml	Solution for injection	Cattle	Intramuscular, intravenous use
Germany	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Methoxasol-T 20/100 mg/ml	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Oral solution	Pig, broiler	In drinking water use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Germany	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 2.5 ml spot-on solution for dogs over 10 kg up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Germany	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 4 ml spot-on solution for dogs over 25 kg up to 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Germany	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 6 ml spot-on solution for dogs over 40 kg up to 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Cutaneous use
Germany	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 250 mg/1250 mg spot-on solution for dogs over 10 kg up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Germany	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 400 mg/2000 mg spot-on solution for dogs over 25 kg up to 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Germany	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 2.5 ml spot-on solution for dogs over 10 kg up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Germany	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 4 ml spot-on solution for dogs over 25 kg up to 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Germany	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 6 ml spot-on solution for dogs over 40 kg up to 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Cutaneous use
Greece	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Greece	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Greece	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use
Greece	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès (Barcelona) Spain	Cadorex	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Greece	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen Inj.Sol 300 mg/ml	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Greece	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Florfenikel	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Greece	Laboratorios Syva, S.A.U. Avda. Párroco Pablo Díez, 49-57 24010 León Spain	Florfenis	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Greece	Bimeda Chemicals Ltd Broomhill Road Dublin 24 Ireland	Hostacyclin	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Greece	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Metaxol	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Greece	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Methoxasol	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig, chicken (broiler)	In drinking water use
Greece	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Mycoflor	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Greece	Intervet Hellas A.E. Ag. Dimitriou 63 174 55 Alimos, Athens Greece	Nuflor Minidose	Florfenicol	450 mg/ml	Solution for injection	Cattle	Intramuscular, subcutaneous use
Greece	Intervet Hellas A.E. Ag. Dimitriou 63 174 55 Alimos, Athens Greece	Nuflor Inj.Sol 300 mg/ml	Florfenicol	300 mg/ml	Solution for injection	Cattle, sheep	Intramuscular, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Greece	Intervet Hellas A.E. Ag. Dimitriou 63 174 55 Alimos, Athens Greece	Nuflor swine	Florfenicol	300 mg/ml	Solution for injection	Pig	Intramuscular use
Greece	Virbac S.A. 1ere Avenue 2065 M L.I.D. 06516 Carros France	Oxylong	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Greece	Intervet Hellas A.E. Ag. Dimitriou 63 174 55 Alimos, Athens Greece	Resflor	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Greece	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan Inj.Sol	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Greece	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	T.S-Sol	Trimethoprim Sulfamethoxazole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattening pigs), chicken (broiler)	In drinking water use
Greece	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan	Meloxicam	20 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use
Greece	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-act spot-on.so (135,2+1009,6)mg/2ml pipette	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Greece	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-act spot-on.so (270,4+2019,2)mg/4ml	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use
Greece	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-act spot-on.so (405,6+3028,8)mg/6ml pipette	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Greece	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix spot-on.so	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Greece	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix spot-on.so	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Greece	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Greece	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Cutaneous use
Greece	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Greece	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Greece	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Cyclosol LA	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Greece	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Divamectin	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Pour-on use
Greece	Γ. ΤΡΑΪΚΟΥΔΗΣ & ΣΙΑ ΕΠΕ (Δ.Τ. FARMA-MIX ΕΠΕ) 17 km Thessalonikis-Drymos Serron Drymos 57200 Greece	Farma Mix Florfarm	Florfenicol	100 mg/ml	Solution for use in drinking water	Broiler	Oral use
Greece	Intervet Hellas A.E. Ag. Dimitriou 63 174 55 Alimos, Athens Greece	Florvetol Cattle	Florfenicol	300 mg/ml	Solution for injection	Cattle	Intramuscular, subcutaneous use
Greece	Intervet Hellas A.E. Ag. Dimitriou 63 174 55 Alimos, Athens Greece	Florvetol Swine	Florfenicol	300 mg/ml	Solution for injection	Pig	Intramuscular use
Greece	Bremer Pharma Gmbh Werkstrasse 42 34414 Warburg Germany	Hefrotrim	Trimethoprim Sulfadimidine	40 mg/ml 215.8 mg/ml	Solution for injection	Calf, pig	Intramuscular, intravenous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Hungary	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix spot on 10-25 kg közötti kutyáknak A.U.V.	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Hungary	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix spot on 25-40 kg közötti kutyáknak A.U.V.	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Hungary	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix spot on 40-60 kg közötti kutyáknak A.U.V.	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use
Hungary	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan 20 mg/ml oldatos injekció szarvasmarhák, sertések és lovak számára A.U.V.	Meloxicam	20 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use
Hungary	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 2000 mg/400 mg rácsepegtető oldat 25 kg feletti kutyáknak A.U.V.	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Hungary	Dr. Jozsef Varga 7100 Szekszárd, Rozsnyai Matyas u. 15 Hungary	Bobolhairtó sampon kutyák részére A.U.V.	Permethrin Tetrametrin	933 mg/100 ml 23.5 mg/100 ml	Shampoo	Dog	External use
Hungary	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès (Barcelona) Spain	Cadorex 300 mg/ml oldatos injekció szarvasmarhák, juhok és sertések számára A.U.V.	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Hungary	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Cyclosol LA 200 mg/ml oldatos injekció A.U.V.	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Hungary	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Diatrim 200 mg/ml + 40 mg/ml oldatos injekció	Trimethoprim Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Hungary	Univet Limited Tullyvin Cootehill, Co. Cavan Ireland	Diaziprim oldatos injekció szarvasmarhák és sertések részére A.U.V.	Trimethoprim Sulfadiazine	40 mg/ml 200 mg/ml	Suspension for injection	Cattle, pig	Intramuscular use
Hungary	Cenavisa, S.L. Camí Pedra Estela s/n 43205 Reus Spain	Doxycen belsőleges oldat	Doxycycline hyclate	200 mg/ml	Oral solution	Pig, chicken	In drinking water use
Hungary	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen 300 mg/ml oldatos injekció szarvasmarhák és sertések számára A.U.V.	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Hungary	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Florfenikel 300 mg/ml oldatos injekció szarvasmarhák és sertések számára A.U.V.	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Hungary	Laboratorios Syva, S.A.U. Avda. Párroco Pablo Díez, 49-57 24010 León Spain	Florfenis 300 mg/ml oldatos injekció szarvasmarhák, juhok és sertések részére A.U.V.	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Hungary	Merial 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act rácsepegtető oldat 10-20 kg-os kutyáknak	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
Hungary	Merial 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act rácsepegtető oldat 20-40 kg-os kutyáknak	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use
Hungary	Merial 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act rácsepegtető oldat 40-60 kg-os kutyáknak	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Hungary	Industrial Veterinaria, S.A. C/ Esmeralda, 19 08950 Esplugues de Llobregat (Barcelona) Spain	Ivergen Premium L.A. oldatos injekció szarvasmarhák, sertések és juhok részére A.U.V.	Ivermectin	10 mg/ml	Solution for injection	Cattle, pig, sheep	Subcutaneous use
Hungary	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Metaxol 20/100 mg/ml oldat ivóvízbe keveréshez sertések és háziyúkok számára A.U.V.	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig, chicken (broiler)	In drinking water use
Hungary	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Methoxasol T 20/100 mg/ml oldat ivóvízbe keveréshez sertések és háziyúkok számára A.U.V.	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig, chicken	Oral use
Hungary	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Mycoflor 300 mg/ml oldatos injekció szarvasmarhák és sertések számára A.U.V.	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Hungary	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Neocyclin LA injekció A.U.V.	Oxytetracycline	200 mg/ml	Solution for injection	Cattle	Intramuscular, intravenous use
Hungary	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Nifencol 300 mg/ml oldatos injekció szarvasmarha és sertés részére	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Hungary	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate H18 W620 Monaghan Ireland	Norodine 200/40 mg/ml oldatos injekció A.U.V.	Trimethoprim Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Hungary	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor injekció A.U.V.	Florfenicol	300 mg/ml	Solution for injection	Cattle, sheep	Intramuscular, subcutaneous use
Hungary	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor Minidose 450 mg/ml injekció szarvasmarha részére	Florfenicol	450 mg/ml	Solution for injection	Cattle	Intramuscular, subcutaneous use
Hungary	Alfasan International B.V. Kuipersweg 9 3449 JA Woerden The Netherlands	Primaphenon 200 mg/ml oldatos injekció kutyák részére A.U.V.	Phenylbutazone	200 mg/ml	Solution for injection	Dog	Intravenous use
Hungary	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Remacycline L.A. 200 mg/ml oldatos injekció A.U.V.	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, pig	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Hungary	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Resflor 300/16,5 mg/ml injekció szarvasmarhák részére A.U.V.	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Hungary	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan 300 mg/ml oldatos injekció szarvasmarha és sertés részére A.U.V.	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Hungary	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	T.S.-sol 20/100 mg/ml oldat ivóvízbe keveréshez sertések és háziyúkok számára A.U.V.	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Hungary	Virbac S.A. 1ere Avenue 2065 M L.I.D. 06516 Carros France	Terralon 20% L.A. injekció A.U.V.	Oxytetracycli ne	20 g/100 ml	Solution for injection	Cattle, pig, sheep, goat	Intramuscular, subcutaneous use
Iceland	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Florselect vet. 300 mg/ml Stungulyf, lausn Nautgripir og svín	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Ireland	Laboratorios Syva, S.A.U. Avda. Párroco Pablo Díez, 49-57 24010 León Spain	Florfenis 300 mg/ml solution for injection for cattle, sheep and pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Ireland	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 60 mg spot-on solution for large cats	Praziquantel	60 mg/1.5 ml	Spot-on solution	Cat	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Ireland	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ridaworm 40 mg spot-on solution for medium cats	Praziquantel	40 mg/ml	Spot-on solution	Cat	Spot-on use
Ireland	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ridaworm 60 mg spot-on solution for large cats	Praziquantel	60 mg/1.5 ml	Spot-on solution	Cat	Spot-on use
Ireland	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan, 20 mg/ml, solution for injection for cattle, pigs and horses	Meloxicam	20 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use
Ireland	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Diatrim 200 mg/ml + 40 mg/ml solution for injection	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Ireland	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Advantix Spot-on solution for dogs over 40 kg up to 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use
Ireland	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès (Barcelona) Spain	Cadorex 300 mg/ml solution for injection for cattle, sheep and pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Ireland	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Metaxol 20/100 mg/ml solution for use in drinking water for pigs and chickens	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Ireland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 2000 mg/400 mg spot-on solution for dogs over 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Ireland	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen 300 mg/ml Solution for injection for cattle and pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Ireland	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Nifencol 300 mg/ml solution for injection for cattle and pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Ireland	Laboratorios Calier, S.A. C/ Barcelonès, 26 08520 Les Franqueses del Vallès (Barcelona) Spain	Florinject 300 mg/ml solution for injection for cattle and pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Ireland	Intervet Ireland Limited Magna Business Park, Citywest Road Dublin 24 Ireland	Nuflor 300 mg/ml solution for injection for cattle and sheep	Florfenicol	300 mg/ml	Solution for injection	Cattle, sheep	Intramuscular, subcutaneous use
Ireland	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Florfenikel 300 mg/ml solution for injection for cattle and pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Ireland	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Mycoflor 300 mg/ml solution for injection for cattle and pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Ireland	Pharmaq AS Skogmo Industriområde Industrivegen 50 7863 Overhalla Norway	AMX 10 mg/ml concentrate for solution for fish treatment	Deltamethrin	10 mg/ml	Concentrate for solution for fish treatment	Atlantic salmon, Rainbow trout	Water-borne use
Ireland	Intervet Ireland Limited Magna Business Park, Citywest Road Dublin 24 Ireland	Nuflor Minidose 450 mg/ml solution for injection for cattle	Florfenicol	450 mg/ml	Solution for injection	Cattle	Intramuscular, subcutaneous use
Ireland	Interchem (Ireland) Ltd. 29 Cookstown Industrial Estate Dublin 24 Ireland	Sulphamet 40/200 Solution for Injection	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Ireland	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan 300 mg/ml solution for injection for cattle and swine	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Ireland	Intervet Ireland Limited Magna Business Park, Citywest Road Dublin 24 Ireland	Resflor 300/16.5 mg/mL solution for injection for cattle	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Ireland	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Acomec 5 mg/ml Pour-On Solution for Cattle	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Topical use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Ireland	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Fatromectin 5 mg/ml pour-on solution for cattle	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Topical use
Ireland	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Advantix Spot-on solution for dogs over 10 kg up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog (over 10 kg up to 25 kg)	Spot-on use
Ireland	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Advantix Spot-on solution for dogs over 25 kg up to 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Ireland	Intervet Ireland Limited Magna Business Park, Citywest Road Dublin 24 Ireland	Nuflor Swine 300 mg/ml solution for injection	Florfenicol	300 mg/ml	Solution for injection	Pig	Intramuscular use
