

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10989/008/001**
Case No: 7004640

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Eurovet Animal Health B.V.

Handelsweg 25, 5531 AE Bladel, Netherlands

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Tylovet 20% w/v Solution for Injection

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from .

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylovet 20% w/v Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Tylosin (as Tylosin Tartrate) 200.0 mg

Excipients

Benzyl Alcohol 40.0 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

A clear yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, pigs.

4.2 Indications for use, specifying the target species

For the treatment of infections caused by microorganisms susceptible to tylosin. The spectrum of antimicrobial activity of tylosin includes:

Staphylococcus spp

Streptococcus spp.

Corynebacterium spp.

Neisseria spp.

Flavobacterium spp.

Campylobacter spp.

Bacillus anthracis

Moraxella bovis

Clostridium spp.

Haemophilus spp.

Bordetella bronchiseptica

Spirochaetes

Bacteroides spp.

Mycoplasma spp.

4.3 Contraindications

Do not use in case of hypersensitivity to the active ingredient or to any other macrolide antibiotics.

Do not use in new-born animals.

Do not use in equines.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

This product contains benzyl alcohol which has been documented to cause adverse reactions in neonates. For this reason this product should not be used in very young animals.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Special Precautions to be taken by the Person Administering the Product to Animals

Avoid skin contact with solution.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Do not mix with other solutions, since this may cause precipitation of the active ingredients.

4.9 Amounts to be administered and administration route

The recommended dosage rate is 10 mg/kg bodyweight twice daily i.e 0.5 ml per 10 kg body weight. For intramuscular administration. Treatment should be carried out for 3 to 5 consecutive days. To ensure a correct dosage, bodyweight should be determined as accurately as possible.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Overdose should be avoided using the most accurate bodyweight estimation.

4.11 Withdrawal Period(s)

Meat and offal: 21 days.

Milk: 96 hours.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, macrolides

ATCvet code: QJ01FA90

5.1 Pharmacodynamic properties

Tylosin produces misreading of the genetic code. The drug probably acts by interacting with more than one site on the 50S ribosomal subunit, or with more than one component of the protein synthesis machinery. Tylosin has a broad spectrum of activity. *In vivo* tylosin is bacteriostatic in action.

5.2 Pharmacokinetic properties

It is absorbed relatively rapidly after injection and is distributed throughout the whole body. Only low concentrations are measured in plasma. In several tissues and tissue fluids, concentrations are achieved that are much higher than those in plasma (including lung and udder). Tylosin is inactivated by hepatic metabolism.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Propylene Glycol
Water for Injection

6.2 Incompatibilities

Do not mix with any other medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf-life after first opening the immediate packaging: 14 days.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C).
Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

100 ml amber coloured type II glass vial sealed with butyl rubber stoppers and aluminium cap.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V.,
Handelsweg 25,
5531 AE Bladel,
The Netherlands.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10989/008/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th september 2008

10 DATE OF REVISION OF THE TEXT