

**Summary of European Union decisions on marketing authorisations in respect of medicinal products
from 1 April 2020 to 30 April 2020***(Decisions taken pursuant to Article 34 of Directive 2001/83/EC ⁽¹⁾ or Article 38 of Directive 2001/82/EC ⁽²⁾)**(2020/C 181/02)***— Issuing, maintenance or modification of a national marketing authorization**

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorization	Member State concerned	Date of notification
17.4.2020	Veterinary medicinal products containing tylosin base (as a single active substance) presented as solutions for injection for intramuscular use in pigs	Tylosin base	See Annex	See Annex	20.4.2020

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

ANNEX

List of the names, pharmaceutical form, strengths of the veterinary medicinal products, animal species, route of administration, applicants and marketing authorisation holders in the Member States

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Austria	Biovet JSC 39, Petar Racov Str. 4550 Peshtera Bulgaria	Axentyl 200 mg/ml Injektionslösung für Rinder, Schafe, Ziegen und Schweine	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Austria	Ceva Santé Animale 10, av. de La Ballastière 33500 Libourne France	Tiljet	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Austria	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Tylan 200 mg/ml — Injektionslösung für Rinder und Schweine	Tylosin base	200 mg/ml	solution for injection	Pigs	Intramuscular use
Austria	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin 200 mg/ml Injektionslösung für Rinder, Schafe, Ziegen und Schweine	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Austria	Vetoquinol Österreich GmbH Gußhausstraße 14/5 1040 Vienna Austria	Tylucyl 200 mg/ml Injektionslösung für Rinder und Schweine	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Belgium	Ceva Santé Animale 10, av. de La Ballastière 33500 Libourne France	Tyljet 200 mg/ml	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Belgium	Cross Vetpharm Group Ltd. Broomhill Road Tallaght, Dublin 24 Ireland	Bilovet 200 mg/ml	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Belgium	Eli Lilly Benelux NV Division Elanco Animal Health Markiesstraat 1 B-1000 Brussel Belgium	Tylan 200	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Belgium	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin 200 mg/ml	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Belgium	Vetoquinol NV/SA Kontichsesteenweg 42 2630 Aartselaar Belgium	Tylucyl 200	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Bulgaria	Biovet JSC 39, Petar Racov Str. 4550 Peshtera Bulgaria	Pharmasin 50 solution for injection	Tylosin base	50 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Bulgaria	Biovet JSC 39, Petar Racov Str. 4550 Peshtera Bulgaria	Tylovet B - 50 solution for injection for cattle, sheep, goats, swine, dogs and cats	Tylosin base	50 mg/ml	Solution for injection	Pigs	Intramuscular use
Bulgaria	Biovet JSC 39, Petar Racov Str. 4550 Peshtera Bulgaria	Tylovet B - 200 solution for injection for cattle, sheep, goats, swine and dogs	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Bulgaria	Biovet JSC 39, Petar Racov Str. 4550 Peshtera Bulgaria	Tylmasin 200 mg/ml solution for injection for cattle, sheep, goats and pigs	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Bulgaria	Ceva Santé Animale 10, av. de La Ballastière 33500 Libourne France	Tyljet 200 mg/ml solution for injection for cattle, sheep, goats and pigs	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Bulgaria	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin 200 mg/ml solution for injection for cattle, sheep, goats and pighs	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Croatia	Ceva Santé Animale 10, av. de La Ballastière 33500 Libourne France	Tyljet, 200 mg/ml, otopina za injekciju za goveda i svinje	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Croatia	Vetoquinol SA Magny-Vernois 70200 Lure France	Tylucyl, 200 mg/mL, otopina za injekciju za goveda i svinje	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Cyprus	Cross Vetpharm Group Ltd. Broomhill Road Tallaght, Dublin 24 Ireland	Bilosin 200 mg/ml Solution for Injection for pigs	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Cyprus	Vetoquinol SA Magny-Vernois 70200 Lure France	Tylucyl 200 mg/ml ενέσιμο διάλυμα για βοοειδή και χοίρους	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Czech Republic	Ceva Santé Animale 10, av. de La Ballastière 33500 Libourne France	Tiljet, 200 mg/ml, Injekční roztok pro skot a prasata	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Czech Republic	Vétoquinol s. r. o. Zámečnická 411 288 02 Nymburk Czech Republic	Tylucyl 200 mg/ml injekční roztok pro skot a prasata	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Denmark	Biovet JSC 39, Petar Racov Str. 4550 Peshtera Bulgaria	Tylovet	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Denmark	Ceva Animal Health A/S Ladegårdsvej 2 DK-7100 Vejle Denmark	Tiljet	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Denmark	Elanco Animal Health A/S Lyskær 3E, 2. tv. 2730 Herlev Denmark	Tylan Vet.	