

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10996/054/001**

Case No: 7005190

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:

Intervet Ireland Limited

Magna Drive, Magna Business Park, Dublin 24, Ireland

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:

Engemycin Soluble 5 % w/w Powder for Oral Solution

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 revoked, shall continue in force from **09/09/2009**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: 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

Engemycin Soluble 5 % w/w Powder for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Oxytetracycline HCL 50 g/kg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder for Oral Solution

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, calves and pigs.

4.2 Indications for use, specifying the target species

The product is indicated for the treatment of a range of bacterial infections caused by, or associated with, oxytetracycline sensitive organisms. A wide range of gram-positive and gram-negative bacteria, certain mycoplasma species and Rickettsia, have been shown to be sensitive in vitro to oxytetracycline.

Major indications:

Cattle: respiratory disease

Calf: bacterial enteritis

Pig: respiratory disease

4.3 Contraindications

Do not use in ruminants receiving root vegetables as part of their diet.

4.4 Special warnings for each target species

The use of tetracyclines during the period of tooth development, including late pregnancy, may lead to tooth discolouration.

4.5 Special precautions for use

Special precaution(s) for use in animals

Remove all other sources of water until the medicated water has been consumed.

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 veterinary medicinal product to animals

Persons preparing medicated drinking water should wear adequate protective clothing and avoid contact with product or inhaling it.

When handling the product wear gloves, avoid skin contact and wash hands after use.

When dispensing the product wear a mask to avoid inhaling the powder.

4.6 Adverse reactions (frequency and seriousness)

The use of tetracyclines during the period of tooth development, including late pregnancy, may lead to tooth discolouration.

Following oral dosage in ruminating animals changes in the ruminal flora may occur but these have generally been found to be of a transitory and reversible nature. Administration of the product at the recommended dosage will usually result in only a small depression of cellulose digestion.

4.7 Use during pregnancy, lactation or lay

Safety of the product has not been established during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The product is recommended for oral administration and may be given in the drinking water or as a drench. A period of treatment for 3-5 days is recommended at the following doses:

Calf: 1-2 measures per 45 kg bodyweight twice daily (9-18 mg oxytetracycline hydrochloride per kg bodyweight per day).

Ruminating Cattle: 1 measure per 100 kg bodyweight twice daily (2-4 mg oxytetracycline hydrochloride per kg bodyweight per day).

Pigs: 1-3 measures per 20 kg bodyweight per day (i.e. 10-30 mg oxytetracycline hydrochloride per kg bodyweight per day). This can be achieved by adding 4-12.5 g oxytetracycline hydrochloride per 45.5 litres of drinking water i.e. 1 x 500 g pack medicates approximately 284 litres at the lower dosage level.

The product is to be used immediately on addition to water and unused material should be discarded.

A 5 ml measure is supplied with the product and this holds 4 g of product.

To ensure a correct dosage, bodyweight should be determined as accurately as possible.

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

None known.

4.11 Withdrawal Period(s)

Meat and Offal:

Cattle - 10 days. Pigs - 7 days.

Milk: Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken 12 hours after treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use; tetracyclines

ATCvet code: QJ01AA06

5.1 Pharmacodynamic properties

The product contains oxytetracycline, a broad spectrum antibiotic with activity against a range of Gram-positive and Gram-negative bacteria.

5.2 Pharmacokinetic properties

The oral dose rate leads to serum concentrations above the minimum inhibitory concentrations for the susceptible organisms.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

Shelf life after dilution according to directions: 24 hours.

6.4 Special precautions for storage

Store below 25°C.

Protect from light.

Store in a dry place.

6.5 Nature and composition of immediate packaging

Product is packed in polythene bags to contain 500g, 2.5kg and 25kg. 500g and 2.5kg packs are placed in a white plastic bucket, 25kg packs are placed in paper bags.

A 5 ml measure is supplied with the product and this holds 4 g of product.

Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd,
Magna Drive
Magna Business Park
Citywest Road,
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/054/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2008

10 DATE OF REVISION OF THE TEXT

9th September 2009