

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan G250 Premix for medicated feeding stuff

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Tylosin activity (as tylosin phosphate) 250 g per kg

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.

4.3 Contraindications

Do not use in known cases of hypersensitivity.

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

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

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.

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 final feed.

4.6 Adverse reactions (frequency and seriousness)

None known.

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 interactions

Lincosamides and aminoglycoside antibiotics antagonise the activity of tylosin.

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 2 kg per tonne for final feed.

For oral administration.

Pigs:

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 400 g 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 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 Tylan G250 premix 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 Tylan G250 premix 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 Tylan G250 premix 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:

... mg Tylan G250 average body weight (kg)
 $\frac{\text{mg Tylan G250}}{\text{kg bodyweight/day}} \times \text{of the animals to be treated} = \dots \text{ mg Tylan G250}$
 Average daily amount of mixed feed intake /kg per animal premix 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 Tylan G250 has to be adjusted accordingly.

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

Tylan G250 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.

4.11 Withdrawal period(s)

Meat:

Pigs: Zero days.

Broilers and pullets: 1 day

Do not use in laying hens producing eggs for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL 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 30°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 products or waste materials derived from the use of such products

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

7 MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/034/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th May 1999
Date of last renewal: 13th May 2009

10 DATE OF REVISION OF THE TEXT

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