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Denmark	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Tylamasin	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Denmark	Vetoquinol Scandinavia AB Lyngbyvej 20 2100 København Ø Denmark	Tylucyl	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Estonia	Ceva Santé Animale 10, av. de La Ballastière 33500 Libourne France	Tyljet	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Estonia	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Estonia	Vetoquinol SA Magny-Vernois 70200 Lure France	Tylucyl	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Finland	Ceva Santé Animale 10, av. de La Ballastière 33500 Libourne France	Tyljet	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Finland	Elanco Animal Health A/S Lyskær 3E, 2. tv. 2730 Herlev Denmark	Tylan vet	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
France	Aniserve GmbH Geyerspergerstr. 27 80689 Munchen Germany	Tylovectin 200 solution injectable pour bovins, caprins et porcins	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
France	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Tallaght Dublin 24 Ireland	Bilovet 200 mg/ml solution injectable	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
France	Biovet JSC 39, Petar Racov Str. 4550 Peshtera Bulgaria	Axentyl 200 mg/ml solution injectable pour bovins, ovins, caprins et porcins	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
France	Ceva Santé Animale 10, av. de La Ballastière 33500 Libourne France	Tiljet 200 mg/ml solution injectable pour bovins ovins caprins et porcins	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
France	Ceva Santé Animale 10, av. de La Ballastière 33500 Libourne France	Tylosine Ceva 200 Mg/Ml Solution Injectable Pour Bovins Ovins Caprins Et Porcins	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
France	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin 200 mg/ml solution injectable pour bovis ovins caprins et porcins	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
France	Lilly France 24 Boulevard Vital Bouhot 92200 Neuilly Sur Seine France	Tylan 200	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
France	Vetoquinol SA Magny-Vernois 70200 Lure France	Tylucyl 200 mg/ml solution injectable pour bovins et porcins	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Germany	Bela-Pharm GmbH & Co.KG Lohner Str. 19 49377 Vechta Germany	Tylobel 25 %	Tylosin base	250 mg/ml	Solution for injection	Pigs	Intramuscular use
Germany	Bimeda Chemicals Broomhill Road Tallaght Dublin 24 Ireland	Bilovet 200 mg/ml Injektionslösung für Rinder und Schweine	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Germany	Biovet JSC 39, Petar Racov Str. 4550 Peshtera Bulgaria	Tylmasin 200 mg/ml Injektionslösung für Rinder, Schafe, Ziegen und Schweine	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Germany	Ceva Santé Animale 10, av. de La Ballastière 33500 Libourne France	Tiljet 200 mg/ml solution for injection for cattle, pigs, sheep and goates	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Germany	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin 200 mg/ml Injektionslösung für Rinder, Schafe, Ziegen und Schweine	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Germany	Lilly Deutschland GmbH Abteilung Elanco Animal Health Werner-Reimers-Str. 2-4 D-61352 Bad Homburg Germany	Tylan 200	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Germany	Selectavet Dr Otto Fischer Am Kögelberg 5 D-83629 Weyarn/Holzolling Germany	Tylosel-200	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Germany	Vetoquinol GmbH Reichenbachstr. 1 D-85737 Ismaning Germany	Tylucyl 200 mg/ml	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Greece	Biovet JSC 39, Petar Racov Str. 4550 Peshtera Bulgaria	Tylmasin	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Greece	Ceva Hellas LLC 15 Agiou Nikolaou Street 17455 Alimos Greece	Tiljet	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Greece	Eli Lilly Regional Operations GmbH, Elanco Animal Health, Kölblgasse 8 — 10, 1030 Vienna, Austria	Tylan 200	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Greece	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Greece	Vetoquinol SA Magny-Vernois 70200 Lure France	Tylucyl	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Hungary	Biovet JSC 39, Petar Racov Str. 4550 Peshtera Bulgaria	Tylmasin 200 mg/ml oldatos injekció szarvasmarhák, juhok, kecskék és sertések részére	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Hungary	Ceva-Phylaxia Zrt. Szállás u. 5. 