

**Summary of European Union decisions on marketing authorisations in respect of medicinal products  
from 1 July 2017 to 31 August 2017**

*(Decisions taken pursuant to Article 34 of Directive 2001/83/EC<sup>(1)</sup> or Article 38 of Directive 2001/82/EC<sup>(2)</sup>)*

(2017/C 328/02)

**— Issuing, maintenance or modification of a national marketing authorisation**

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorisation	Member State concerned	Date of notification
7.8.2017	Paracetamol/ibuprofen 500 mg/150 mg Film-coated tablets and associated names	paracetamol/ibuprofen	See Annex I	See Annex I	8.8.2017
10.7.2017	Veterinary medicinal products containing tylosin that are administered parenterally and intended for the treatment of bovine mastitis caused by <i>Mycoplasma</i> spp.	tylosin	See Annex II	See Annex II	11.7.2017
19.7.2017	Cardioxane	dexrazoxane	See Annex III	See Annex III	24.7.2017
28.8.2017	Symbioflor 2 and associated names containing <i>Escherichia coli</i> bacteria (cells and autolysate)	Symbioflor 2 and associated names containing <i>Escherichia coli</i> bacteria (cells and autolysate)	See Annex IV	See Annex IV	30.8.2017
14.7.2017	Denagard 45 % and associated names	Tiamulin hydrogen fumarate	See Annex V	See Annex V	17.7.2017

**— Refusal of a national marketing authorisation**

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorisation	Member State concerned	Date of notification
10.7.2017	Veterinary medicinal products containing tylosin that are administered parenterally and intended for the treatment of bovine mastitis caused by <i>Mycoplasma</i> spp.	tylosin	See Annex II	See Annex II	11.7.2017

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

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

## ANNEX I

## List of medicinal products and presentations

Member State EU/EEA	Applicant	(Invented) Name	INN + Strength	Pharmaceutical form <sup>4</sup>	Route of administration <sup>5</sup>
Austria	Vale Pharmaceuticals Limited, Unit 1B Gurtinafleur Business Park, Gurtinafleur Clonmel, Co. Tipperary, Ireland	Ibucomb	500 mg/150 mg	film coated tablet	oral
Belgium	Vale Pharmaceuticals Limited, Unit 1B Gurtinafleur Business Park, Gurtinafleur Clonmel, Co. Tipperary, Ireland	Combogesic	500 mg/150 mg	film coated tablet	oral
Croatia	Vale Pharmaceuticals Limited, Unit 1B Gurtinafleur Business Park, Gurtinafleur Clonmel, Co. Tipperary, Ireland	Combogesic	500 mg/150 mg	film coated tablet	oral
France	Vale Pharmaceuticals Limited, Unit 1B Gurtinafleur Business Park, Gurtinafleur Clonmel, Co. Tipperary, Ireland	Paracetamol/Ibuprofen Vale	500 mg/150 mg	film coated tablet	oral
Germany	Vale Pharmaceuticals Limited, Unit 1B Gurtinafleur Business Park, Gurtinafleur Clonmel, Co. Tipperary, Ireland	Paracetamol/Ibuprofen Vale	500 mg/150 mg	film coated tablet	oral
Ireland	Clonmel Healthcare Waterford Road Clonmel Co. Tipperary E91 D768 Ireland	Easolief Duo	500 mg/150 mg	film coated tablet	oral
Luxembourg	Vale Pharmaceuticals Limited, Unit 1B Gurtinafleur Business Park, Gurtinafleur Clonmel, Co. Tipperary, Ireland	Paracomb	500 mg/150 mg	film coated tablet	oral

