

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

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**25kg BAG**

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

Tylan G20 Premix for medicated feedingstuff

**2. STATEMENT OF ACTIVE SUBSTANCES**

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

**3. PHARMACEUTICAL FORM**

Premix for medicated feedingstuff  
Granular

**4. PACKAGE SIZE**

Net weight: 25 kg

**5. TARGET SPECIES**

Pigs

**6. INDICATION(S)**

The prevention and control of enzootic pneumonia. The treatment and control of *Lawsonia intracellularis*.  
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:**

*Prevention and control of enzootic pneumonia:*

3-6 mg tylosin activity/kg bodyweight, which may normally be achieved by adding the product at a rate of 5 kg per tonne to give 100 g tylosin activity 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 bodyweight, which may normally be achieved by adding the product at a rate of 5 kg per tonne to give 100 g tylosin activity equivalent per tonne of feed. Feed as the only ration for 21 days.

The product should be thoroughly mixed into the complete feed.

To ensure thorough dispersion of the product it should first be mixed with a suitable quantity of feed ingredients (20-50 kg) before incorporation in the final mix. The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of Tylan G20 has to be adjusted accordingly. Incorporation must be in accordance with the veterinary prescription.

## 8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero Days

## 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.

### **Contraindication:**

Do not use in known cases of hypersensitivity.

### **Warning:**

For use in pig feed only.

## 10. EXPIRY DATE

Use Before: {month/year}

## 11. SPECIAL STORAGE CONDITIONS

Store in a dry place.

Do not store above 30°C.

After mixing in feed, use within 3 months.

**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 national requirements.

**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 00879/4172  
IE: VPA VPA22020/034/001

**17. MANUFACTURER'S BATCH NUMBER**

Lot No: {number}

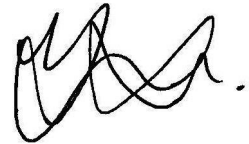
**OTHER INFORMATION**

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 Huingue,  
France

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 22 December 2020