1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan G50 Premix for medicated feedingstuff for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each kg contains 50g tylosin activity (as tylosin phosphate)

Qualitative composition of excipients and other constituents
Soybean mill run
lsopar M

Light tan coloured, free flowing granular material.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each 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.

The presence of the disease in the group or flock must be established before the product is used.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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.

Use of the product should be in accordance with official, national and regional antimicrobial policies. Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

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 package leaflet or the label to the physician. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the label for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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 2 kg 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 the veterinary medicinal product has to be adjusted accordingly.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01FA90

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3 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.

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA22020/034/003

8. DATE OF FIRST AUTHORISATION

26/11/1999

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

15/04/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).