Member State EU/EEA	Applicant	(Invented) Name	INN + Strength	Pharmaceutical form <sup>4</sup>	Route of administration <sup>5</sup>
The Netherlands	Vale Pharmaceuticals Limited, Unit 1B Gurtinafleu Business Park, Gurtinafleu Clonmel, Co. Tipperary, Ireland	Paraprofen	500 mg/150 mg	film coated tablet	oral
Portugal	Vale Pharmaceuticals Limited, Unit 1B Gurtinafleu Business Park, Gurtinafleu Clonmel, Co. Tipperary, Ireland	Maxigesic	500 mg/150 mg	film coated tablet	oral
Spain	Vale Pharmaceuticals Limited, Unit 1B Gurtinafleu Business Park, Gurtinafleu Clonmel, Co. Tipperary, Ireland	Dolostop Plus 500 mg/150 mg comprimidos recubiertos con película	500 mg/150 mg	film coated tablet	oral
United Kingdom (UK/H/6034/001/DC)	Vale Pharmaceuticals Limited, Unit 1B Gurtinafleu Business Park, Gurtinafleu Clonmel, Co. Tipperary, Ireland	Paracetamol/Ibuprofen 500 mg/150 mg film coated tablets	500 mg/150 mg	film coated tablet	oral
United Kingdom (UK/H/6035/001/DC)	Vale Pharmaceuticals Limited, Unit 1B Gurtinafleu Business Park, Gurtinafleu Clonmel, Co. Tipperary, Ireland	Paracetamol/Ibuprofen 500 mg/150 mg film coated tablets	500 mg/150 mg	film coated tablet	oral
United Kingdom (UK/H/6176/001/DC)	Vale Pharmaceuticals Limited, Unit 1B Gurtinafleu Business Park, Gurtinafleu Clonmel, Co. Tipperary, Ireland	Novogesic 500 mg/150 mg film coated tablets	500 mg/150 mg	film coated tablet	oral

## ANNEX II

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

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Pharmaceutical form	Strength	Animal species	Route of administration
Austria	Huvepharma NV Uitbreidingsstraat 80 2600 Antwerpen Belgium	PHARMASIN 200 mg/ml Injektionslösung für Rinder, Schafe, Ziegen und Schweine	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
Austria	Bilovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	TYLAXEN 200 mg/ml Injektionslösung für Rinder, Schafe, Ziegen und Schweine	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
Austria	Vana GmbH Wolfgang Schmäzl- Gasse 6 1020 Wien Austria	Vanatyl 200 mg/ml — Injektionslösung für Tiere	Tylosin	Solution for injection	200,000 IU/ml	Cattle Calves Sheep Goats Pigs Dogs	IM
Belgium	Cross Vetpharma Group Ltd Broomhill Road, Tallagh Dublin 24 Ireland	Bilovet	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM
Belgium	VEETOQUINOL SA/NV Kontichsesteenweg 42 2630 Aartselaar Belgium	Tylucyl	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM slow IV (cattle)

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Pharmaceutical form	Strength	Animal species	Route of administration
Bulgaria	Biovet JSC 39, Petar Rakov Str. 4550 Pesthera Bulgaria	PHARMASIN 200 mg/ml solution for injection for cattle, sheep, goats and pigs	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
Croatia	VEETOQUINOL SA Magny-Vernois 70200 Lure France	Tylucyl 200 mg/mL otopina za injekcije za goveda i svinje	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM slow IV (cattle)
Cyprus	VEETOQUINOL SA Magny-Vernois 70200 Lure France	Tylucyl 200 mg/ml raztopina za injiciranje za govedo in prašiče	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM slow IV (cattle)
Denmark	Biovet JSC 39, Petar Rakov Str. 4550 Pesthera Bulgaria	Tylaxene	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
Denmark	Huvepharma NV Uitbreidingstraat 80 BE-2600 Antwerpen Belgium	Tylmasin	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
Denmark	Vetoquinol Scandinavia AB Lyngbyvej 20 DK-2100 København Denmark	Tylucyl	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM slow IV (cattle)

