SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan G250 Premix for Medicated Feedingstuff

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff.

Light tan coloured, free flowing granular material.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs, broilers and pullets.

4.2 Indications for use, specifying the target species

Pigs:
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.

Broilers and pullets:
Treatment and prevention of respiratory infections caused by *Mycoplasma gallisepticum* and *Mycoplasma synoviae*, when the disease has been diagnosed in the flock.

Treatment and prevention of necrotic enteritis caused by *Clostridium perfringens*, when the disease has been diagnosed in the flock.

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

4.3 Contraindications

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

Do not use in animals vaccinated with tylosin-sensitive vaccines either at the same time or within one week previously.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Use of the product should be in accordance with official, national and regional antimicrobial policies.

Special precautions for use in animals

For incorporation into medicated feedingstuffs 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 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

Other precautions
Not applicable

4.6 Adverse reactions (frequency and seriousness)

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 package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

No studies have been conducted in the target species population. Use only according to the benefit-risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Lincosamides and aminogylcoside antibiotics antagonise the activity of tylosin.

4.9 Amount(s) 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 2 kg per tonne for final feed.

For oral administration.

Pigs:
Prevention and control of enzootic pneumonia:

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 400 g 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 the veterinary medicinal product with 20-50 kg of a suitable feed component, prior to incorporation into the bulk of the feed to be prepared.

Broilers and pullets:
For the treatment and prevention of respiratory infections:
127 mg tylosin per kg bodyweight (corresponding to 508 mg of the veterinary medicinal product per kg bodyweight) for the first 5 days of life. It is strongly recommended to repeat the treatment of the birds at the age of 3-4 weeks.

For the treatment and prevention of necrotic enteritis:
10 – 20 mg tylosin per kg bodyweight (corresponding to 40 – 80 mg of the veterinary medicinal product per kg bodyweight) for 7 days.

For the preparation of the medicated feed the body weight of the animals to be treated and their actual daily feed consumption should be taken into due account. Consumption may vary depending on factors like age, breed, husbandry system. To provide the required amount of active substance in mg per kg mixed feed the following calculation should be made:

$$\frac{\text{…. mg veterinary medicinal product /kg bodyweight/day} \times \text{average body weight (kg) of animals to be treated}}{\text{Average daily amount of mixed feed intake /kg per animal}} = \text{… mg veterinary medicinal product per kg/ mixed feed}$$

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.

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

The veterinary medicinal product 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.

4.11 Withdrawal period(s)

Meat and offal:
Pigs: Zero days.
Broilers and pullets: 1 day
Not authorised for use in birds producing eggs for human consumption.

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* spps 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

Starch Pregelatinised
Soya Bean Feed Special (solvent extracted)

6.2 Major 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) (3-ply kraft paper sack) Do not store above 25°C. Store in a dry place.

Bag (ii) (multiwalled sack). Do not store above 25°C. Store in a dry place.

The product will remain stable in finished feed for three months when stored below 25°C.

6.5 Nature and composition of immediate packaging

25kg 3-ply kraft paper sack, middle ply having an extrusion coating of low density polyethylene, stitched with tape and jute/cord filler.

25kg 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

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann Strasse 4
D-27472 Cuxhaven
Groden
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 52127/5085

9. DATE OF FIRST AUTHORISATION

14 January 1998

10. DATE OF REVISION OF THE TEXT

April 2025

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

Approved 29 April 2025
Gavin Hall