

**MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING
WHERE THERE IS NO PACKAGE LEAFLET, I.e. Combined label and package
leaflet
25 kg printed bag**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan G250 Premix for medicated feeding stuff

2. COMPOSITION

Each kg contains 250g tylosin activity (as tylosin phosphate)

Granular

3. PACKAGE SIZE

25 kg

4. TARGET SPECIES

Pigs, broilers and pullets

5. INDICATIONS FOR USE

Indications for use

Pigs:

The prevention and control of enzootic pneumonia.

The treatment and control of *Lawsonia intracellularis*.

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.

6. CONTRAINDICATIONS

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.

7. SPECIAL WARNINGS

Special precautions for safe use in the target species:

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

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.

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

Interactions with other medicinal products and other forms of interaction:

Lincosamides and aminoglycoside antibiotics antagonise the activity of tylosin.

8. ADVERSE REACTIONS

Pigs, broilers and pullets:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or

you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details on this label, or via your national reporting system.

9. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Incorporation must be in accordance with the veterinary prescription.

Mixing Directions:

For incorporation into medicated feedingstuffs only.

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

Pigs:

Prevention and control of enzootic pneumonia:

3-6 mg tylosin activity/kg bodyweight (BW), which may normally be achieved by adding the product at the rate of 400 g per tonne to give 100 g tylosin base equivalent per tonne of feed. Feed as the only ration for 21 days.

Treatment and control of *Lawsonia intracellularis*:

3-6 mg tylosin activity/kg BW, which may normally be achieved by adding the product at the rate of 400 g per tonne to give 100 g tylosin base equivalent per tonne of feed. Feed as the only ration for 21 days.

Broilers and pullets:

For the treatment and prevention of respiratory infections:

127 mg tylosin per kg BW (corresponding to 508 mg of the veterinary medicinal product per kg BW) 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 BW (corresponding to 40-80 mg of the veterinary medicinal product per kg BW) for 7 days.

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.

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.

To provide the required amount of active substance in mg per kg mixed feed the following calculation should be made:

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

10. ADVICE ON CORRECT ADMINISTRATION

11. WITHDRAWAL PERIODS

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.

12. SPECIAL STORAGE PRECAUTIONS

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.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 52127/5085

25 kg bag

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

17. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:

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

Manufacturer responsible for batch release:

Elanco UK AH Limited
Elanco Speke Operations
Fleming Road
Speke
Liverpool, L24 9LN
United Kingdom

Or

Elanco France S.A.S.
26 rue de la Chapelle, 68330 Huningue,
France

18. OTHER INFORMATION

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19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

FOR ANIMAL TREATMENT ONLY.

20. EXPIRY DATE

Exp {month/year}

21. BATCH NUMBER

Lot {number}

22. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight of children.

Approved 29 April 2025

Gavin Hall