1107 Budapest Hungary	Tiljet 200 mg/ml solution for injection for cattle, pigs, sheep and goats	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Hungary	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin 200 mg/ml oldatos injekció szarvasmarhák, juhok, kecskék és sertések részére	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Hungary	Vetoquinol SA Magny-Vernois 70200 Lure France	Tylucyl 200 mg/ml oldatos injekció szarvasmarhák és sertések részére	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Ireland	Bimeda Chemicals Broomhill Road Tallaght Dublin 24 Ireland	Bilosin 200 mg/ml, solution for injection	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Ireland	Biovet JSC 39, Petar Racov Str. 4550 Peshtera Bulgaria	Tylosin Biovet JSC 200 mg/ml solution for injection for cattle, sheep, goats and pigs	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Ireland	Cross Vetpharm Group Ltd. Broomhill Road Tallaght, Dublin 24 Ireland	Bilovet 200 mg/ml solution for injection for cattle and pigs	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Ireland	Elanco GmbH, Heinz-Lohmann-Strasse 4 27472 Cuxhaven Germany	Tylan 200, 200 mg/ml solution for injection	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Ireland	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin 200 mg/ml solution for injection for cattle and pigs	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Ireland	Vetoquinol Ireland Limited First Floor, Segrave House 19-20 Earlsfort Terrace Dublin 2 Ireland	Tylucyl 200 mg/ml solution for injection for cattle and pigs	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Italy	Biovet JSC 39, Petar Racov Str. 4550 Peshtera Bulgaria	Axentyl 200 mg/ml soluzione iniettabile per bovini, ovini, ca- prini e suini	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Italy	Ceva Santé Animale 10, av. de La Ballastière 33500 Libourne France	Tiljet 20, 200 mg/ml, soluzione iniettabile per bovini, suini, cani.	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Italy	Ceva Santé Animale 10, av. de La Ballastière 33500 Libourne France	Tylosine Ceva	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	Cross Vetpharm Group Ltd. Broomhill Road Tallaght, Dublin 24 Ireland	Bilovet 200 mg/ml soluzione iniettabile per bovini e suini	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Italy	Eli Lilly Italia SpA Via Gramsci 731-733, 50019 Sesto Fiorentino — FI Italy	Tylan® 200, 200 mg/ml soluzione iniettabile, per bovini e suini.	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Italy	FATRO S.P.A. Via Emilia, 285 40064 Ozzano Dell'Emilia (Bologna) Italy	Supratil 200 mg/ml soluzione iniettabile per bovini e suini	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Italy	FATRO S.P.A. Via Emilia, 285 40064 Ozzano Dell'Emilia (Bologna) Italy	Vetil, 200 mg/ml, soluzione iniettabile per bovini, suini e cani	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Italy	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin 200 mg/ml soluzione iniettabile per bovini, ovini, caprini e suini	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Italy	Vetoquinol Italia S.r.l. Via Piana 265 47032 Bertinoro (FC) Italy	Tylucyl 200 mg/ml soluzione iniettabile per bovini e suini	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Latvia	Ceva Santé Animale 10, av. de La Ballastière 33500 Libourne France	Tylosine Ceva 200 mg/ml šķīdums injekcijām liellopiem un cūkām	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Latvia	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin 200 mg/ml šķīdums injekcijām liellopiem, aitām, kazām un cūkām	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Latvia	Vetoquinol SA Magny-Vernois 70200 Lure France	Tylucyl 200 mg/ml šķīdums injekcijām liellopiem un cūkām	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Lithuania	Ceva Santé Animale 10, av. de La Ballastière 33500 Libourne France	Tilject 200 mg/ml injekcinis tirpals galvijams ir kaulēms.	