Ireland	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Imec 5 mg/ml pour-on solution for cattle	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Topical use
Ireland	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Qualimec Cattle Pour-on	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Topical use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Ireland	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Bimectin 0.5% cattle pour-on solution	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Topical use
Ireland	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Kilo-mec 0.5 % pour-on solution for cattle	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Topical use
Ireland	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Mastermectin 0.5% pour-on solution for cattle	Ivermectin	0.5% w/v/ml	Pour-on solution	Cattle	Topical use
Ireland	AlfaMed Ltd. Unit 6, Fermoy Enterprise Park Fermoy, Co. Cork Ireland	Alfatrim 40/200 Solution for Injection	Trimethoprim Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Ireland	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Osmonds Lineout 0.5 % Pour-on	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Topical use
Ireland	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Ecomectin 5 mg/ml pour-on solution for cattle	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Pour-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Ireland	Chem-Pharm Ltd. Ballyvaughan, Co. Clare Ireland	Intertrim solution for injection	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Ireland	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Tallaght, Dublin 24 Ireland	Oxycomplex NS Solution for Injection	Oxytetracycli ne Flunixin Meglumine	100 mg/ml 20 mg/ml	Solution for injection	Cattle	Intramuscular, intravenous use
Ireland	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate H18 W620 Monaghan Ireland	Primidoxine solution for injection	Trimethopri m Sulfadoxine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Ireland	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Co-Trimoxazole 24% w/v solution for injection	Trimethopri m Sulfamethox azole	40 mg/ml 200 mg/ml	Solution for injection	Cattle	Intramuscular use
Ireland	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Oxytetracycline 20% w/v L.A. Solution for Injection.	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle	Intramuscular use
Ireland	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Chanoprim solution for injection	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Ireland	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Cyclosol LA 200 mg/ml solution for injection	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Ireland	Univet Limited Tullyvin Cootehill, Co. Cavan Ireland	Aquaprim Solution for Injection	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Ireland	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Tallaght, Dublin 24 Ireland	Tetroxy LA 200 mg/ml Solution for Injection	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular use
Ireland	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate H18 W620 Monaghan Ireland	Norodine 24% solution for injection	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Ireland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 2000 mg/400 mg spot-on solution for dogs over 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Ireland	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 2.5 millilitre(s) spot-on solution	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Ireland	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 4.0 millilitre(s) spot-on solution	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Ireland	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 6.0 millilitre(s) spot-on solution	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Ireland	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 2.5 ml spot-on solution for dogs over 10 kg up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Ireland	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 4 ml spot-on solution for dogs over 25 kg up to 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Ireland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Daclotrix 2000 mg/400 mg spot-on solution for dogs over 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Ireland	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 6 ml spot-on solution for dogs over 40 kg up to 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Cutaneous use
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Advantix Spot-on per cani oltre 10 kg fino a 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog (over 10 kg up to 25 kg)	Spot-on use
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Advantix Spot-on per cani oltre 25 kg fino a 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Advantix Spot-on per cani oltre 40 kg fino a 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan 20 mg/ml, soluzione iniettabile per bovini, suini e cavalli	Meloxicam	20 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use
Italy	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 2000 mg/400 mg soluzione spot-on per cani oltre 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Italy	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès (Barcelona) Spain	Cadorex 300 mg/ml soluzione iniettabile per bovini, ovini e suini	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Italy	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate H18 W620 Monaghan Ireland	Norodine 24 soluzione iniettabile per bovini, equini, suini, cani e gatti	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intravenous, subcutaneous use
Italy	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ridaworm 40 mg soluzione spot-on per gatti di taglia media.	Praziquantel	40 mg/ml	Spot-on solution	Cat	Spot-on use
Italy	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ridaworm 60 mg soluzione spot-on per gatti di taglia grande	Praziquantel	60 mg/1.5 ml	Spot-on solution	Cat	Spot-on use
Italy	Fatro S.p.A. Via Emilia, 285 Ozzano Emilia (BO) Italy	Denfus spray, spray cutaneo per bovini	Thiamphenic ol	3,750 g	Cutaneous spray, solution	Cattle	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Diatrim 200 mg/ml + 40 mg/ml soluzione iniettabile	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Italy	Vétoquinol SA Magny-Vernois, B.P. 189 70204 Lure Cedex France	Droncit Spot-on 20 mg soluzione spot-on per gatti	Praziquantel	20 mg	Spot-on Solution	Cat	Spot-on use
Italy	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Ecomectin 5 mg/ml pour- on bovini	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Pour-on use
Italy	Fatro S.p.A. Via Emilia, 285 Ozzano Emilia (BO) Italy	Effe 70 300 mg/ml soluzione iniettabile per bovini, ovini e suini	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Italy	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Fatromectin 5 mg/ml soluzione pour-on per bovini	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Topical use
Italy	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen 300 mg/ml soluzione iniettabile per bovini e suini	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	Unione Commerciale Lombarda S.p.A. Via G. Di Vittorio, 36 25125 Brescia Italy	Florfen 300 mg/ml soluzione iniettabile per bovini, suini di peso superiore a 35 kg e scrofe.	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Italy	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Florfenikel 300 mg/ml soluzione iniettabile per bovini e suini	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Italy	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Florflu 300/16.5 mg/ml soluzione iniettabile per bovini	Florfenicol Flunixin	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Italy	Laboratorios Calier, S.A. C/ Barcelonès, 26 08520 Barcelona Spain	Florinject 300 mg/ml soluzione iniettabile per bovini e suini	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Italy	Laboratorios Karizoo, S.A. Pol. Industrial La Borda Mas Pujades, 11-12 08140 Barcelona Spain	Florfeksyl 300 mg/ml soluzione iniettabile per bovini, ovini e suini	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Italy	Intervet Rue Olivier de Serres 49071 Beaucouze Cedex France	Florvetol bovini iniettabile	Florfenicol	300 mg/ml	Solution for injection	Cattle	Intramuscular, subcutaneous use
Italy	Intervet Rue Olivier de Serres 49071 Beaucouze Cedex France	Florvetol suini	Florfenicol	300 mg/ml	Solution for injection	Pig	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	Boehringer Ingelheim Animal Health Italia S.p.A. Via Lorenzini 8 20139 Milano Italy	Frontline Tri-Act soluzione spot-on per cani 10-20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog (10-20 kg)	Spot-on use
Italy	Boehringer Ingelheim Animal Health Italia S.p.A. Via Lorenzini 8 20139 Milano Italy	Frontline Tri-Act soluzione spot-on per cani 20-40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog (20-40 kg)	Spot-on use
Italy	Boehringer Ingelheim Animal Health Italia S.p.A. Via Lorenzini 8 20139 Milano Italy	Frontline Tri-Act soluzione spot-on per cani 40-60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog (40- 60 kg)	Spot-on use
Italy	Laboratorios Karizoo, S.A. Pol. Industrial La Borda Mas Pujades, 11-12 08140 Caldes De Montbui (Barcelona) Spain	K-Flor 300 mg/ml soluzione iniettabile per bovini,ovini e suini	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Italy	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Metaxol 20/100 mg/ml soluzione per uso nell'acqua da bere per suini e polli	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Italy	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Methoxasol 20/100 mg/ml soluzione per uso in acqua da bere per suini e polli	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig, chicken (broiler)	In drinking water use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Mycoflor 300 mg/ml, soluzione iniettabile per bovini e suini	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Italy	Fatro S.p.A. Via Emilia, 285 Ozzano Emilia (BO) Italy	Neopridimet soluzione orale, 200 mg + 40 mg/ml, per uso in acqua da bere per polli da carne e conigli.	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for use in drinking water	Broiler, rabbit	Oral use
Italy	MSD Animal Health S.r.l Via Fratelli Cervi snc Palazzo Canova 20054 Segrate (MI) Italy	Nuflor 300 mg/ml soluzione iniettabile per bovini e ovini	Florfenicol	300 mg/ml	Solution for injection	Cattle, sheep	Intramuscular, subcutaneous use
Italy	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor minidose 450 mg/ml, soluzione iniettabile per bovini	Florfenicol	450 mg/ml	Solution for injection	Cattle	Intramuscular, subcutaneous use
Italy	MSD Animal Health S.r.l Via Fratelli Cervi snc Palazzo Canova 20054 Segrate (MI) Italy	Nuflor Suini Iniettabile 300 mg/ml soluzione iniettabile	Florfenicol	300 mg/ml	Solution for injection	Pig	Intramuscular use
Italy	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	OxyTF Long Acting, 200 mg/ml soluzione iniettabile per bovini e suini	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Petcuten Spot-on per cani oltre 10 kg fino a 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog (over 10 kg up to 25 kg)	Spot-on use
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Petcuten Spot-on per cani oltre 25 kg fino a 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Petcuten soluzione spot-on per cani oltre 40 kg fino a 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Petsidill spot-on per cani oltre 10 kg fino a 25 Kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on Solution	Dog (over 10 kg up to 25 kg)	Spot-on use
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Petsidill Spot-on per cani oltre 25 kg fino a 40 Kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on Solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Petsidill spot-on per cani oltre 40 Kg fino a 60 Kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on Solution	Dog (over 40 kg up to 60 kg)	Spot-on use
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Poli-Ecto soluzione spot-on per cani oltre 10 kg fino a 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog (over 10 kg up to 25 kg)	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Poli-Ecto soluzione spot-on per cani oltre 25 kg fino a 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Italy	Elanco Italia S.p.A. Via dei Colatori, 12 50019 Sesto Fiorentino (FI) Italy	Poli-Ecto soluzione spot-on per cani oltre 40 kg fino a 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use
Italy	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 60 mg soluzione spot-on per gatti di taglia grande	Praziquantel	60 mg/1.5 ml	Spot-on solution	Cat	Spot-on use
Italy	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Preventix soluzione spot- on per cani oltre 10 kg fino a 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Italy	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Preventix soluzione spot- on per cani oltre 25 kg fino a 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Italy	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix soluzione spot-on per cani oltre 10 kg fino a 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Italy	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix soluzione spot-on per cani oltre 25 kg fino a 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	Intervet Rue Olivier de Serres 49071 Beaucouze Cedex France	Resflor 300/16,5 mg/ml soluzione iniettabile per bovini	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Italy	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan 300 mg/ml, soluzione iniettabile, per bovini e suini	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Italy	Dox-al Italia S.p.A. Piazzale Cadorna 10 20123 Milano Italy	Sulfatrimdox 200 g/l + 40 g/l soluzione orale per uso in acqua da bere per polli da carne e conigli	Trimethopri m Sulfadiazine	40 g/l 200 g/l	Oral solution	Broiler, rabbit	In drinking water use
Italy	Laboratorios Syva, S.A.U. Avda. Párroco Pablo Díez, 49-57 24010 León Spain	Syvaflor 300 mg/ml soluzione iniettabile per bovini, ovini e suini	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Italy	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	T.S.-sol 20/100 mg/ml, soluzione per uso nell'acqua da bere per suini e polli	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Italy	Virbac S.A. 1ere Avenue 2065 M L.I.D. 06516 Carros France	Terralon 20% L.A. 200 mg/ml soluzione iniettabile per bovini, suini, ovini e caprini.	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig, sheep, goat	Intramuscular, intravenous use
Italy	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Italy	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Cutaneous use
Italy	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Italy	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Italy	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Cutaneous use
Latvia	Virbac S.A. 1ere Avenue 2065 M L.I.D. 06516 Carros France	Terralon LA 200 mg/ml šķīdums injekcijām liellopiem, aitām, kazām un cūkām	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig, sheep, goat	Intramuscular, subcutaneous use
Latvia	Bremer Pharma Gmbh Werkstrasse 42 34414 Warburg Germany	Hefrotrim šķīdums injekcijām zirgiem, liellopiem, cūkām, suņiem, kaķiem	Trimethopri m Sulfadimidin e sodium	40 mg/ml 215.8 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intramuscular, intravenous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Latvia	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan 300 mg/ml šķīdums injekcijām liellopiem un cūkām	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Latvia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act šķīdums pilināšanai uz ādas suņiem 10 - 20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog (10-20 kg)	Spot-on use
Latvia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act šķīdums pilināšanai uz ādas suņiem 20 - 40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog (20-40 kg)	Spot-on use
Latvia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act šķīdums pilināšanai uz ādas suņiem 40 - 60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog (40- 60 kg)	Spot-on use
Latvia	Bremer Pharma Gmbh Werkstrasse 42 34414 Warburg Germany	Trimethosulf šķīdums injekcijām liellopiem, aitām, cūkām, suņiem, kaķiem	Trimethopri m Sulfathiazole Sulfadiazine Sulfamerazin e	40 mg/ml 40 mg/ml 60 mg/ml 100 mg/ml	Solution for injection	Cattle, pig, sheep, dog, cat	Intramuscular use
Latvia	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Barcelona Spain	Cadorex 300 mg/ml šķīdums injekcijām liellopiem, aitām un cūkām	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Latvia	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix šķīdums pilināšanai uz ādas suņiem 40 – 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Spot-on use