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Pharmaceutical form	Strength	Animal species	Route of administration
Estonia	Vétoquinol SA, Magny-Vernois 70200 Lure France	Tylucyl	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM slow IV (cattle)
Finland	VEETOQUINOL SA/NV Kontichsesteenweg 42 2630 Aartselaar Belgium	Tylucyl	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM slow IV (cattle)
France	LILLY France 24 Boulevard Vital Bouhot 92200 Neuilly Sur Seine France	TYLAN 200	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
France	HUVEPHARMA Uitbreidingsstraat 53 2600 Antwerp Belgium	PHARMASIN 200 MG/ML SOLUTION INJECTABLE POUR BOVINS OVINS CAPRINS ET PORCINS	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
France	Biovet JSC 39, Petar Rakov Str. 4550 Pesthera Bulgaria	TYLAXEN 200 MG/ML SOLUTION INJECTABLE POUR BOVINS, OVINS, CAPRINS ET PORCINS	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
France	CROSS VETPHARM GROUP Broomhill Road Dublin 24 Tallaght Ireland	BILOVET 200 MG/ML SOLUTION INJECTABLE	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Pharmaceutical form	Strength	Animal species	Route of administration
France	VEETOQUINOL Magny Verinois 70200 Lure France	TYLUCYL 200 MG/ML SOLUTION INJECTABLE POUR BOVINS ET PORCINS	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM slow IV (cattle)
Germany	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	Tylmasin 200 mg/ml Injektionslösung für Rinder, Schafe, Ziegen und Schweine	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
Germany	Vétoquinol GmbH Parkstr. 10 88212 Ravensburg Germany	Tylucyl 200 mg/ml	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM slow IV (cattle)
Germany	HUVEPHARMA NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Pharmasin 200 mg/ml Injektionslösung für Rinder, Schafe, Ziegen und Schweine	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
Germany	Bimeda Chemicals Export a Division of Cross Vetpharm Group, Ltd. Broomhill Road, Tallagh Dublin 24 Ireland	Bilovet 200 mg/ml Injektionslösung für Rinder und Schweine	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM
Greece	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	TYLAXEN	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Pharmaceutical form	Strength	Animal species	Route of administration
Hungary	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen Belgium	PHARMASIN 200 mg/ml oldatos injekció szarvasmarhák, juhok, kecskék és sertések részére	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
Hungary	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	TYLAXEN 200 mg/ml oldatos injekció szarvasmarhák, juhok, kecskék és sertések részére	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
Hungary	VEETOQUINOL SA Magny Vernois 70200 LURE France	Tylucyl 200 mg/ml oldatos injekció szarvasmarhák és sertések részére	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM slow IV (cattle)
Ireland	Eli Lilly & Company Limited Elanco Animal Health Priestley Road Basingstoke Hampshire RG24 9NL United Kingdom	Tylan 200, 200 mg/ml Solution for Injection	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM
Ireland	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	Tylaxen 200 mg/ml solution for injection for cattle, sheep, goats and pigs.	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)



Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Pharmaceutical form	Strength	Animal species	Route of administration
Ireland	Huvepharma N.V. Uitbreidingsstraat 80 2600 Antwerpen Belgium	Pharماسin 200 mg/ml solution for injection for cattle, sheep, goats and pigs	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
Ireland	Cross Vetpharm Group Ltd. Broomhill Road, Tallaght Dublin 24 Ireland	Bilovet 200 mg/ml So- lution for Injection for cattle and pigs.	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM
Italy	Veroquinol Italia S.r.l. Via Piana 265 47032 Bertinoro (FC) Italy	TYLUCYL 200 mg/ml soluzione iniettabile per bovini e suini	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM slow IV (cattle)
Italy	FATRO S.p.A. Via Emilia 285 40064 Ozzano Emilia (BO) Italy	VETIL	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs Dogs	IM
Italy	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	TYLAXEN 200 mg/ml soluzione iniettabile	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
Italy	ELI LILLY ITALIA S.p.A. Via Gramsci, 7 31/7 33 50019 Sesto Fiorentino Firenze Italy	TYLAN 200	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Pharmaceutical form	Strength	Animal species	Route of administration
Italy	HUVEPHARMA NV Uitbreidingstraat 80 2600 Anversa Belgium	PHARMASIN 200 mg/ ml soluzione iniettabile per bovini, ovini, caprini e suini	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
Latvia	Veroquinol S.A. Magny-Vernois B.P. 189 Lure Cedex France	Tylucyl	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM slow IV (cattle)
The Netherlands	CROSS VETPHARM GROUP Ltd. Broomhill Road, Tallaght Dublin 24 Ireland	BILOVET 200 mg/ml oplossing voor injectie voor runderen en var- kens	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM
Poland	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpia Belgium	Pharmasin	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
Poland	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	Tylaxen	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
Poland	Aniserve UG Geysersper- gerstrasse 27 80689 Munich Germany	Bilovet 200	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Pharmaceutical form	Strength	Animal species	Route of administration
Poland	Vetoquinol Biowet Sp. z o.o. ul. Kosynierów Gdynskich 13-14 66-400 Gorzów Wielkopolski Poland	Tylucyl 200 mg/ml solution for injection	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM slow IV (cattle)
Portugal	Vetoquinol S.A. Magny-Vernois B.P. 189 Lure Cedex France	Tylucyl 200 mg/ml, solução injetável para bovinos e suínos	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM slow IV (cattle)
Portugal	Huvepharma NV Uitbreidingsstraat 80 2600 Antwerpen Belgium	PHARMASIN 200 mg/ml solução injetável para bovinos, ovinos, caprinos e suínos	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
Portugal	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	TYLAXEN 200 mg/ml solução injetável para bovinos, ovinos, caprinos e suínos	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
Portugal	Lilly Portugal — Produtos Farmacêuticos, Lda R. Cesário Verde, 5 — piso 4 Linda-a-Pastora 2790-326 Queijas Portugal	Tylan 200 mg/ml Solução injetável para bovinos e suínos	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Pharmaceutical form	Strength	Animal species	Route of administration
Romania	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	Tylaxen 200 mg/ml	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
Romania	Cross Vetpharm Group Ltd. Broomhill Road, Tallaght Dublin 24 Ireland	Bilovet 200 mg/ml	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM
Slovak Republic	Vétoquinol s.r.o. Zámečnická 411 288 02 Nymburk Czech Republic	TYLUCYL 200 mg/ml injekčný roztok pre hovädzí dobytok a ošípané	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM slow IV (cattle)
Slovak Republic	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	TYLOVET B-200 mg/ml injekčný roztok	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM
Slovenia	VETOQUINOL SA Magny-Vernois 70200 Lure France	Tylucyl 200 mg/ml raztopina za injiciranje za govedo in prašiče	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM slow IV (cattle)