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Lithuania	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin 200 mg/ml injekcinis tirpalas kaulēms, galvijams, avims ir ožkoms	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Lithuania	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin 50 mg/ml injekcinis tirpalas kaulēms, galvijams, avims, ožkoms, šunims ir katēms	Tylosin base	50 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Lithuania	Vetoquinol SA Magny-Vernois 70200 Lure France	Tylucyl 200 mg/ml injekcinis tirpalas galvijams ir kiaulėms	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Luxembourg	Ceva Santé Animale 10, av. de La Ballastière 33500 Libourne France	Tyljet 200 mg/ml	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Luxembourg	Cross Vetpharm Group Ltd. Broomhill Road Tallaght, Dublin 24 Ireland	Bilovet 200 mg/ml	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Luxembourg	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin 200 mg/ml	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Luxembourg	Vetoquinol NV/SA Kontichsesteenweg 42 2630 Aartselaar Belgium	Tylucyl 200	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Netherlands	Aniserve Geyerspergerstrasse 27 80689 Munchen Germany	Tylovectin 200 mg oplossing voor injectie voor runderen, gei- tenen varkens	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Netherlands	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Tallaght Dublin 24 Ireland	Bilovet 200 mg/ml oplossing voor injectie voor runderen en varkens	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Netherlands	Elanco GmbH, Heinz-Lohmann-Strasse 4 27472 Cuxhaven Germany	Tylan 200 injectie oplossing voor injectie voor rund, kalf en varken	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Netherlands	Floris Veterinaire Produkten B.V. Kempelandstraat 33-35 5262 GK Vught The Netherlands	Tylosine 20 % P.I.	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Netherlands	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin 200 mg/ml oplossing voor injectie voor runderen en varkens	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Netherlands	Vetoquinol B.V. Postbus 3191 Hertogenbosch 5232 DD's Hertogenbosch The Netherlands	Tylucyl 200 mg/ml oplossing voor injectie voor runderen en varkens.	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Norway	Ceva Santé Animale 10, av. de La Ballastière 33500 Libourne France	Tyljet	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Poland	Biovet JSC 39, Petar Racov Str. 4550 Peshtera Bulgaria	Tylozyna Biovet JSC	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Poland	Ceva Animal Health Polska Sp. z o.o. Ul. Okrzei 1a 03-715 Warsaw Poland	Tiljet 200 mg/ml solution for injection for cattle, pigs, sheep and goats	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Poland	Cross Vetpharm Group Ltd. Broomhill Road Tallaght, Dublin 24 Ireland	Bilovet	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Poland	Drwalewskie Zakłady Przemysłu Bioweterynaryjnego S.A. 6 Grójecka str. 05-651 Drwalew Poland	Biotyl 200	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Poland	Drwalewskie Zakłady Przemysłu Bioweterynaryjnego S.A. 6 Grójecka str. 05-651 Drwalew Poland	Biotyl 50	Tylosin base	50 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Poland	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Poland	Vetoquinol Biowet Sp. z o.o. ul. Kosynierów Gdyńskich 13-14 66-400 Gorzów Wielkopolski Poland	Tylucyl	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Portugal	Biovet JSC 39, Petar Racov Str. 4550 Peshtera Bulgaria	Tylmasin 200 mg/ml solução injetável para bovinos, ovinos, caprinos e suínos	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Portugal	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin 200 mg/ml solução injetável para bovinos, ovinos, caprinos e suínos	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Portugal	Laboratorios Syva S.A.U Av. del Parroco Pablo Diez, 49 24010 San Andrés del Rabanedo Léon Spain	Jectyl 200 mg/ml solução injetável para bovinos, suínos e cães	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Portugal	Lilly Portugal, Produtos Farmacêuticos, Lda Torre Ocidente Rua Galileu Galilei, N.º 2, Piso 7 Fração A/D 1500-392 Lisboa Portugal	Tylan 200 mg/ml Solução injetável para bovinos e suínos	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Portugal	Vétoquinol, Unipessoal Lda. Rua Consigliéri Pedroso, 123– Edifício H 2730-056 Barcarena Portugal	Tylucyl 200 mg/ml, solução injetável para bovinos e suínos	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Romania	Biovet JSC 39, Petar Racov Str. 4550 Peshtera Bulgaria	Tylmasin	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Romania	Cross Vetpharm Group Ltd. Broomhill Road Tallaght, Dublin 24 Ireland	Bilovet 200 mg/ml	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Romania	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin 200 mg/ml solution for injection for cattle and pigs	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Romania	Vetoquinol SA Magny-Vernois 70200 Lure France	Tylucyl 200	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Slovak Republic	Biovet JSC 39, Petar Racov Str. 4550 Peshtera Bulgaria	Tylovet B- 200 mg/ml injekčný roztok pre hovädzí dobytok