

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**25 kg bag**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Tylan G250 Premix for medicated feeding stuff

**2. STATEMENT OF ACTIVE SUBSTANCES**

Tylosin Phosphate  
Tylosin (as tylosin phosphate).  
250 g of tylosin base activity per kg.

**3. PHARMACEUTICAL FORM**

Premix for medicated feeding stuff  
Granular

**4. PACKAGE SIZE**

Net weight 25 kg

**5. TARGET SPECIES**

Pigs, broilers and pullets

**6. INDICATION(S)**

**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.

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

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

**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 Tylan G250 premix 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 Tylan G250 premix 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 Tylan G250 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:

$$\frac{\text{.... mg Tylan G250 Premix /kg BW/day}}{\text{Average daily amount of mixed feed intake /kg per animal}} \times \frac{\text{average BW (kg) of the animals to be treated}}{\text{Premix per kg/ mixed feed}} = \dots \text{ mg Tylan G250 Premix per kg/ mixed feed}$$

**8. WITHDRAWAL PERIOD(S)**

Withdrawal period(s): Pigs: Zero days. Broilers and pullets: 1 day.

Do not use in laying hens producing eggs for human consumption. Incorporation must be in accordance with the veterinary prescription.

**9. SPECIAL WARNING(S), IF NECESSARY**

**Operator Warning:**

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.

**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.

**Warnings:**

Lincosamides and aminoglycoside antibiotics antagonise the activity of tylosin.

**10. EXPIRY DATE**

Use Before: {month/year}

**11. SPECIAL STORAGE CONDITIONS**

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.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

FOR ANIMAL TREATMENT ONLY. TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION.

**UK Only:**

Prescription Only Medicine – Veterinary

POM-V

**IE Only:**  
Prescription Only Medicine

POM

**14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"**

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Marketing Authorisation Holder (UK only):

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

Marketing Authorisation Holder (IE only):

Elanco GmbH  
Heinz-Lohmann-Strasse 4  
27472 Cuxhaven  
Germany

**16. MARKETING AUTHORISATION NUMBER(S)**

UK: Vm 00879/4173  
IE: VPA 22020/034/002

**17. MANUFACTURER'S BATCH NUMBER**

Lot No {number}

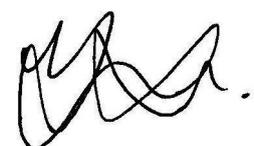
**OTHER INFORMATION**

Site of 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



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