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Pharmaceutical form	Strength	Animal species	Route of administration
Spain	CROSS VETPHARM GROUP LIMITED, Broomhill Road, Tallaght Dublin 24 Ireland	BILOVET 200 mg/ml SOLUCIÓN INYECTABLE PARA BOVINO Y PORCINO	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM
Spain	VETOQUINOL ESPECIALIDADES VETERINARIAS, S.A. A. Fuencarral Alcobendas km 15 700 Edificio Europa I Portal 3 2º5 28108 Alcobendas (Madrid) Spain	TYLUCIL 200 mg/ml SOLUCIÓN INYECTABLE	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM slow IV (cattle)
Spain	Huvepharma NV Uitbreidingsstraat 80 2600 Antwerpen Belgium	PHARMASIN 200 MG/ML SOLUCIÓN INYECTABLE PARA BOVINO OVINO CAPRINO Y PO	Tylosin	Solution for injection	200,000 IU/ml	Cattle Sheep Goats Pigs	IM slow IV (cattle)
Spain	Biovet JSC, 39 Petar Rakov Str. 4550 Peshtera Bulgaria	TYLAXEN 200 MG/ML SOLUCIÓN INYECTABLE PARA BOVINO OVINO CAPRINO Y PORC	Tylosin	Solution for injection	200,000 IU/ml	Cattle sheep Goats Pigs	IM slow IV (cattle)
Sweden	Veroquinol Scandinavia AB Box 9 265 21 Åstorp Sweden	Tylucyl	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM slow IV (cattle)

Member State EU/EEA	Applicant/Marketing authorisation holder	Name	INN	Pharmaceutical form	Strength	Animal species	Route of administration
United Kingdom	Cross Vetpharm Group Ltd. Broomhill Road, Tallaght Dublin 24 Ireland	Bilovet 200 mg/ml Solution for Injection for Cattle and Pigs	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM
United Kingdom	Eli Lilly & Company Ltd Elanco Animal Health Priestley Road Basingstoke Hampshire RG24 9NL United Kingdom	Tylan 200, 200 mg/ml Solution for Injection	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM
United Kingdom	Vetoquinol UK Ltd Vetoquinol House Great Slade Buckingham Industrial Park Buckingham MK18 1PA United Kingdom	Tylucyl 200 mg/ml solution for injection for cattle and pigs	Tylosin	Solution for injection	200,000 IU/ml	Cattle Pigs	IM slow IV (cattle)