Latvia	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate H18 W620 Monaghan Ireland	Norodine 24 šķīdums injekcijām zirgiem, liellopiem, cūkām, suņiem un kaķiem	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Latvia	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen 300 mg/ml šķīdums injekcijām liellopiem un cūkām	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Latvia	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 2000 mg/400 mg šķīdums pilināšanai uz ādas suņiem virs 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg)	Spot-on use
Latvia	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Tallaght, Dublin 24 Ireland	Tetroxy L.A. 200 mg/ml šķīdums injekcijām liellopiem, aitām un cūkām	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular use
Latvia	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan 20 mg/ml šķīdums injekcijām liellopiem, cūkām un zirgiem	Meloxicam	20 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use
Latvia	UAB Interchemie werken De Adelaar LT Terminalo g.13, Biruliškės LT-54469, Kauno r. Lithuania	LV Tiamulin Oral 125 mg/ml šķīdums lietošanai ar dzeramo ūdeni cūkām, vistām un tītariem	Tiamulin hydrogen fumarate	125 mg/ml	Solution for use in drinking water	Pig, chicken, turkey	In drinking water use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Latvia	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 250 mg/1250 mg šķīdums pilināšanai uz ādas suņiem no 10 kg līdz 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Latvia	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 400 mg/2000 mg šķīdums pilināšanai uz ādas suņiem no 25 kg līdz 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Lithuania	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate H18 W620 Monaghan Ireland	Norodine 24, injekcinis tirpalas	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Lithuania	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix, užlašinamasis tirpalas > 40–60 kg svorio šunims	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Spot-on use
Lithuania	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix, užlašinamasis tirpalas > 10-25 kg svorio šunims	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Lithuania	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix, užlašinamasis tirpalas > 25-40 kg svorio šunims	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Lithuania	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Tallaght, Dublin 24 Ireland	Tetroxy LA 200 mg/ml injekcinis tirpalas	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Lithuania	UAB Interchemie werken De Adelaar LT Terminalo g.13, Biruliškės LT-54469, Kauno r. Lithuania	Introflor-100, 100 mg/ml geriamasis tirpalas kiaulėms ir paukščiams	Florfenicol	10 mg/ml	Oral solution	Pig, chicken	In drinking water use
Lithuania	Virbac S.A. 1ere Avenue 2065 M L.I.D. 06516 Carros France	Terralon LA, 200 mg/ml, injekcinis tirpalas galvijams, avims, ožkoms ir kiaulėms	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, pig, sheep, goat	Intramuscular, subcutaneous use
Lithuania	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Remacycline L.A.200 mg/ml injekcinis tirpalas galvijams, avims ir kiaulėms	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Lithuania	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Dexa-Kel 02, injekcinis tirpalas	Dexamethasone	2.64 mg/ml	Solution for injection	Cattle, horse, dog	Intramuscular, intravenous, intraarticular use
Lithuania	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	T.S.-SOL, geriamasis tirpalas	Trimethoprim Sulfamethoxazole	20 mg/ml 80 mg/ml	Oral solution	Pig, chicken	In drinking water use
Lithuania	Industrial Veterinaria, S.A. C/ Esmeralda, 19 08950 Barcelona Spain	Promectine 10 mg/ml, injekcinis tirpalas galvijams ir kiaulėms	Ivermectin	10 mg/ml	Solution for injection	Cattle, pig	Subcutaneous use
Lithuania	UAB Interchemie werken De Adelaar LT Terminalo g.13, Biruliškės LT-54469, Kauno r. Lithuania	Intertrim 200/40 mg/ml injekcinis tirpalas	Trimethoprim Sulfamethoxazole	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig, sheep, goat	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Lithuania	UAB Interchemie werken De Adelaar LT Terminalo g.13, Biruliškės LT-54469, Kauno r. Lithuania	Tiasan 100 mg/ml injekcinis tirpalas kiaulėms	Tiamulin	100 mg/ml	Solution for injection	Pig	Intramuscular use
Lithuania	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Cyclosol LA 200 mg/ml, injekcinis tirpalas	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Lithuania	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan 300 mg/ml, injekcinis tirpalas galvijams ir kiaulėms	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Lithuania	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act, užlašinamasis tirpalas 40- 60 kg šunims	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Lithuania	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act, užlašinamasis tirpalas 10- 20 kg šunims	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
Lithuania	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act, užlašinamasis tirpalas 20- 40 kg šunims	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Lithuania	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 2000 mg/400 mg užlašinamasis tirpalas šunims, sveriantiems daugiau kaip 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Lithuania	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen 300 mg/ml injekcinis tirpalas galvijams ir kiaulėms	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Lithuania	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Metaxol 20/100 mg/ml tirpalas, skirtas naudoti su geriamuoju vandeniu	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Lithuania	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan 20 mg/ml, injekcinis tirpalas galvijams, kiaulėms ir arkliams	Meloxicam	20 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use
Lithuania	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Resflor, 300 mg + 16,5 mg/ml injekcinis tirpalas galvijams	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Lithuania	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 250/1250 spot- on solution for dogs over 10 up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Lithuania	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 400/2000 spot- on solution for dogs over 25 up to 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Luxembourg	Dechra Veterinary Products Achterstenhoek 48 2275 Lille Belgium	Cyclosol 200 Long Acting	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Luxembourg	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Dexa 0,2%	Dexamethasone	2 mg/ml	Solution for injection	Cattle	Intravenous use
Luxembourg	Emdoka John Lijsenstraat 16 2321 Hoogstraten Belgium	Emdotrim 10% SOL	Trimethoprim Sulfadiazine	16.7 mg/ml 83.3 mg/ml	Solution for use in drinking water	Chicken	Oral use
Luxembourg	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Oxy-Kel 20% Long Acting	Oxytetracycline	200 mg/ml	Solution for injection	Cattle	Intramuscular use
Luxembourg	V.M.D. n.v. Hoge Mauw 900 2370 Arendonk Belgium	Prednisolone 1%	Prednisolone	10 mg/ml	Solution for injection	Dog, cat	Intramuscular use
Luxembourg	V.M.D. n.v. Hoge Mauw 900 2370 Arendonk Belgium	Prednisolone 2,5%	Prednisolone	25 mg/ml	Solution for injection	Dog	Intramuscular use
Luxembourg	V.M.D. n.v. Hoge Mauw 900 2370 Arendonk Belgium	Vetodexin 0,2%	Dexamethasone	2.64 mg/ml	Solution for injection	Cattle, dog	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Luxembourg	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Dog 250/1250	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Luxembourg	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Dog 400/2000	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Luxembourg	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Dog 600/3000	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Spot-on use
Luxembourg	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontline Protect voor honden 10-20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
Luxembourg	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontline Protect voor honden 20-40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use
Luxembourg	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontline Protect voor honden 40-60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Luxembourg	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Ecomectin	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Pour-on use
Luxembourg	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Florfenikel	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Luxembourg	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Mycoflor	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Luxembourg	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor	Florfenicol	300 mg/ml	Solution for injection	Cattle, sheep	Intramuscular, subcutaneous use
Luxembourg	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor Minidose	Florfenicol	450 mg/ml	Solution for injection	Cattle	Intramuscular, subcutaneous use
Luxembourg	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor swine	Florfenicol	300 mg/ml	Solution for injection	Pig	Intramuscular use
Luxembourg	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Resflor 300	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Luxembourg	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Luxembourg	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Luxembourg	Laboratorios Calier, S.A. C/ Barcelonès, 26 08520 Barcelona Spain	Florinject	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Luxembourg	Dechra Regulatory B.V. Handelsweg 25 5531 AE Bladel Netherlands	Methoxasol	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig, chicken (broiler)	In drinking water use
Luxembourg	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontect voor honden 10- 20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
Luxembourg	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontect voor honden 20- 40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Luxembourg	Boehringer Ingelheim Animal Health Belgium S.A. Arnaud Fraiteurlaan 15-23 1050 Brussels Belgium	Frontect voor honden 40- 60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Luxembourg	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 2000 mg/400 mg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Luxembourg	Dechra Regulatory B.V. Handelsweg 25 5531 AE Bladel Netherlands	Metaxol	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Luxembourg	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	T.S. Sol	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Luxembourg	Dechra Regulatory B.V. Handelsweg 25 5531 AE Bladel Netherlands	Diatrim	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Luxembourg	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Barcelona Spain	Flodoex	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Luxembourg	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Nifencol	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Luxembourg	Laboratorios Syva, S.A.U. Avda. Párroco Pablo Díez, 49-57 24010 León Spain	Florfenis	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Malta	Kepro B.V., Maagdenburgstraat 17 7421 ZA Deventer The Netherlands	Florum 20% Oral	Florfenicol	200 mg/ml	Solution for use in drinking water	Pig, poultry (broiler)	Oral use
Malta	Kepro B.V., Maagdenburgstraat 17 7421 ZA Deventer The Netherlands	Kepcox 2.5% Oral	Toltrazuril	25 mg/ml	Oral solution	Chicken (pullets, breeder s), turkey	In drinking water use
Malta	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Riketron, 200 mg/ml + 40 mg/ml, solution for injection for horses, cattle, pigs	Trimethopri m Sulfadimidin e sodium	40 mg/ml 215.8 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous use
Malta	V.M.D. n.v. Hoge Mauw 900 2370 Arendonk Belgium	Vetodexin 0.2% solution for injection	Dexamethas one	2.64 mg/ml	Solution for injection	Cattle, dog	Intramuscular use
Malta	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan 300 mg/ml solution for injection for cattle and swine	Florfenicol	300 mg/ml	Solution for injection	Cattle, swine	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Malta	Cenavisa, S.L. Camí Pedra Estela s/n 43205 Reus Spain	Florfenicen 300 mg/ml injectable solution for cattle, sheep and pig	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Malta	Interchemie Werken De Adelaar Eesti AS Vanapere tee 14 Viimsi 74013 Harjumaa Estonia	Introflor-300 solution for injection for cattle and sheep	Florfenicol	300 mg/ml	Solution for injection	Cattle, sheep	Intramuscular, subcutaneous use
Malta	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot-on solution for dogs 10- 20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
Malta	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot-on solution for dogs 20- 40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use
Malta	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot-on solution for dogs 40 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Netherlands	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix spot-on oplossing voor honden vanaf 10 kg tot 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Netherlands	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix spot-on oplossing voor honden vanaf 25 kg tot 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Netherlands	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix spot-on solution voor honden van meer dan 40 kg tot 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use
Netherlands	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan, 20 mg/ml, oplossing voor injectie voor rundvee, varkens en paarden	Meloxicam	20 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use
Netherlands	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 2000 mg/400 mg spot-on oplossing voor honden met een gewicht van meer dan 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Netherlands	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès (Barcelona) Spain	Cadorex 300 mg/ml oplossing voor injectie voor runderen, schaapen en varken	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Netherlands	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Cyclosol LA, 200 mg/ml oplossing voor injectie	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Netherlands	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Diatrim 200 mg/ml + 40 mg/ml oplossing voor injectie	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig, dog, cat	Intramuscular, intravenous, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Netherlands	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Diatrim 200 mg/ml + 40 mg/ml oplossing voor injectie	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig, dog, cat	Intramuscular, subcutaneous use
Netherlands	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Dophamec cattle pour-on, pour-on oplossing voor runderen	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Pour-on use
Netherlands	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Far tmps 20/80 mg, oplossing voor oraal gebruik in drinkwater voor vleeskuikens	Trimethopri m Sulfamethox azole	20 mg/ml 80 mg/ml	Solution for use in drinking water	Chicken (broiler)	In drinking water use
Netherlands	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen 300 mg/ml oplossing voor injectie voor runderen en varkens	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Netherlands	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Florfenikel 300 mg/ml, oplossing voor injectie voor runderen en varkens	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Netherlands	Laboratorios Syva, S.A.U. Avda. Párroco Pablo Díez, 49-57 24010 León Spain	Florfenis 300 mg/ml oplossing voor injectie voor runderen, schapen en varkens	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Netherlands	Laboratorios Calier, S.A. C/ Barcelonès, 26 08520 Les Franqueses del Vallès (Barcelona) Spain	Florinject 300 mg/ml oplossing voor injectie voor rund en varken	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Netherlands	Boehringer Ingelheim Animal Health Netherlands B.V. Comeniusstraat 6 1817 MS Alkmaar The Netherlands	Frontline Tri-act spot-on oplossing voor honden 10- 20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
Netherlands	Boehringer Ingelheim Animal Health Netherlands B.V. Comeniusstraat 6 1817 MS Alkmaar The Netherlands	Frontline Tri-act spot-on oplossing voor honden 20- 40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use
Netherlands	Boehringer Ingelheim Animal Health Netherlands B.V. Comeniusstraat 6 1817 MS Alkmaar The Netherlands	Frontline Tri-act spot-on oplossing voor honden 40- 60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Netherlands	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Metaxol 20/100 mg/ml oplossing voor gebruik in drinkwater voor varkens en kippen	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Netherlands	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Methoxasol 20/100 mg/ml oplossing voor gebruik in drinkwater voor varkens en kippen	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig, chicken (broiler)	In drinking water use
