ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

2kg printed bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan G50 Premix for medicated feedingstuff

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Premix for medicated feedingstuff
Granular

4. PACKAGE SIZE

Net weight 2 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 2 kg per tonne to give 100 g tylosin base 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 2 kg per tonne to give 100 g tylosin base 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 G50 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.

In the finished feed the product will remain stable for 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 00879/4174
IE: VPA 22020/034/003

17. MANUFACTURER'S BATCH NUMBER

Lot No: {number}

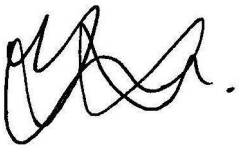
OTHER INFORMATION

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



Approved: 22 December 2020