## ANNEX III

## List of medicinal products and presentations

Member State EU/ EEA	Marketing authorisation holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Czech Republic	Clinigen Healthcare Ltd. Pitcairn House, Crown Square First Avenue, Burton-on-Trent, Staffordshire, DE14 2WW United Kingdom	Cardioxane	500 mg	Powder for solution for infusion	Intravenous use
France	Clinigen Healthcare Ltd. Pitcairn House, Crown Square First Avenue, Burton-on-Trent, Staffordshire, DE14 2WW United Kingdom	Cardioxane	500 mg	Powder for solution for infusion	Intravenous use
Germany	Clinigen Healthcare Ltd. Pitcairn House, Crown Square First Avenue, Burton-on-Trent, Staffordshire, DE14 2WW United Kingdom	Cardioxane	500 mg	Powder for solution for infusion	Intravenous use
Italy	Clinigen Healthcare Ltd. Pitcairn House, Crown Square First Avenue, Burton-on-Trent, Staffordshire, DE14 2WW United Kingdom	Cardioxane	500 mg	Powder for solution for infusion	Intravenous use
The Netherlands	Clinigen Healthcare Ltd. Pitcairn House, Crown Square First Avenue, Burton-on-Trent, Staffordshire, DE14 2WW United Kingdom	Cardioxane	500 mg	Powder for solution for infusion	Intravenous use
Poland	Clinigen Healthcare Ltd. Pitcairn House, Crown Square First Avenue, Burton-on-Trent, Staffordshire, DE14 2WW United Kingdom	Cardioxane	500 mg	Powder for solution for infusion	Intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Spain	Clinigen Healthcare Ltd. Pitcairn House, Crown Square First Avenue, Burton-on-Trent, Staffordshire, DE14 2WW United Kingdom	Cardioxane 500 mg polvo para solución para perfusión	500 mg	Powder for solution for infusion	Intravenous use
United Kingdom	Clinigen Healthcare Ltd. Pitcairn House, Crown Square First Avenue, Burton-on-Trent, Staffordshire, DE14 2WW United Kingdom	Cardioxane	500 mg	Powder for solution for infusion	Intravenous use



## ANNEX IV

## List of nationally authorised medicinal products

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical Form
Austria	Symbiopharm Gmbh	Symbioflor E. Coli	<i>Escherichia Coli</i> 15 — 45 Mega Cells/ml	Oral Drops, Suspension
Germany	Symbiopharm Gmbh	Symbioflor 2	<i>Escherichia Coli</i> 15 — 45 Mega Cells/ml	Oral Drops, Suspension
Hungary	Symbiopharm Gmbh	Symbioflor <i>Escherichia</i>	<i>Escherichia Coli</i> 15 — 45 Mega Cells/ml	Oral Drops, Suspension

## ANNEX V

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

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Austria	Elanco Europe Ltd. Lilly House, Priestley Road Basingstoke, Hampshire RG24 9NL United Kingdom	Denagard 450 mg/g Granulat zum Eingeben über das Trinkwasser	Tiamulin hydrogen fumarate	450 mg/g	Granules	Pigs, chickens, turkeys	Oral
Belgium	VMD nv Hoge Mauw 900 2370 Arendonk Belgium	Tiamutin 45 % Pigs	Tiamulin hydrogen fumarate	450 mg/g	Granules for use in drinking water	Pigs	Oral
Belgium	VMD nv Hoge Mauw 900 2370 Arendonk Belgium	Tiamutin 45 % Chicken-Turkey	Tiamulin hydrogen fumarate	450 mg/g	Granules for use in drinking water	Chickens, turkeys	Oral
Belgium	VMD nv Hoge Mauw 900 2370 Arendonk Belgium	Tiamutin 45 % Pigs-Chicken-Turkey	Tiamulin hydrogen fumarate	450 mg/g	Granules for use in drinking water	Pigs, chickens, turkeys	Oral
Czech Republic	Elanco Europe Ltd. Lilly House, Priestley Road Basingstoke, Hampshire RG24 9NL United Kingdom	DENAGARD 450 mg/g granule pro přípravu perorálního roztoku	Tiamulin hydrogen fumarate	450 mg/g	Granules for use in drinking water	Pigs, chickens (broilers, pullets, layers and breeders), turkeys (fattening and breeding birds)	Oral