Netherlands	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Methoxasol-T 20/100 mg/ml orale oplossing voor varkens en slachtkuikens	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Oral solution	Pig, broiler	In drinking water use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Netherlands	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Mycoflor 300 mg/ml oplossing voor injectie voor runderen en varkens	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Netherlands	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Nifencol 300 mg/ml oplossing voor injectie voor runderen en varkens	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Netherlands	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate H18 W620 Monaghan Ireland	Norodine 24, 40/200 mg, oplossing voor injectie	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, calf, pig, dog, cat	Intramuscular use
Netherlands	Intervet Nederland BV Wim de Körverstraat 35 5831 AN Boxmeer Netherlands	Nuflor Minidose 450 mg/ml oplossing voor injectie voor runderen	Florfenicol	450 mg/ml	Solution for injection	Cattle	Intramuscular, subcutaneous use
Netherlands	Intervet Nederland BV Wim de Körverstraat 35 5831 AN Boxmeer Netherlands	Nuflor swine injectable 300 mg/ml oplossing voor injectie	Florfenicol	300 mg/ml	Solution for injection	Pig	Intramuscular use
Netherlands	Intervet Nederland BV Wim de Körverstraat 35 5831 AN Boxmeer Netherlands	Nuflor 300 mg/ml oplossing voor injectie voor runderen en schapen	Florfenicol	300 mg/ml	Solution for injection	Cattle, sheep	Intramuscular, subcutaneous use
Netherlands	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Petcuten spot-on oplossing voor honden van meer dan 10 kg tot en met 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog (over 10 kg up to 25 kg)	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Netherlands	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Petcuten spot-on oplossing voor honden van meer dan 25 kg tot en met 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Netherlands	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Petcuten spot-on oplossing voor honden van meer dan 40 kg tot en met 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use
Netherlands	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 60 mg spot-on oplossing voor grote katten	Praziquantel	60 mg/1.5 ml	Spot-on solution	Cat	Spot-on use
Netherlands	Intervet Nederland BV Wim de Körverstraat 35 5831 AN Boxmeer Netherlands	Resflor 300/16,5 mg/ml oplossing voor injectie voor runderen	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Netherlands	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ridaworm 40 mg spot-on oplossing voor middelgrote katten	Praziquantel	40 mg/ml	Spot-on solution	Cat	Spot-on use
Netherlands	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ridaworm 60 mg spot-on oplossing voor grote katten	Praziquantel	60 mg/1.5 ml	Spot-on solution	Cat	Spot-on use
Netherlands	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan 300 mg/ml, oplossing voor injectie voor runderen en varkens.	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Netherlands	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	T. S. Sol 20/100 mg/ml, oplossing voor gebruik in drinkwater voor varkens en kippen	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Netherlands	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	T.S.-Sol, oplossing voor drinkwatermedicatie voor varkens en slachtkippen	Trimethopri m Sulfamethox azole	20 mg/ml 80 mg/ml	Solution for use in drinking water	Pig, chicken (broiler)	In drinking water use
Netherlands	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	T.S.-Sol 20/100, oplossing voor orale toediening voor vleesvarkens en vleeskuikens.	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Oral solution	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Netherlands	Veterinaire Groothandel Wijchen B.V. Graafschap Hornelaan 137A 6001 AC Weert Nederland	Advantix 250/1250 spot- on oplossing voor honden	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog (over 10 kg up to 25 kg)	Spot-on use
Netherlands	Veterinaire Groothandel Wijchen B.V. Graafschap Hornelaan 137A 6001 AC Weert Nederland	Advantix 400/2000 spot- on oplossing voor honden	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Netherlands	Polymeds B.V. Osloweg 99A 9723BK Groningen Nederland	Advantix spot-on oplossing voor honden vanaf 10 kg tot 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog (over 10 kg up to 25 kg)	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Netherlands	Polymeds B.V. Osloweg 99A 9723BK Groningen Nederland	Advantix spot-on oplossing voor honden vanaf 25 kg tot 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Netherlands	Polymeds B.V. Osloweg 99A 9723BK Groningen Nederland	Advantix spot-on oplossing voor honden vanaf 10 kg tot 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog (over 10 kg up to 25 kg)	Spot-on use
Norway	Pharmaq AS Postboks 267 Skøyen 0213 Oslo Norway	Alpha Max	Deltamethrin	10 mg/ml	Concentrate for solution for fish treatment	Atlantic salmon, Rainbow trout	Water-borne use
Norway	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Bayvantic vet	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Norway	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Bayvantic vet	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Norway	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Bayvantic vet	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use
Norway	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxtmeer Netherlands	Resflor vet	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Norway	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Florselect vet	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Poland	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-On (250 mg + 1250 mg)/2,5 ml; roztwór do nakrapiania	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Poland	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix Spot-On (400 mg + 2000 mg)/4 ml; roztwór do nakrapiania	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Poland	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan	Meloxicam	5 mg/ml	Solution for injection	Dog, cat	Intravenous, subcutaneous use
Poland	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan	Meloxicam	20 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use
Poland	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Poland	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Barcelona Spain	Cadorex	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Poland	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Diatrim	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Poland	Biofaktor Sp. z o.o. Skierniewice 96-100 Czysta 4 Poland	Ditrisol	Trimethopri m Sulfamethox azole	20 mg/ml 80 mg/ml	Oral solution	Pig, chicken	In drinking water use
Poland	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Poland	Przedsiębiorstwo Farmaceutyczne Okoniewscy "Vetos-Farma" Sp. z o.o. Bielawa 58-260 Dzierżoniowska 21 Poland	Florfenikol Vetos-Farma	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Poland	Przedsiębiorstwo Farmaceutyczne Okoniewscy "Vetos-Farma" Sp. z o.o. Bielawa 58-260 Dzierżoniowska 21 Poland	Florfenikol Vetos-Farma	Florfenicol	26,75 mg/ml (2,5 g/100 g)	Oral solution	Chicken	In drinking water use
Poland	Laboratorios Syva, S.A.U. Avda. Párroco Pablo Díez, 49-57 24010 León Spain	Florfenis	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Poland	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
Poland	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use
Poland	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Poland	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Kelaflor	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Poland	Lovapharm Consulting B.V. Eindhoven 5645 KH Rijsven 3 The Netherlands	Lovaflor	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Poland	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Metaxol	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Poland	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Mycoflor	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Poland	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Nifencol	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Poland	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor 300 mg/ml roztwór do wstrzykiwań dla bydła i świń	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Poland	Mevet, S.A.U. Av. Industria, Pol. Industrial El Segre, parcela 409-410, 25191 Lleida Spain	Pulmovall	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Poland	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Resflor 300/16,5 mg/ml roztwór do wstrzykiwań dla bydła	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Poland	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan 300 mg/ml roztwór do wstrzykiwań dla bydła i świń	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Poland	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Trimsulfasol	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Poland	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Trimsulfasol, (80 mg + 20 mg)/ ml, roztwór doustny dla świń i kur	Trimethoprim Sulfamethoxazole	20 mg/ml 80 mg/ml	Oral solution	Pig, chicken	In drinking water use
Poland	Laboratorios Karizoo, S.A. Pol. Industrial La Borda Mas Pujades, 11-12 08140 Barcelona Spain	Florfeksyl 300 mg/ml solution for injection for cattle, sheep and pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Poland	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 250/1250 spot-on solution for dogs over 10 up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Poland	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 400/2000 spot-on solution for dogs over 25 up to 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Poland	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 2.5 ml spot-on solution for dogs over 10 kg up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Poland	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 4 ml spot-on solution for dogs over 25 kg up to 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Poland	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 6 ml spot-on solution for dogs over 40 kg up to 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Poland	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 2.5 ml spot-on solution for dogs over 10 kg up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Poland	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 4 ml spot-on solution for dogs over 25 kg up to 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Poland	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 6 ml spot-on solution for dogs over 40 kg up to 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Cutaneous use
Poland	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix spot-on (600 mg + 3000 mg)/6 ml; roztwór do nakrapiania	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Cutaneous use
Portugal	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix solução para unção punctiforme para cães com mais de 10 kg até 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Portugal	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix solução para unção punctiforme para cães com mais de 25 kg até 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Portugal	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix solução para unção punctiforme para cães com mais de 40 kg até 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Portugal	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan 20 mg/ml, solução injetável para bovinos, suínos e equinos	Meloxicam	20 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use
Portugal	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 2000 mg/400 mg solução para unção punctiforme para cães com mais de 25 Kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Portugal	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès (Barcelona) Spain	Cadorex 300 mg/ml, solução injetável para bovinos, ovinos e suínos	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Portugal	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen 300 mg/ml solução injetável para bovinos e suínos	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Portugal	Boehringer Ingelheim Animal Health Portugal Unipessoal, Lda. Avenida de Pádua, 11 1800-294 Lisboa Portugal	Frontline Tri-Act Solução para unção punctiforme para cães 10-20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
Portugal	Boehringer Ingelheim Animal Health Portugal Unipessoal, Lda. Avenida de Pádua, 11 1800-294 Lisboa Portugal	Frontline Tri-Act Solução para unção punctiforme para cães 20-40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Portugal	Boehringer Ingelheim Animal Health Portugal Unipessoal, Lda. Avenida de Pádua, 11 1800-294 Lisboa Portugal	Frontline Tri-Act Solução para unção puntiforme para cães 40-60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Portugal	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Metaxol 20/100 mg/ml solução para administração na água de bebida para suínos e frangos	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Portugal	MSD Animal Health, Lda. Edifício Vasco da Gama, 19 Quinta da Fonte, Porto Salvo 2770-192 Paço de Arcos Portugal	Resflor 300/16,5 mg/ml Solução Injetável para Bovinos	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Portugal	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan 300 mg/ml, solução injectável para bovinos e suínos	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Italy	Virbac S.A. 1ere Avenue 2065 M L.I.D. 06516 Carros France	Terralon LA 200 mg/ml šķīdums injekcijām liellopiem, aitām, kazām un cūkām	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig, sheep, goat	Intramuscular, subcutaneous use
Italy	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 2000 mg/400 mg soluzione Spot-on per cani oltre 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Portugal	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 2000 mg/400 mg solução para unção punctiforme para cães com mais de 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Portugal	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Diatrim 200 mg/ml + 40 mg/ml solução injetável	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Portugal	Cenavisa, S.L. Camí Pedra Estela s/n 43205 Reus Spain	Doxycen 200 mg/ml solução oral para suínos e frangos de engorda	Doxycycline	200 mg/ml	Oral solution	Pig, broiler	In drinking water use
Portugal	Laboratorios Syva, S.A.U. Avda. Párroco Pablo Díez, 49-57 24010 León Spain	Florfenis 300 mg/ml Solução injetável para bovinos, ovinos e suínos	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Portugal	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Mycoflor 300 mg/ml solução injetável para bovinos e suínos	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Portugal	Mevet, S.A.U. Av. Industria, Pol. Industrial El Segre, parcela 409-410, 25191 Lleida Spain	Pulmovall 300 mg/ml solução injetável para bovinos, ovinos e suínos	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Portugal	MSD Animal Health, Lda. Edifício Vasco da Gama, 19 Quinta da Fonte, Porto Salvo 2770-192 Paço de Arcos Portugal	Nuflor Minidose 450 mg/ml solução injetável para bovinos	Florfenicol	450 mg/ml	Solution for injection	Cattle	Intramuscular, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Portugal	Calier Portugal, S.A. Centro Empresarial Sintra Estoril II 2710 – 335 Sintra Portugal	Florinject 300 mg/ml solução injetável para bovinos e suínos	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Portugal	Cenavisa, S.L. Camí Pedra Estela s/n 43205 Reus Spain	Cenflor 300 mg/ml solução injetável para bovinos, ovinos e suínos	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Portugal	MSD Animal Health, Lda. Edifício Vasco da Gama, 19 Quinta da Fonte, Porto Salvo 2770-192 Paço de Arcos Portugal	Nuflor 300 mg/ml solução injetável para bovinos e ovinos	Florfenicol	300 mg/ml	Solution for injection	Cattle, sheep	Intramuscular, subcutaneous use
Portugal	MSD Animal Health, Lda. Edifício Vasco da Gama, 19 Quinta da Fonte, Porto Salvo 2770-192 Paço de Arcos Portugal	Nuflor 300 mg/ml solução injetável para suínos	Florfenicol	300 mg/ml	Solution for injection	Pig	Intramuscular use
Portugal	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Florfenikel	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Portugal	Eco Animal Health Europe Limited 6th Floor, South Bank House Barrow Street Dublin 4, D04 TR29 Ireland	Ecomectin	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Pour-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Romania	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 2000 mg/400 mg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Romania	Laboratorios Calier, S.A. C/ Barcelonès, 26 08520 Les Franqueses del Vallès (Barcelona) Spain	Florinject 300 mg/ml solution for injection for cattle and pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Romania	Crida Pharm S.R.L. Str. Intrarea Vagonetului, 2, 47 București Romania	Florcid Inj.	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Romania	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Remacycline LA, 200 mg/ml	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular use