a ošípané	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Slovak Republic	Ceva Santé Animale 10, av. de La Ballastière 33500 Libourne France	Tyljet 200 mg/ml solution for injection for cattle and pigs	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Slovak Republic	Vétoquinol s.r.o Zámečnická 411 288 02 Nymburg Česká Republika	Tylucil 200 mg/ml injekčný roztok pre hovädzí dobytok a ošípané	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Slovenia	Ceva Santé Animale 10, av. de La Ballastière 33500 Libourne France	Tiljet 200 mg/ml solution for injection for cattle and pigs	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Slovenia	Vetoquinol SA Magny-Vernois 70200 Lure France	Tylucyl 200 mg/ml raztopina za injiciranje za govedo in prašiče	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Spain	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Tallaght Dublin 24 Ireland	Bilovet 200 mg/ml solucion inyectable para bovino y porcino	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Spain	Biovet JSC 39, Petar Racov Str. 4550 Peshtera Bulgaria	Tilosina Biovet JSC 200 mg/ml solucion inyectable para bovino ovino caprino y porcino	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Ceva Salud Animal, S.A. Avinguda Diagonal, 609 — 615 08028 Barcelona Spain	Tyljet 200 mg/ml solution for injection for cattle and pigs	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Spain	Elanco GmbH, Heinz-Lohmann-Strasse 4 27472 Cuxhaven Germany	Trelacon 200.000 UI/ml solution injectable	Tylosin base	200 mg/ml	Solution for Injection	Pigs	Intramuscular use
Spain	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin 200 mg/ml solution injectable para bovino ovino caprino y porcino	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Spain	Industrial Veterinaria, S.A. Esmeralda, 19 08950 Esplugues de Llobregat Barcelona Spain	Tilosina 200 mg/ml Ganadexil solution injectable	Tylosin base	200 mg/ml	Solution for Injection	Pigs	Intramuscular use
Spain	Laboratorios e Industrias Iven, S.A. Calle de Luis I, 56 28031 Madrid Spain	Tilosiven 200 mg/ml solution injectable	Tylosin base	200 mg/ml	Solution for Injection	Pigs	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Laboratorios e Industrias Iven, S.A. Calle de Luis I, 56 28031 Madrid Spain	Tisergen 200 mg/ml	Tylosin base	200 mg/ml	Solution for Injection	Pigs	Intramuscular use
Spain	Laboratorios Syva S.A.U Av. del Parroco Pablo Diez, 49 24010 San Andrés del Rabanedo Léon Spain	Tilosul	Tylosin base	200 mg/ml	Solution for Injection	Pigs	Intramuscular use
Spain	Mevet Polígono Ind El Segre Avenida de la Industria, Parc 410 25191 Lleida, Llérida Spain	Tilovall 200 mg/ml solución inyectable	Tylosin base	200 mg/ml	Solution for Injection	Pigs	Intramuscular use
Spain	Vetoquinol Especialidades Veterinarias S.A. Carreta de Fuencarral, 24 Edificio Europa I 28108 Madrid Spain	Tylucyl 200 mg/ml solución inyectable para bovino y cerdos	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
Sweden	Ceva Animal Health AB Annedalsvägen 9 227 64 Lund Sweden	Tiljet	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use

Member State EU/ EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Sweden	Elanco Animal Health A/S Lyskær 3E, 2. tv. 2730 Herlev Denmark	Tylan Vet	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
Sweden	Vetoquinol Scandinavia AB Torgattan 2 26521 Åstorp Sweden	Tylucyl	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
United Kingdom	Aniserve Geyerspergerstrasse 27 80689 Munchen Germany	Tylovectin 200 solution for in- jection for cattle, goats and pigs	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
United Kingdom	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Tallaght Dublin 24 Ireland	Bilosin 200 mg/ml, solution for injection	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
United Kingdom	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Tallaght Dublin 24 Ireland	Bilovet 200 mg/ml solution for injection for cattle and pigs	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use
United Kingdom	Ceva Santé Animale 10, av. de La Ballastière 33500 Libourne France	Tiljet 200 mg/ml solution for injection for cattle and pigs	Tylosin base	200 mg/ml	Solution for in- jection	Pigs	Intramuscular use

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
United Kingdom	Eli Lilly and Company Limited Elanco Animal Health Priestley Road Basingstoke Hampshire RG24 9NL UK	Tylan 200, 200 mg/ml solution for injection	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use
United Kingdom	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen (Berchen) Belgium	Pharmasin 200 mg/ml solution for injection for cattle and pigs	Tylosin base	200 mg/ml	Solution for injection	Pigs	Intramuscular use