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Finland	Elanco Europe Ltd. Lilly House, Priestley Road Basingstoke, Hampshire RG24 9NL United Kingdom	Denagard vet 450 mg/g rakeet	Tiamulin hydrogen fumarate	450 mg/g	Granules	Pigs	Oral to be administered in drinking water
Germany	Elanco Europe Ltd. Lilly House, Priestley Road Basingstoke, Hampshire RG24 9NL United Kingdom	Denagard 45 % Granulat	Tiamulin hydrogen fumarate	45 % w/w (36,4 % tiamulin w/w)	Granules	Pigs, chickens, turkeys	In drinking water
Germany	Elanco Europe Ltd. Lilly House, Priestley Road Basingstoke, Hampshire RG24 9NL United Kingdom	Denagard 45 % oral	Tiamulin hydrogen fumarate	45 % w/w (36,4 % tiamulin w/w)	Granules	Pigs	Use in drinking water or in feed
Greece	Elanco Europe Ltd. Lilly House, Priestley Road Basingstoke, Hampshire RG24 9NL United Kingdom	DENAGARD 45 %, κοκκία για πόσιμο διάλυμα	Tiamulin hydrogen fumarate	450 mg/g	Granules for oral solution	Pigs, chickens, turkeys	Oral
Hungary	Elanco Europe Ltd. Lilly House, Priestley Road Basingstoke, Hampshire RG24 9NL United Kingdom	Denagard 45 % granulátum felsőleges oldathoz A.U.V.	Tiamulin hydrogen fumarate	450 mg/g	Granules for use in drinking water	Pigs, chickens, turkeys	In drinking water use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	Elanco Europe Ltd. Lilly House, Priestley Road Basingstoke, Hampshire RG24 9NL United Kingdom	DENAGARD 45 %	Tiamulin hydrogen fumarate	450 mg/g	Powder for use in drinking water	Pigs, chickens	Oral
Latvia	Novartis Animal Health d.o.o. Verovškova 57 1000 Ljubljana Slovenia	Denagard 45 % WSG	Tiamulin hydrogen fumarate	450 mg/g	Water soluble granules	Pigs, chickens, turkeys	In drinking water use
Lithuania	Novartis Animal Health d.o.o. Verovškova 57 1000 Ljubljana Slovenia	DENAGARD 45 %, van-denyje tirpios granulės	Tiamulin hydrogen fumarate	450 mg/g, corresponds to 365 mg tiamulin/g	Water soluble granules	Pigs, chickens (broiler, replacement pullet, layer/breeder), turkeys (grower and breeder)	Oral
The Netherlands	Elanco Europe Ltd. Lilly House, Priestley Road Basingstoke, Hampshire RG24 9NL United Kingdom	DENAGARD 45 % W.S. G. voor varkens en kippen	Tiamulin hydrogen fumarate	450 mg/g	Granulate for administration through the drinking water	Pigs, chickens	Oral
Poland	Novartis Animal Health d.o.o. Verovškova 57 1000 Ljubljana Slovenia	Denagard 45 % granulát dla świń, kur i indyków	Tiamulin hydrogen fumarate	450 mg/g	Granules	Pigs, chickens, turkeys	Oral use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Portugal	Elanco Europe Ltd. Lilly House, Priestley Road Basingstoke, Hampshire RG24 9NL United Kingdom	Denagard 450 mg/g granulado oral para suínos, galinhas e perus	Tiamulin hydrogen fumarate	450 mg/g	Oral granules	Swine, chickens (broilers, layers/breeders), turkeys (for fattening and breeding)	Oral, administered in drinking water
Romania	Elanco Europe Ltd. Lilly House, Priestley Road Basingstoke, Hampshire RG24 9NL United Kingdom	Denagard 45 %	Tiamulin hydrogen fumarate	45 mg tiamulin hydrogen fumarate/g product	Granules for use in drinking water	Pigs, chickens (broiler, replacement pullet, layer/breeder), turkeys (grower and breeder)	In drinking water
Slovak Republic	Elanco Europe Ltd. Lilly House, Priestley Road Basingstoke, Hampshire RG24 9NL United Kingdom	Denagard 450 mg/g granulát na perorálny roztok	Tiamulin hydrogen fumarate	450 mg/g	Granules for oral solution	Pigs, chickens (broilers, laying and breeding hens), turkeys	Oral
Spain	Elanco Europe Ltd. Lilly House, Priestley Road Basingstoke, Hampshire RG24 9NL United Kingdom	Denagard 450 mg/g Granulado Oral	Tiamulin hydrogen fumarate	450 mg/g	Granules for use in drinking water	Pigs, chickens, turkeys	Oral