Romania	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen 300 mg/ml	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Romania	V.M.D. n.v. Hoge Mauw 900 2370 Arendonk Belgium	Dexaveto 0.2%	Dexamethasone sodium phosphate	2.64 mg/ml	Solution for injection	Cattle, horse, pig, goat, dog, cat	Intramuscular, intravenous, intraarticular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Romania	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès (Barcelona) Spain	Cadorex 300 mg/ml solution for injection for cattle, sheep and pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Romania	Mevet, S.A.U. Av. Industria, Pol. Industrial El Segre, parcela 409-410, 25191 Lleida Spain	Pulmoval 300 mg/ml solution for injection for cattle, sheep and pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Romania	Laboratorios Syva, S.A.U. Avda. Párroco Pablo Díez, 49-57 24010 León Spain	Florfenis 300 mg/ml solution for injection for cattle, sheep and pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Romania	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	FlorFlu 300/16.5	Florfenicol Flunixin	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Romania	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	T.S.-SOL 20/100 mg/ml	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Romania	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Metaxol 20/100 mg/ml	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Romania	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Resflor 300/16.5 mg/ml	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Romania	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor 300 mg/ml	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Romania	S.C. Delos Impex '96 S.R.L. Str. Horia, Cloșca și Crișan, nr. 81 Otopeni, Jud. Ilfov, 075100 Romania	Florfenidem 300	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Romania	Belgica de Weerd B.V. Van de Reijtstraat 21 4814 NE Breda The Netherlands	Cobel 12.5 mg	Colistin sulfat	250 000 UI/ml	Solution for use in drinking water	Pigeons- not used for human consum ption	Oral use
Romania	Crida Pharm S.R.L. Str. Intrarea Vagonetului, 2, 47 București Romania	Sulfatrim	Trimethopri m Sulfamethox azole	20 mg/ml 80 mg/ml	Oral solution	Pig, chicken (broiler)	In drinking water use
Romania	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	T.S.-SOL	Trimethopri m Sulfamethox azole	20 mg/ml 80 mg/ml	Oral solution	Pig, poultry (hen)	In drinking water use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Romania	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate H18 W620 Monaghan Ireland	Norodine 24	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, sheep, dog, cat	Intramuscular, intravenous, subcutaneous use
Romania	S.P. Veterinaria, S.A. Ctr. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Mycoflor 300 mg/ml solution for injection for cattle and pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Romania	S.C. Delos Impex '96 S.R.L. Str. Horia, Cloșca și Crișan, nr. 81 Otopeni, Jud. Ilfov, 075100 Romania	Florfenidem 10%, 100 mg/ml	Florfenicol	100 mg/ml	Solution for use in drinking water	Pig, bird (broiler, breeder s, pullets replace ment)	Oral use
Romania	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan, 300 mg/ml	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Romania	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix soluție spot-on pentru câini cu greutatea de la 10 kg până la 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Romania	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix soluție spot-on pentru câini cu greutatea de la 25 kg până la 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Romania	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix soluție spot-on pentru câini cu greutatea de peste 40 kg până la 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Spot-on use
Romania	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act soluție spot-on pentru câini de 10-20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
Romania	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act soluție spot-on pentru câini de 20-40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use
Romania	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act soluție spot-on pentru câini de 40-60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Romania	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Dexa-Kel 0,2	Dexamethas one sodium phosphate	2.64 mg/ml	Solution for injection	Cattle, horse, pig, goat, dog	Intramuscular, intravenous, intraarticular use
Romania	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan	Meloxicam	20 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Slovak Republic	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix spot-on roztok pre psy nad 40 kg do 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use
Slovak Republic	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan, 20 mg/ml, roztok na injekcie pre hovädzí dobytok, ošípané a kone	Meloxicam	20 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use
Slovak Republic	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 2000 mg/400 mg roztok na kvapkanie na kožu pre psov nad 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Slovak Republic	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès (Barcelona) Spain	Cadorex 300 mg/ml injekčný roztok pre hovädzí dobytok, ovce a ošípané	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Slovak Republic	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate H18 W620 Monaghan Ireland	Norodine 40 mg/200 mg/ml injekčný roztok	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Slovak Republic	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor 300 mg/ml injekčný roztok pre hovädzí dobytok a ošípané	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Slovak Republic	Virbac S.A. 1ere Avenue 2065 M L.I.D. 06516 Carros France	Terralon LA 200 mg/ml injekčný roztok	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Slovak Republic	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Resflor injekčný roztok pre hovädzí dobytok	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Slovak Republic	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen 300 mg/ml, injekčný roztok pre hovädzí dobytok a ošípané	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Slovak Republic	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Florfenikel 300 mg/ml injekčný roztok pre hovädzí dobytok a ošípané	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Slovak Republic	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot-on roztok na nakvapkanie na kožu pre psy 10-20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
Slovak Republic	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot-on roztok na nakvapkanie na kožu pre psy 20- 40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use
Slovak Republic	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act spot-on roztok na nakvapkanie na kožu pre psy 40- 60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Slovak Republic	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Nifencol 300 mg/ml injekčný roztok pre hovädzí dobytok a ošípané	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Slovak Republic	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Mycoflor 300 mg/ml injekčný roztok pre hovädzí dobytok a ošípané	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Slovak Republic	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Metaxol 20/100 mg/ml roztok na podanie v pitnej vode pre ošípané a kuru domácu	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Slovak Republic	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Methoxasol 20/100 mg/ml roztok na použitie v pitnej vode pre ošípané a kurčatá	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig, chicken (broiler)	In drinking water use
Slovak Republic	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan 300 mg/ml injekčný roztok pre hovädzí dobytok a ošípané	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Slovenia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act kožni nanos, raztopina za pse 10 - 20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Slovenia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act kožni nanos, raztopina za pse 20 - 40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use
Slovenia	Boehringer Ingelheim Animal Health France SCS 29 Avenue Tony Garnier 69007 Lyon France	Frontline Tri-Act kožni nanos, raztopina za pse 40 - 60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Slovenia	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès (Barcelona) Spain	Cadorex 300 mg/ml raztopina za injiciranje za govedo, ovce in prašiče	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Slovenia	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 2000 mg/400 mg, kožni nanos, raztopina za pse nad 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Slovenia	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor Minidose 450 mg/ml, raztopina za injiciranje za govedo	Florfenicol	450 mg/ml	Solution for injection	Cattle	Intramuscular, subcutaneous use
Slovenia	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan 300 mg/ml raztopina za injiciranje za govedo in prašiče	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Slovenia	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Diatrim 200 mg/ml + 40 mg/ml raztopina za injiciranje	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Slovenia	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	FlorFlu 300/16,5 mg/ml raztopina za injiciranje za govedo	Florfenicol Flunixin	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Slovenia	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Resflor 300/16,5 mg/ml raztopina za injiciranje za govedo	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Slovenia	Intervet International B.V. Wim de Kôrverstraat 35 5831 AN Boxmeer Netherlands	Nuflor 300 mg/ml raztopina za injiciranje	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Slovenia	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix kožni nanos, raztopina za pse od 10 kg do 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Slovenia	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix kožni nanos, raztopina za pse od 25 do 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Slovenia	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix kožni nanos, raztopina za pse od 40 do 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Slovenia	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 250/1250 spot- on solution for dogs over 10 up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Slovenia	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 400/2000 spot- on solution for dogs over 25 up to 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Spain	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Kelaflor 300 mg/ml solucion inyectable para bovino y porcino	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Spain	MSD Animal Health, S.L. Pol. Ind. El Montalvo I, C/ Zeppelin, 6. Parcela 38 37008 Salamanca Spain	Flomac 450 mg/ml solucion inyectable para bovino	Florfenicol	450 mg/ml	Solution for injection	Cattle	Intramuscular, subcutaneous use
Spain	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan 20 mg/ml solucion inyectable para bovino, porcino y caballos	Meloxicam	20 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use
Spain	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ridaworm 40 mg solucion spot-on para gatos medianos	Praziquantel	40 mg/ml	Spot-on solution	Cat	Spot-on use
Spain	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ridaworm 60 mg Solucion spot-on para gatos grandes	Praziquantel	60 mg/1.5 ml	Spot-on solution	Cat	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Barcelona Spain	Cadorex 300 mg/ml solucion inyectable para bovino, ovino y porcino	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Spain	Mevet, S.A.U. Av. Industria, Pol. Industrial El Segre, parcela 409-410, 25191 Lleida Spain	Pulmovall 300 mg/ml solucion inyectable para bovino, ovino y porcino	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Spain	Laboratorios Syva, S.A.U. Avda. Párroco Pablo Díez, 49-57 24010 León Spain	Florfenis 300 mg/ml Solucion inyectable para bovino, ovino y porcino	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Spain	MSD Animal Health, S.L. Pol. Ind. El Montalvo I, C/ Zeppelin, 6. Parcela 38 37008 Salamanca Spain	Resflor solucion inyectable	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
Spain	Boehringer Ingelheim Animal Health España S.A.U. C/Prat de la Riba, 50 08174 Barcelona Spain	Frontline Tri-act Solucion spot-on para perros 10 - 20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
Spain	Boehringer Ingelheim Animal Health España S.A.U. C/Prat de la Riba, 50 08174 Barcelona Spain	Frontline Tri-act Solucion spot-on para perros 20 - 40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Boehringer Ingelheim Animal Health España S.A.U. C/Prat de la Riba, 50 08174 Barcelona Spain	Frontline Tri-act Solucion spot-on para perros 40 - 60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
Spain	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 250 mg/1250 mg solución spot-on para perros de más de 10 kg hasta 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Spain	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Protectix 400 mg/2000 mg solución spot-on para perros de más de 25 kg hasta 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Spain	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Preventix 250/1250 mg solución spot-on para perros de más de 10 kg hasta 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Spain	Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Preventix 400 mg/2000 mg solución spot-on para perros de más de 25 kg hasta 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Spain	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan 300 mg/ml Solucion inyectable para bovino y porcino	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Spain	MSD Animal Health, S.L. Pol. Ind. El Montalvo I, C/ Zeppelin, 6. Parcela 38 37008 Salamanca Spain	Nuflor 300 mg/ml solucion inyectable para bovino y ovino	Florfenicol	300 mg/ml	Solution for injection	Cattle, sheep	Intramuscular, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Nifencol 300 mg/ml solucion inyectable para bovino y porcino	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Spain	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 2000 mg/400 mg solucion para uncion dorsal puntual para perros de más de 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Spain	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Mycoflor 300 mg/ml solucion inyectable para bovino y porcino	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Spain	MSD Animal Health, S.L. Pol. Ind. El Montalvo I, C/ Zeppelin, 6. Parcela 38 37008 Salamanca Spain	Nuflor 300 mg/ml solucion inyectable porcino	Florfenicol	300 mg/ml	Solution for injection	Pig	Intramuscular use
Spain	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 60 mg solucion spot-on para gatos grandes	Praziquantel	60 mg/1.5 ml	Spot-on solution	Cat	Spot-on use
Spain	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Damtix 2000 mg/400 mg solucion para uncion dorsal puntual para perros de más de 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Spain	Vetpharma Animal Health S.L. Gran Via De Carles III 98 7th Floor 08028 (Barcelona) Spain	Filmtix 2.5 ml spot-on solution for dogs over 10 kg up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 4 ml solucion spot-on para perros de mas de 25 kg hasta 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Spain	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 6 ml Solucion spot-on para perros de mas de 40 kg hasta 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Cutaneous use
Spain	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 2,5 ml solucion spot-on para perros de mas de 10 kg hasta 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use
Spain	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 4 ml solucion spot-on para perros de mas de 25 kg hasta 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Spain	AB7 Santé 9 Chemin des Monges 31450 Deyme France	Pulsix 6 ml solucion spot-on para perros de mas de 40 kg hasta 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Cutaneous use
Spain	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Daclotrix 2000 mg/400 mg solucion para uncion dorsal puntual para perros de mas de 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
Spain	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix solucion spot-on para perros de mas de 40 kg hasta 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix solucion spot-on para perros de mas de 10 hasta 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
Spain	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Advantix solucion spot-on para perros de mas de 25 hasta 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Spain	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Poli-ecto Solucion spot-on para perros de mas de 10 hasta 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog (over 10 kg up to 25 kg)	Spot-on use
Spain	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Poli-ecto Solucion spot-on para perros de mas de 25 hasta 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
