SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan G50 Premix for Medicated Feedingstuff

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Tylosin activity (as tylosin phosphate) 50 g per kg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Premix for medicated feedingstuff.

Light tan coloured, free flowing granular material.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

For the prevention and control of 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

Do not use in known cases of hypersensitivity.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Official, national and regional antimicrobial policies should be taken into account when the product is used.

i) Special precautions for use in animals

For use in pig feeds only.

To ensure thorough dispersion of the product it should first be mixed with a small quantity of feed ingredients before incorporation into the final mix.

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

Tylosin may induce irritation. Macrolides, such as tylosin, may also cause hypersensitivity (allergy) following injection, inhalation, ingestion or contact with skin or eye. Hypersensitivity to tylosin may lead to cross reactions to other macrolides and vice versa. Allergic reactions to these substances may occasionally be serious and therefore direct contact should be avoided.

To avoid exposure during preparation of the medicated feed, wear overalls, safety glasses, impervious gloves and wear either a disposable half mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143. Wash hands after use.

In the event of accidental skin contact, wash thoroughly with soap and water. In case of accidental eye contact, flush the eyes with plenty of clean, running water.

Do not handle the product if you are allergic to ingredients in the product.

If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Only to be incorporated by a manufacturer who is approved to mix at a rate of below 2 kg per tonne of final feed.

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 incorporation into dry feed at the registered mill.

A manufacturer who is approved to incorporate directly at any concentration, veterinary medicinal products or premixtures containing such products must be responsible for mixing when incorporation is less than 2kg per tonne for final feed.

For oral administration.

Prevention and control of enzootic pneumonia:
3-6 mg tylosin activity/kg bodyweight, which may normally be achieved by adding the product at the rate of 2 kg per tonne, giving 100 g tylosin base per tonne. Feed as the only ration for 21 days.

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 2 kg per tonne, giving 100 g tylosin base per tonne. Feed as the only ration for 21 days.

The required levels of tylosin are obtained by mixing the appropriate quantity of premix with 20-50 kg of a suitable feed component, prior to incorporation into the bulk of the feed to be prepared.

The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of Tylan G50 has to be adjusted accordingly.

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

Produced 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

Meat: Zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Macrolides
ATCvet code: QJ01FA90

5.1 Pharmacodynamic 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.

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

5.2 Pharmacokinetic particulars

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 mill run
Isopar M

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after incorporation into meal or pelleted feed: 3 months.

6.4 Special precautions for storage

Bag i) (2 layered multi-walled sack) Do not store above 25°C. Store in a dry place.
Bag ii) (3 layered multi-walled sack) Do not store above 30°C. Store in a dry place.

In the finished feed the product will remain stable for three months.

6.5 Nature and composition of immediate packaging

2 kg multiwalled sack comprising two layers (outer: bleached kraft paper and inner: low density polyethylene) stitched with tape and jute/cord filler.

2 kg multiwalled sack comprising three layers (outer: bleached kraft paper, mid: kraft paper and inner: kraft paper, low density polythene, aluminium foil, low density polyethylene), with heat sealed closure.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Unused veterinary medicinal product or waste materials from such veterinary medicinal products should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBERS

UK: Vm 00879/4174

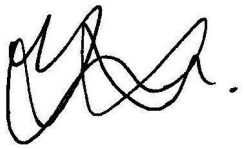
Ireland: VPA No. 10047/4/4

9. DATE OF FIRST AUTHORISATION

22 October 1998

10. DATE OF REVISION OF THE TEXT

September 2020



Approved: 24 September 2020