

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10047/004/002**
Case No: 7004284

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:

Elanco Animal Health, Eli Lilly and Company Limited

Priestly Road, Basingstoke, Hampshire RG24 9NL, England

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:

Tylan G100 Premix

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 **30/06/2008** until **30/09/2008**.

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

Tylan G100 Premix

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each kg contains:

Active Substance

Tylosin activity as tylosin phosphate	100 g
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For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Premix for medicated feeding stuff

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs

4.2 Indications for use, specifying the target species

For the prevention and control of swine dysentery and enzootic pneumonia. For the treatment and control of Lawsonia intracellularis, the organism associated with Porcine Intestinal Adenomatosis (Ileitis) and Porcine Haemorrhagic Enteropathy.

4.3 Contraindications

For use in pig feeds only.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

In the event of skin contact, wash thoroughly with soap and water.

For persons mixing the product into feed

May cause skin irritation. Avoid direct skin contact. Wear overalls and impervious gloves when mixing and handling the product. Wash contaminated skin.

If the operations involve the risk of exposure to dust, wear either a disposal half mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

No adverse effects to tylosin have been seen in fertility, multi-generation or teratology studies.

4.8 Interaction with other medicinal products and other forms of interaction

None observed.

4.9 Amounts to be administered and administration route

For oral administration.

Prevention and control of swine dysentery and enzootic pneumonia:

3-6 mg tylosin activity / kg bodyweight, which may normally be achieved by adding the product at the rate of 1 kg per tonne, giving 100 g tylosin base per tonne. Feed as the only ration for 21 days, followed by feed containing 400 g of the product per tonne of feed (giving 40 g tylosin base equivalent per tonne) until the end of the period of risk.

Treatment and control of *Lawsonia Intracellularis*:

3-6 mg tylosin activity / kg bodyweight, which may normally be achieved by adding the product at the rate of 1 kg per tonne, giving 100 g tylosin base per tonne. Feed as the only ration for 21 days.

The product should be thoroughly mixed into the complete feed.

Mix the appropriate quantity of tylan G 100 premix to obtain the recommended levels of tylosin with 20 - 50 kg of a suitable feed component prior to incorporation into the bulk of the feed to be prepared.

When incorporated at a rate of below 2 kg per tonne of final feed, the product must only be mixed by a manufacturer who is approved to mix at that level.

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

Tylan G 100 Premix has been shown to produce no adverse effects when fed to pigs at 600 ppm in the feed (six times the recommended maximum level) for 28 days.

The LD 50 for both the rat and the mouse is >6200 mg tylosin activity/kg.

4.11 Withdrawal Period(s)

Nil.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Tylosin is a macrolide antibiotic produced by a strain of *Streptomyces fradiae*. It exerts its antimicrobial effect by inhibiting protein synthesis of susceptible micro-organisms.

5.1 Pharmacodynamic properties

The tylosin spectrum of activity includes Gram-positive bacteria, some Gram-negative strains such as *Pasteurella*, and *Mycoplasma* spp at concentrations of 16 ug/ml or less

5.2 Pharmacokinetic properties

Absorption: Tylosin reaches maximal blood levels between 1 and 3 hours after an oral dose. Minimal or no blood levels remain 24 hours after an oral dose.

Distribution: After oral doses were given to pigs, tylosin was found in all tissues, between 30 minutes and two hours after administration, except for the brain and spinal cord.

Biotransformation and Elimination: It has been shown that most of the material which is excreted is to be found in the faeces and consists of tylosin (factor A), relomycin (factor D) and dihydrodesmycosin.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Soybean oil, or mineral oil
Soybean mill run

6.2 Incompatibilities

None known.

6.3 Shelf-life

Premix: 24 months
After mixing with feed: 3 months

6.4 Special precautions for storage

Do not store above 30°C.
Store in a dry place.

6.5 Nature and composition of immediate packaging

Flexible laminate bag with aluminium foil layer containing 25 kg of light tan granules.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Eli Lilly and Co Ltd.,
Elanco Animal Health,
Priestley Road,
Basingstoke,
Hampshire RG24 9NL,
England.

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10047/4/2

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2003

10 DATE OF REVISION OF THE TEXT

30th June 2008