Spain	Bayer Animal Health GmbH Kaiser-Wilhelm-Allee 20 51373 Leverkusen Germany	Poli-ecto Solucion spot-on para perros de mas de 40 kg hasta 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use
Spain	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Methoxasol 20/100 mg/ml solucion para administración en agua de bebida para porcino y pollos	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig, chicken (broiler)	In drinking water use
Spain	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Metaxol 20/100 mg/ml solucion para administración en agua de bebida para porcino y pollos	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Trimsulfasol 20/100 mg/ml solucion para administración en agua de bebida para porcino y pollos	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
Spain	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Diatrim 200 mg/ml + 40 mg/ml Solucion inyectable	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Spain	Cenavisa, S.L. Camí Pedra Estela s/n 43205 Reus Spain	Florfenicen 300 mg/ml solucion inyectable para bovino, ovino y porcino	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Spain	Laboratorios Calier, S.A. C/ Barcelonès, 26 08520 Les Franqueses del Vallès (Barcelona) Spain	Florinject 300 mg/ml Solucion inyectable para bovino y porcino	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Spain	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen 300 mg/ml solucion inyectable para bovino y porcino	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Spain	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Florflu 300/16,5 mg/ml Solucion inyectable para bovino	Florfenicol Flunixin	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Industrial Veterinaria, S.A. C/ Esmeralda, 19 08950 Esplugues de Llobregat (Barcelona) Spain	Flodoex 300 mg/ml solucion inyectable	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Spain	Laboratorios e industrias Iven, S.A. Luis I, 56. Pol. Industrial Vallecas 28031 Madrid Spain	Oxiciven L.A. 200 mg/ml Solucion inyectable	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, pig, sheep, goat	Intramuscular use
Spain	Cenavisa, S.L. Camí Pedra Estela s/n 43205 Reus Spain	Censulfatrim solucion inyectable	Trimethoprim Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
Spain	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Trimacrol Gan	Trimethoprim Sulfadiazine	80 mg/ml 400 mg/ml	Suspension for injection	Cattle, horse, pig, sheep, goat	Intramuscular use
Spain	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Neumovex	Trimethoprim Sulfadiazine	25 mg/ml 136 mg/ml	Solution for use in drinking water	Piglets	In drinking water use
Spain	Industrial Veterinaria, S.A. C/ Esmeralda, 19 08950 Esplugues de Llobregat (Barcelona) Spain	Suictine	Ivermectin	10 mg/ml	Solution for injection	Pig	Subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Florvex 300 mg/ml Solucion inyetable	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
Spain	Virbac España, S.A. Angel Guimera, 179-181 08950 Esplugues de Llobregat (Barcelona) Spain	Terralon 200 mg/ml LA	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, Sheep	Intramuscular use
Spain	Cenavisa, S.L. Camí Pedra Estela s/n 43205 Reus Spain	Oxycen L.A. 200 mg/ml Solucion inyetable	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, pig, sheep, goat	Intramuscular use
Spain	Laboratorios e industrias Iven, S.A. Luis I, 56. Pol. Industrial Vallecas 28031 Madrid Spain	Oxiretard 200 mg/ml L. A. Solucion inyetable	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, pig, sheep, goat	Intramuscular use
Spain	Mevet, S.A.U. Av. Industria, Pol. Industrial El Segre, parcela 409-410, 25191 Lleida Spain	Pulmovall 300 mg/ml Solucion inyetable	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
Spain	Industrial Veterinaria, S.A. C/ Esmeralda, 19 08950 Esplugues de Llobregat (Barcelona) Spain	Promectine	Ivermectin	10 mg/ml	Solution for injection	Cattle	Subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Sweden	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate H18 W620 Monaghan Ireland	Hippotrim vet	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous use
Sweden	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Tallaght, Dublin 24 Ireland	Tetroxy prolongatum vet	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular use
Sweden	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Florselect vet	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
Sweden	Boehringer Ingelheim Animal Health Nordics A/S Strødamvej 52 2100 Copenhagen Denmark	Frontect 10-20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Cutaneous use
Sweden	Boehringer Ingelheim Animal Health Nordics A/S Strødamvej 52 2100 Copenhagen Denmark	Frontect 20-40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Cutaneous use
Sweden	Boehringer Ingelheim Animal Health Nordics A/S Strødamvej 52 2100 Copenhagen Denmark	Frontect 40-60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
UK/Northern Ireland ¹	Vetoquinol UK Limited Pury Hill Business Park, Steadings Barn Towcester NN12 7LS United Kingdom	Droncit Spot-on 20 mg solution	Praziquantel	20 mg	Spot-on solution	Cat	Spot-on use
UK/Northern Ireland ¹	Elanco Europe Ltd. Form 2 Bartley Way Hook RG27 9XA United Kingdom	Advantix Spot-on Solution for Dogs over 10 kg up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Spot-on use
UK/Northern Ireland ¹	Elanco Europe Ltd. Form 2 Bartley Way Hook RG27 9XA United Kingdom	Advantix Spot-on Solution for Dogs over 25 kg up to 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog (over 25 kg up to 40 kg)	Spot-on use
UK/Northern Ireland ¹	Elanco Europe Ltd. Form 2 Bartley Way Hook RG27 9XA United Kingdom	Advantix Spot-on Solution for Dogs over 40 kg up to 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog (over 40 kg up to 60 kg)	Spot-on use
UK/Northern Ireland ¹	Pharmaq AS Skogmo Industriområde Industrivegen 50 7863 Overhalla Norway	AMX 10 mg/ml concentrate for solution for fish treatment	Deltamethrin	10 mg/ml	Concentrate for solution for fish treatment	Atlantic salmon, Rainbow trout	Water-borne use
UK/Northern Ireland ¹	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan, 20 mg/ml, solution for injection for cattle, pigs and horses	Meloxicam	20 mg/ml	Solution for injection	Cattle, horse, pig	Intramuscular, intravenous, subcutaneous use
UK/Northern Ireland ¹	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Animeloxan 5 mg/ml solution for injection for dogs and cats	Meloxicam	5 mg/ml	Solution for Injection	Dog, cat	Intravenous, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
UK/Northern Ireland ¹	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Ataxxa 2000 mg/400 mg spot-on solution for dogs over 25 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Spot-on use
UK/Northern Ireland ¹	Eco Animal Health Ltd. 78 Coombe Road New Malden KT3 4QS United Kingdom	Bimectin 5 mg/ml Pour-on Solution for Cattle	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Pour-on use
UK/Northern Ireland ¹	Pets Choice Limited Whitebirk Industrial Estate Lower Philips Road, Blackburn BB1 5UD United Kingdom	Bob Martin Clear Wormer 20mg Spot-on Solution for Cats and Kittens	Praziquantel	20 mg/0.5 ml	Spot-on solution	Cat	Spot-on use
UK/Northern Ireland ¹	Livisto Int'l S.L. Av. Universitat Autònoma 29 08290 Cerdanyol del Vallès (Barcelona) Spain	Cadorex 300 mg/ml solution for injection for cattle, sheep and pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular, subcutaneous use
UK/Northern Ireland ¹	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Cyclosol LA, 200 mg/ml solution for injection	Oxytetracycline	200 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
UK/Northern Ireland ¹	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Diatrim 200 mg/ml + 40 mg/ml Solution for Injection	Trimethoprim Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, pig, dog, cat	Intramuscular, intravenous, subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
UK/Northern Ireland ¹	Zoetis UK Limited 1st Floor, Birchwood Building Springfield Drive Leatherhead KT22 7LP United Kingdom	Duphatrim IS Injectable Solution	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
UK/Northern Ireland ¹	Eco Animal Health Ltd. 78 Coombe Road New Malden KT3 4QS United Kingdom	Ecomectin 5 mg/ml Pour- on solution for cattle	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Pour-on use
UK/Northern Ireland ¹	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ezi-Wormer 20 mg spot-on solution for cats and kittens	Praziquantel	20 mg	Spot-on solution	Cat	Spot-on use
UK/Northern Ireland ¹	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Flordofen 300 mg/ml Solution for Injection for Cattle and Pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
UK/Northern Ireland ¹	Kela N.V. Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Florfenikel 300 mg/ml Solution for Injection for Cattle and Pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
UK/Northern Ireland ¹	Laboratorios Calier, S.A. C/ Barcelonès, 26 08520 Les Franqueses del Vallès (Barcelona) Spain	Florinject 300 mg/ml Solution for Injection for Cattle and Pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
UK/Northern Ireland ¹	Krka d.d. Novo Mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Flovuxin 300/16.5 mg/ml Solution for Injection for Cattle	Florfenicol Flunixin	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
UK/Northern Ireland ¹	Boehringer Ingelheim Animal Health UK Limited Ellesfield Avenue Bracknell RG12 8YS United Kingdom	Frontline Tri-Act Spot-on Solution for Dogs 10-20 kg	Fipronil Permethrin	135.2 mg/2 ml 1009.6 mg/2 ml	Spot-on solution	Dog	Spot-on use
UK/Northern Ireland ¹	Boehringer Ingelheim Animal Health UK Limited Ellesfield Avenue Bracknell RG12 8YS United Kingdom	Frontline Tri-Act Spot-on Solution for Dogs 20-40 kg	Fipronil Permethrin	270.4 mg/4 ml 2019.2 mg/4 ml	Spot-on solution	Dog	Spot-on use
UK/Northern Ireland ¹	Boehringer Ingelheim Animal Health UK Limited Ellesfield Avenue Bracknell RG12 8YS United Kingdom	Frontline Tri-Act Spot-on Solution for Dogs 40-60 kg	Fipronil Permethrin	405.6 mg/6 ml 3028.8 mg/6 ml	Spot-on solution	Dog	Spot-on use
UK/Northern Ireland ¹	Vetoquinol UK Limited Pury Hill Business Park, Steadings Barn Towcester NN12 7LS United Kingdom	Johnson's Easy Spot-On Solution Wormer for Cats & Kittens 20 mg	Praziquantel	20 mg	Spot-on solution	Cat	Spot-on use
UK/Northern Ireland ¹	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Melovem 30 mg/ml solution for injection for cattle and pigs	Meloxicam	30 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
UK/Northern Ireland ¹	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Metaxol 20/100 mg/ml Solution for Use in Drinking Water for Pigs and Chickens	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
UK/Northern Ireland ¹	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel Netherlands	Methoxasol 20/100 mg/ml solution for use in drinking water for pigs and chickens	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig, chicken (broiler)	In drinking water use
UK/Northern Ireland ¹	S.P. Veterinaria, S.A. Ctra. Reus-Vinyols, km.4,1 43330 Riudoms (Tarragona) Spain	Mycoflor, 300 mg/ml Solution for Injection for Cattle and Pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
UK/Northern Ireland ¹	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Nifencol 300 mg/ml Solution for Injection for Cattle and Pigs	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular, subcutaneous use
UK/Northern Ireland ¹	Norbrook Laboratories Limited Station Works Newry BT35 6JP Northern Ireland	Norodine 24 solution for injection	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
UK/Northern Ireland ¹	MSD Animal Health UK Limited Walton Manor, Walton Milton Keynes MK7 7AJ United Kingdom	Nuflor 300 mg/ml solution for injection for cattle and sheep	Florfenicol	300 mg/ml	Solution for injection	Cattle, sheep	Intramuscular, subcutaneous use
UK/Northern Ireland ¹	MSD Animal Health UK Limited Walton Manor, Walton Milton Keynes MK7 7AJ United Kingdom	Nuflor Minidose 450 mg/ml Solution for Injection for Cattle	Florfenicol	450 mg/ml	Solution for injection	Cattle	Intramuscular, subcutaneous use
UK/Northern Ireland ¹	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 60 mg spot-on solution for large cats	Praziquantel	60 mg/1.5 ml	Spot-on solution	Cat	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
UK/Northern Ireland ¹	Eco Animal Health Ltd. 78 Coombe Road New Malden KT3 4QS United Kingdom	Qualimec 5 mg/ml pour-on solution for cattle	Ivermectin	5 mg/ml	Pour-on solution	Cattle	Topical use
UK/Northern Ireland ¹	Vetoquinol UK Limited Pury Hill Business Park, Steadings Barn Towcester NN12 7LS United Kingdom	Quantex 20 mg Spot-on Solution	Praziquantel	20 mg	Spot-on solution	Cat	Spot-on use
UK/Northern Ireland ¹	MSD Animal Health UK Limited Walton Manor, Walton Milton Keynes MK7 7AJ United Kingdom	Resflor 300/16.5 mg/ml solution for injection for cattle	Florfenicol Flunixin (as flunixin meglumine)	300 mg/ml 16.5 mg/ml	Solution for injection	Cattle	Subcutaneous use
UK/Northern Ireland ¹	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Ridaworm 20 mg spot-on solution for cats and kittens	Praziquantel	20 mg/0.5 ml	Spot-on solution	Cat	Spot-on use
UK/Northern Ireland ¹	Laboratorios Hipra S.A. Avinguda La Selva 135 17170 Amer (Girona) Spain	Selectan 300 mg/ml Solution for Injection for Cattle and Swine	Florfenicol	300 mg/ml	Solution for injection	Cattle, pig	Intramuscular use
UK/Northern Ireland ¹	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	TapeNil 20 mg spot-on solution for cats and kittens	Praziquantel	20 mg	Spot-on solution	Cat	Spot-on use
UK/Northern Ireland ¹	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Tallaght, Dublin 24 Ireland	Tetroxy L.A. 200 mg/ml Oxytetracycline solution for injection	Oxytetracycli ne	200 mg/ml	Solution for injection	Cattle, pig, sheep	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
UK/Northern Ireland ¹	Norbrook Laboratories Limited Station Works Newry BT35 6JP Northern Ireland	Trimacare 24% solution for injection	Trimethopri m Sulfadiazine	40 mg/ml 200 mg/ml	Solution for injection	Cattle, horse, pig, dog, cat	Intramuscular, intravenous, subcutaneous use
UK/Northern Ireland ¹	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer Netherlands	Trimsulfasol 20/100 mg/ml solution for use in drinking water for pigs and chickens	Trimethopri m Sulfamethox azole	20 mg/ml 100 mg/ml	Solution for use in drinking water	Pig (fattenin g pigs), chicken (broiler)	In drinking water use
UK/Northern Ireland ¹	Ceva Animal Health Ltd Unit 3, Anglo Office Park, White Lion Road Amersham HP7 9FB United Kingdom	Vectra 3D Spot-on Solution for Dogs > 40 kg	Dinotefuran Pyriproxyfen Permethrin	436 mg/8 ml 38.7 mg/8 ml 3,175 mg/8 ml	Spot-on solution	Dog	Spot-on use
UK/Northern Ireland ¹	Ceva Animal Health Ltd Unit 3, Anglo Office Park, White Lion Road Amersham HP7 9FB United Kingdom	Vectra 3D spot-on solution for dogs > 10–25 kg	Dinotefuran Pyriproxyfen Permethrin	196 mg/3.6 ml 17.4 mg/3.6 ml 1,429 mg/3.6 ml	Spot-on solution	Dog	Spot-on use
UK/Northern Ireland ¹	Ceva Animal Health Ltd Unit 3, Anglo Office Park, White Lion Road Amersham HP7 9FB United Kingdom	Vectra 3D spot-on solution for dogs > 25–40 kg	Dinotefuran Pyriproxyfen Permethrin	256 mg/4.7 ml 22.7 mg/4.7 ml 1,865 mg/4.7 ml	Spot-on solution	Dog	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
UK/Northern Ireland ¹	Ceva Animal Health Ltd Unit 3, Anglo Office Park, White Lion Road Amersham HP7 9FB United Kingdom	Vectra 3D spot-on solution for dogs > 4–10 kg	Dinotefuran Pyriproxyfen Permethrin	87 mg/1.6 ml 7.7 mg/1.6 ml 635 mg/1.6 ml	Spot-on solution	Dog	Spot-on use
UK/Northern Ireland ¹	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Wormax 20 mg spot-on solution for cats and kittens	Praziquantel	20 mg	Spot-on solution	Cat	Spot-on use
UK/Northern Ireland ¹	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	WormCat 20 mg spot-on solution for cats and kittens	Praziquantel	20 mg	Spot-on solution	Cat	Spot-on use
UK/Northern Ireland ¹	Vetoquinol UK Limited Pury Hill Business Park, Steadings Barn Towcester NN12 7LS United Kingdom	Wormclear praziquantel 20 mg spot-on solution for cats	Praziquantel	20 mg	Spot-on solution	Cat	Spot-on use
UK/Northern Ireland ¹	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	WormIt 20 mg spot-on solution for cats and kittens	Praziquantel	20 mg	Spot-on solution	Cat	Spot-on use
UK/Northern Ireland ¹	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 2.5 ml spot-on solution for dogs over 10 kg up to 25 kg	Imidacloprid Permethrin	250 mg/2.5 ml 1250 mg/2.5 ml	Spot-on solution	Dog	Cutaneous use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
UK/Northern Ireland ¹	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 4 ml spot-on solution for dogs over 25 kg up to 40 kg	Imidacloprid Permethrin	400 mg/4 ml 2000 mg/4 ml	Spot-on solution	Dog	Cutaneous use
UK/Northern Ireland ¹	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain	Filmtix 6 ml spot-on solution for dogs over 40 kg up to 60 kg	Imidacloprid Permethrin	600 mg/6 ml 3000 mg/6 ml	Spot-on solution	Dog	Cutaneous use

Annex ID

List of nationally authorised veterinary medicinal products recommended for variation of the marketing authorisations (quantitative NMP concentration, target animal safety warnings and user safety warnings both during application and post-application)

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Bulgaria	Farma Vet Ltd. Shumen, 40 Otec Paisii str. Bulgaria	Deltapharm	Deltamethrin	50 mg/ml	Concentrate for cutaneous solution	Cattle, sheep, dog	Cutaneous use
Cyprus	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Tallaght, Dublin 24 Ireland	Ecofleece 10% w/w, συμπύκνωμα για εμβάπτιση, για πρόβατα	Cypermethrin	10% w/w	Concentrate for dip solution	Sheep	Topical use
France	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 40 mg solution pour spot-on pour chats de taille moyenne	Praziquantel	40 mg/ml	Spot-on solution	Cat	Spot-on use
Germany	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 40 mg lösung zum auftropfen für mittelgroße katzen	Praziquantel	40 mg/ml	Spot-on solution	Cat	Spot-on use
Ireland	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 40 mg spot-on solution for medium cats	Praziquantel	40 mg/ml	Spot-on solution	Cat	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Ireland	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Tallaght, Dublin 24 Ireland	Cyperguard concentrate for dip emulsion	Cypermethrin	10% w/w/ml	Concentrate for dip emulsion	Sheep	Topical use
Ireland	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Tallaght, Dublin 24 Ireland	Ecofleece 10% w/w sheep dip concentrate	Cypermethrin	10% w/w	Concentrate for dip suspension	Sheep	Topical use
Italy	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 40 mg soluzione spot-on per gatti di taglia media	Praziquantel	40 mg/ml	Spot-on solution	Cat	Spot-on use
Malta	V.M.D. n.v. Hoge Mauw 900 2370 Arendonk Belgium	Deltaveto-5 EC Liquid	Deltamethrin	50 g/l	Cutaneous emulsion	Cattle, horse, pig, sheep, goat, dog	External use
Netherlands	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 40 mg spot-on oplossing voor middelgrote katten	Praziquantel	40 mg/ml	Spot-on solution	Cat	Spot-on use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN/Active substance	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 40 mg solucion spot-on para gatos medianos	Praziquantel	40 mg/ml	Spot-on solution	Cat	Spot-on use
Spain	Divasa Farmavic, S.A. Ctra. Sant Hipolit, Km. 71 08503 Gurb, Vic Spain	Cloramivet spray	Chloramphenico l	30 mg/g	Cutaneous spray, solution	Dog, cat	Cutaneous use
UK/Northern Ireland ¹	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, Co Galway Ireland	Prazpronto 40 mg spot-on solution for medium cats	Praziquantel	40 mg/ml	Spot-on solution	Cat	Spot-on use

Annex II
Scientific conclusions and grounds for amendment of the product
information

Overall summary of the scientific evaluation of veterinary medicinal products containing N-methyl pyrrolidone as an excipient

Introduction

N-methyl pyrrolidone (NMP) is an excipient which has been used for decades in a number of veterinary medicinal products as a solvent.

It has subsequently been assessed as being developmentally toxic according to different European committees (Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency (ECHA); Scientific Committee on Consumer Safety (SCCS); Scientific Committee on Occupational Exposure Limits (SCOEL)) (SCCS, 2011²; ECHA, 2014³; SCOEL, 2016⁴).

Moreover, according to Annex VI of the Regulation (EC) No 1272/2008 - classification, labelling and packaging of substances and mixtures (CLP)⁵, NMP is legally classified as 'Repr. 1B (may damage the unborn child)'.

Germany noted that a number of veterinary medicinal products containing NMP as an excipient authorised in various Member States do not contain user or target animal safety warnings related to the potential teratogenic effects of NMP in their product information (summary of product characteristics – SPC, labelling and package leaflet).

Quantitative user risk assessment according to the CVMP guideline on user safety for pharmaceutical veterinary medicinal products (EMA/CVMP/543/03-Rev.1)⁶ and CVMP guideline on user safety of topically administered veterinary medicinal products (EMA/CVMP/SWP/721059/2014)⁷ revealed that most of the NMP-containing products without a warning phrase in their product information pose an unacceptable risk to pregnant women with margins of exposure being substantially below 100.

Furthermore, Germany noted that recently authorised generic products contain user safety warnings for NMP, while such warnings are still missing in the product information of the corresponding reference products. The same situation was apparent regarding target animal safety.

In view of the teratogenic potential of NMP and the identified inconsistencies in user and target animal safety warnings approved for similar products on the market, Germany considered that it is in the interest of the Union to initiate a review of veterinary medicinal products containing NMP as an excipient. Where appropriate, risk mitigation measures should be implemented to ensure the safe use of the concerned veterinary medicinal products on a European level.

Therefore, Germany referred the matter to the Agency's Committee for Veterinary Medicinal Products (CVMP) in the interest of protecting user and animal safety in the Union.

Overall summary of the scientific evaluation

The CVMP was requested to review all available data for veterinary medicinal products containing N-methyl pyrrolidone as an excipient, and to give a scientific opinion on whether the outcome of an

² SCCS, 2011. Opinion on N-Methyl-2-pyrrolidone (NMP) adopted by the Scientific Committee on Consumer Safety - [link](#)

³ ECHA, 2014. Background document to the Opinion on the Annex XV dossier proposing restrictions on 1-methyl-2-pyrrolidone (NMP) - [link](#)

⁴ SCOEL, 2016. SCOEL/REC/119 N-Methyl-2-Pyrrolidone. Recommendation from the Scientific Committee on Occupational Exposure Limits - [link](#)

⁵ Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

⁶ CVMP guideline on user safety for pharmaceutical veterinary medicinal products (EMA/CVMP/543/03-Rev.1) - [link](#)

⁷ CVMP guideline on user safety of topically administered veterinary medicinal products (EMA/CVMP/SWP/721059/2014)-
[link](#)

updated user risk assessment, performed according to current user safety guidelines (EMA/CVMP/543/03-Rev.1⁶ and EMA/CVMP/SWP/721059/2014⁷), for the veterinary medicinal products under consideration would identify a potential risk for pregnant users. In case such a risk was identified, it was requested to establish adequate risk mitigation measures. Furthermore, it was necessary to consider additional information in the product information on the use of the concerned products in target animals during pregnancy or lay.

Veterinary medicinal products containing NMP that are authorised in the European Economic Area are presented in the following pharmaceutical forms: products for injection, solutions for infusion, spot-on products, pour-on products, shampoo, sheep dip products, spray products and concentrates for oral solutions for use in drinking water or for solutions for fish treatment.

User safety

The CVMP was asked to consider the user safety of veterinary medicinal products containing NMP as an excipient with regards to its potential to induce developmental toxicity.

The reproductive and developmental toxicity of NMP following oral exposure was previously described and assessed by the CVMP in the MRL summary report for 1-Methyl-2-pyrrolidone (EMA/MRL/615/99-FINAL-Rev.1)⁸.

In addition, developmental toxicity studies by other routes of administration were previously assessed and published by different European agencies and scientific committees (SCCS, 2011²; ECHA, 2014³; SCOEL, 2016⁴; Akesson, Bengt & International Programme on Chemical Safety, WHO, 2001⁹). Overall, the CVMP considered that NMP is an established teratogen in laboratory animals following various routes of exposure.

During this referral procedure an updated user risk assessment according to the above-mentioned user safety guidelines was performed by the CVMP for the concerned veterinary medicinal products.

In order to perform the user risk assessment, the N-methyl pyrrolidone concentrations of the individual products concerned by this referral procedure were provided by the national competent authorities of the Member States. Applicants/MAHs were asked to inform the CVMP if the NMP concentrations used in the user risk calculations performed by the Committee were incorrect and when necessary, the calculations were revised. However, for some veterinary medicinal products no information on NMP concentrations was provided and in such cases, the CVMP followed a worst-case assumption, whereby the active substance content was subtracted from the product volume and the remaining volume was assumed to contain 100% of the excipient NMP.

The user risk assessment was performed by pharmaceutical form using the following toxicological reference values for the oral and dermal routes of exposure, respectively:

- lowest oral NOAEL = 125 mg per kg body weight per day, derived from oral developmental toxicity studies with NMP in rats (EMA/MRL/615/99-FINAL-Rev.1)⁸.
- lowest dermal NOAEL = 237 mg per kg body weight per day, derived from dermal developmental toxicity studies with NMP in rats (Becci *et al.*, 1982¹⁰; SCCS, 2011²).

The quantitative user risk assessment was only performed for the dermal and oral exposures. The inhalation exposure was not assessed separately because important parameters for these calculations

⁸ EMA, 2008. Committee for Veterinary Medicinal Products: 1-Methyl-2-Pyrrolidone Summary Report (2), (EMA/MRL/615/99-FINAL-Rev.1. May 2008)

⁹ Akesson, Bengt & International Programme on Chemical Safety, 2001. N-methyl-2-pyrrolidone. World Health Organization (WHO) - [link](#)

¹⁰ Becci P.J., Knickerbocker M.J., Reagan E.L., Parent R.A., Llewellyn W.B. (1982). Teratogenicity study of N-methyl pyrrolidone after dermal application to Sprague-Dawley rats. *Fundamental applied toxicology* 2: 73-76.

were missing. However, as the worst-case application rate was very conservative and developmental toxic effects after dermal exposure were more serious than after inhalation exposure, it was anticipated that the user risk assessment following dermal exposure also covers the risk after inhalation exposure.

Although higher margins of exposure (MOEs) are usually considered for teratogenic substances, a MOE of 100 was considered sufficient for the excipient N-Methyl pyrrolidone during the current user risk assessment, due to the conservative assumptions made during the calculations and the use of default values, e.g., 100% dermal absorption.

The quantitative user risk assessment revealed MOEs below 100 for most of the veterinary medicinal products concerned by this referral and consequently, an unacceptable risk for pregnant users. Therefore, the CVMP considered that the implementation of appropriate user safety warnings and risk mitigation measures into the respective product information (summary of product characteristics and package leaflets) for the relevant veterinary medicinal products was necessary for the protection of women of childbearing age, pregnant women or women suspected of being pregnant.

For some veterinary medicinal concerned by this referral (including all products for infusion), the quantitative user risk assessment resulted in MOEs above 100 and hence, the CVMP considered that no user safety warnings should be added in the product information of those products.

Target animal safety

In this referral procedure, the Committee considered whether for veterinary medicinal products containing the excipient N-methyl pyrrolidone, additional information in the product information was necessary for the safe use in target animals during pregnancy or lay.

The excipient NMP has been assessed by different agencies and scientific committees (SCCS, 2011²; ECHA, 2014³; SCOEL, 2016⁴; Akesson, Bengt & International Programme on Chemical Safety, WHO, 2001⁹) and deemed as an established teratogen according to data derived from laboratory animal species that have shown evidence of foetal malformations due to NMP.

The CVMP considered that the potential of developmental toxicity of NMP should be appropriately reflected in the product information of the concerned veterinary medicinal products, except for those cases where the safe use of the product during pregnancy, lactation or lay has been demonstrated in specific safety studies in the target species, i.e., studies that did not provide evidence of teratogenic effects in the respective target species.

Elanco Animal Health Inc. was the only MAH that presented relevant data on target animal safety in the target species. The MAH provided a study report on 3-times overdose during gestation and lactation in bitches for their product Advantix Spot-on without any signs for developmental toxicity, and this is reflected in the approved product information. This study, in which up to 3 times of the maximum recommended treatment dose was repeatedly administered, was already assessed during the marketing authorisation procedure (IT/V/0114/001) where the statement "*Can be used during pregnancy and lactation*" was agreed to be included in the product information. Therefore, the CVMP agreed that the approved wording was kept in the product information for the Advantix spot-on products since a tolerability study in pregnant and lactating bitches was provided and confirmed that the marketed formulation of the product was used in the study. The Committee further concluded that this sentence should also be kept in the product information of the generic products of Advantix with identical composition to the reference product.

Benefit-risk assessment

Benefit assessment

Efficacy of the concerned products in the target species has not been specifically assessed as part of this referral. The veterinary medicinal products under assessment were assessed at the time of authorisation in centralised and national marketing authorisation application procedures and are considered to be effective in the respective target animals.

Risk assessment

Quality, consumer safety, and the environmental risk for the concerned veterinary medicinal products have not been assessed in this referral procedure.

Due to the teratogenic potential of the excipient NMP, the CVMP reviewed the available data and concluded that there is a risk for pregnant users for some of the veterinary medicinal products concerned by this referral procedure as per the user risk assessment performed by the CVMP. In addition, the Committee concluded that there is a risk for target animals during pregnancy or lay, except for those cases where the safe use of the product during pregnancy or lay has been demonstrated in specific safety studies in the target species.

Risk mitigation measures

Based on the available data, user and target animal safety warnings were established and amendments to sections 3.5 and 3.7 (QRD template v9.0), or sections 4.5 and 4.7 (QRD template v8.2) of the summary of product characteristics and corresponding sections of the package leaflet were proposed for veterinary medicinal products as referred to in Annexes IB, IC and ID, as applicable.

Furthermore, as an additional risk mitigation measure, the CVMP concluded that the excipient N-methyl pyrrolidone shall be stated quantitatively in the relevant sections of the product information of the products as referred to in Annexes IB, IC and ID, since that knowledge is considered essential for the safe administration of the veterinary medicinal product, where a risk could not be ruled out and consequently SPC sections 3.5/4.5 or 3.7/4.7 are required to include the above-mentioned warnings.

These measures are considered adequate to ensure user and target animal safety.

Evaluation and conclusions on the benefit-risk balance

Having considered the grounds for the referral procedure and the available data, the CVMP concluded that for veterinary medicinal products as listed in Annex IA, the benefit-risk balance remains favourable.

In addition, for veterinary medicinal products as listed in Annexes IB, IC and ID, the CVMP concluded that safety warnings are needed to mitigate the risk for pregnant users and/or target animals. For these veterinary medicinal products, the Committee concluded that the benefit-risk balance remains favourable subject to the recommended changes in the product information.

Grounds for CVMP opinion

Whereas,

- The CVMP considered the procedure under Article 82 of Regulation (EU) 2019/6 for all veterinary medicinal products containing N-methyl pyrrolidone as an excipient.
- The CVMP reviewed the available data on teratogenic risk for pregnant users associated with the use of veterinary medicinal products containing N-methyl pyrrolidone and an updated user risk

assessment was performed according to current user safety guidelines (EMA/CVMP/543/03-Rev.1⁶ and EMA/CVMP/SWP/721059/2014⁷).

- The CVMP considered additional information in the product information on the use of the concerned products in target animals during pregnancy or lay.
- On the basis of the available data, the CVMP concluded that for the veterinary medicinal products containing N-methyl pyrrolidone as an excipient as referred to in Annex IA, no teratogenic risk is identified for the pregnant user nor target animals.
- On the basis of the available data, the CVMP concluded that for the veterinary medicinal products containing N-methyl pyrrolidone as an excipient as referred to in Annexes IB, IC and ID, teratogenic risk is identified either for pregnant users or target animals.
- The CVMP therefore recommended that appropriate safety warnings have to be included in the product information of all veterinary medicinal products as referred to in Annexes IB, IC and ID, to provide assurance of user and/or target animal safety.

CVMP opinion

In view of the above, the CVMP concluded that the benefit-risk balance of veterinary medicinal products containing N-methyl pyrrolidone as an excipient as referred to in Annex IA remains favourable, and therefore recommended the maintenance of those marketing authorisations.

In addition, the CVMP concluded that the benefit-risk balance of veterinary medicinal products containing N-methyl pyrrolidone as an excipient as referred to in Annexes IB, IC and ID remains favourable subject to the amendments in the product information as described in Annex III.

Therefore, the Committee recommended the variation to the terms of the marketing authorisations for veterinary medicinal products containing N-methyl pyrrolidone as an excipient as referred to in Annexes IB, IC and ID.

Annex III

Amendments to relevant sections of the product information

Note:

These amendments to the relevant sections of the product information are the outcome of the referral procedure.

Amendments to relevant sections of the product information

The existing product information shall be amended (insertion, replacement or deletion of the text, as appropriate) to reflect the agreed wordings as provided below.

For all veterinary medicinal products listed in Annex IB

Summary of Product Characteristics

2. QUALITATIVE AND QUANTITATIVE COMPOSITION (QRD template v9.0 and v8.2)

The excipient N-methyl pyrrolidone should be stated quantitatively in this section since that knowledge is considered essential for the safe administration of the veterinary medicinal product.

3.7 Use during pregnancy, lactation or lay (QRD template v9.0) / **4.7 Use during pregnancy, lactation or lay** (QRD template v8.2)

The following wording should be added including the relevant target species, as applicable. In case a reference to the excipient N-methyl pyrrolidone is already stated in this section, replace it with the following wording including the relevant target species, as applicable:

The safety of the veterinary medicinal product has not been established in <target species> during <pregnancy, lactation,> <lay> or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian. [...]

In case the target species does not undergo pregnancy and lactation, e.g., fish, the following warning should be added:

The safety of the veterinary medicinal product has not been established in <target species> intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian. [...]

Package Leaflet

2. Composition (QRD template v9.0) / **3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)** (QRD template v8.2)

The excipient N-methyl pyrrolidone should be stated quantitatively in this section since that knowledge is considered essential for the safe administration of the veterinary medicinal product.

6. Special warnings (QRD template v9.0) / **12. SPECIAL WARNING(S)** (QRD template v8.2) Pregnancy and lactation:

The following wording should be added including the relevant target species, as applicable. In case a reference to the excipient N-methyl pyrrolidone is already stated in this section, replace it with the following wording including the relevant target species, as applicable:

The safety of the veterinary medicinal product has not been established in <target species> during <pregnancy, lactation,> <lay> or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian. [...]

In case the target species does not undergo pregnancy and lactation, e.g., fish, the following wording should be added:

The safety of the veterinary medicinal product has not been established in <target species> intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian. [...]

For all veterinary medicinal products listed in Annex IC

Summary of Product Characteristics

2. QUALITATIVE AND QUANTITATIVE COMPOSITION (QRD template v9.0 and v8.2)

The excipient N-methyl pyrrolidone should be stated quantitatively in this section since that knowledge is considered essential for the safe administration of the veterinary medicinal product.

3.5 Special precautions for use (QRD template v9.0) / **4.5 Special precautions for use** (QRD template v8.2)

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

*For veterinary medicinal products as referred to in **Annex IC**, a risk during application phase has been identified. Therefore, the following wording should be added as per the relevant pharmaceutical form. In case a reference to the excipient N-methyl pyrrolidone is already stated in this section, replace it with the following wording as per the relevant pharmaceutical form:*

Products for injection:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection. [...]

Spot-on products:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

Pour-on products:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves and protective clothing should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

Shampoo:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

Spray products:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves and disposable mask should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

Concentrates for oral solutions for use in drinking water:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

Concentrates for solution for fish treatment:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

3.7 Use during pregnancy, lactation or lay (QRD template v9.0) / 4.7 Use during pregnancy, lactation or lay (QRD template v8.2)

For veterinary medicinal products which are allowed to be used during pregnancy and lactation based on product specific data, the following wording should be kept:

Can be used during pregnancy and lactation.

For all other veterinary medicinal products, the following wording should be added including the relevant target species, as applicable. In case a reference to the excipient N-methyl pyrrolidone is already stated in this section, replace it with the following wording including the relevant target species, as applicable:

The safety of the veterinary medicinal product has not been established in <target species> during <pregnancy, lactation,> <lay> or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian. [...]

In case the target species does not undergo pregnancy and lactation, e.g., fish, the following warning should be added:

The safety of the veterinary medicinal product has not been established in <target species> intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian. [...]

Package Leaflet

2. Composition (QRD template v9.0) / 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S) (QRD template v8.2)

The excipient N-methyl pyrrolidone should be stated quantitatively in this section since that knowledge is considered essential for the safe administration of the veterinary medicinal product.

6. Special warnings (QRD template v9.0) / **12. SPECIAL WARNING(S)** (QRD template v8.2)

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

*For veterinary medicinal products as referred to in **Annex IC**, a risk during application phase has been identified. Therefore, the following wording should be added as per the relevant pharmaceutical form. In case a reference to the excipient N-methyl pyrrolidone is already stated in this section, replace it with the following wording as per the relevant pharmaceutical form:*

Products for injection:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection. [...]

Spot-on products:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

Pour-on products:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves and protective clothing should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

Shampoo:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

Spray products:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves and disposable mask should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

Concentrates for oral solutions for use in drinking water:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

Concentrates for solution for fish treatment:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women

and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

6. Special warnings (QRD template v9.0) / **12. SPECIAL WARNING(S)** (QRD template v8.2)
Pregnancy and lactation:

For veterinary medicinal products which are allowed to be used during pregnancy and lactation based on product specific data, the following wording should be kept:

Can be used during pregnancy and lactation.

For all other veterinary medicinal products, the following wording should be added including the relevant target species, as applicable. In case a reference to the excipient N-methyl pyrrolidone is already stated in this section, replace it with the following wording including the relevant target species, as applicable:

The safety of the veterinary medicinal product has not been established in <target species> during <pregnancy, lactation,> <lay> or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian. [...]

In case the target species does not undergo pregnancy and lactation, e.g., fish, the following wording should be added:

The safety of the veterinary medicinal product has not been established in <target species> intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian. [...]

For all veterinary medicinal products listed in Annex ID

Summary of Product Characteristics

2. QUALITATIVE AND QUANTITATIVE COMPOSITION (QRD template v9.0 and v8.2)

The excipient N-methyl pyrrolidone should be stated quantitatively in this section since that knowledge is considered essential for the safe administration of the veterinary medicinal product.

3.5 Special precautions for use (QRD template v9.0) / **4.5 Special precautions for use** (QRD template v8.2)

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

*For veterinary medicinal products as referred to in **Annex ID**, a risk has been identified both during application phase and post-application. Therefore, the following wording should be added as per the relevant pharmaceutical form. In case a reference to the excipient N-methyl pyrrolidone is already stated in this section, replace it with the following wording as per the relevant pharmaceutical form:*

Spot-on products:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

Pregnant women and women suspected of being pregnant should avoid direct contact with the application site until the application site is no longer noticeable. [...]

Pour-on products:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves and protective clothing should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

Pregnant women and women suspected of being pregnant should not handle freshly treated animals. [...]

Sheep dip products:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves and protective clothing should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

Pregnant women and women suspected of being pregnant should not handle freshly treated animals. [...]

Spray products:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves and disposable mask should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

Pregnant women and women suspected of being pregnant should avoid direct contact with the application site until the application site is no longer noticeable. [...]

3.7 Use during pregnancy, lactation or lay (QRD template v9.0) / 4.7 Use during pregnancy, lactation or lay (QRD template v8.2)

The following wording should be added including the relevant target species, as applicable. In case a reference to the excipient N-methyl pyrrolidone is already stated in this section, replace it with the following wording including the relevant target species, as applicable:

The safety of the veterinary medicinal product has not been established in <target species> during <pregnancy, lactation,> <lay> or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian. [...]

In case the target species does not undergo pregnancy and lactation, e.g., fish, the following warning should be added:

The safety of the veterinary medicinal product has not been established in <target species> intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian. [...]

Package Leaflet

2. Composition (QRD template v9.0) / 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S) (QRD template v8.2)

The excipient N-methyl pyrrolidone should be stated quantitatively in this section since that knowledge is considered essential for the safe administration of the veterinary medicinal product.

6. Special warnings (QRD template v9.0) / 12. SPECIAL WARNING(S) (QRD template v8.2)

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

*For veterinary medicinal products as referred to in **Annex ID**, a risk has been identified both during application phase and post-application. Therefore, the following wording should be added as per the relevant pharmaceutical form. In case a reference to the excipient N-methyl pyrrolidone is already stated in this section, replace it with the following wording as per the relevant pharmaceutical form:*

Spot-on products:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

Pregnant women and women suspected of being pregnant should avoid direct contact with the application site until the application site is no longer noticeable. [...]

Pour-on products:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves and protective clothing should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

Pregnant women and women suspected of being pregnant should not handle freshly treated animals. [...]

Sheep dip products:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves and protective clothing should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

Pregnant women and women suspected of being pregnant should not handle freshly treated animals. [...]

Spray products:

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves and disposable mask should be worn when handling the veterinary medicinal product by women of childbearing age. [...]

Pregnant women and women suspected of being pregnant should avoid direct contact with the application site until the application site is no longer noticeable. [...]

6. Special warnings (QRD template v9.0) / **12. SPECIAL WARNING(S)** (QRD template v8.2)

Pregnancy and lactation:

The following wording should be added, including the relevant target species as applicable. In case a reference to the excipient N-methyl pyrrolidone is already stated in this section, replace it with the following wording including the relevant target species, as applicable:

The safety of the veterinary medicinal product has not been established in <target species> during <pregnancy, lactation,> <lay> or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian. [...]

In case the target species does not undergo pregnancy and lactation, e.g., fish, the following wording should be added:

The safety of the veterinary medicinal product has not been established in <target species> intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian. [...]