PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

2 kg BAG (front + back labels)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pulmotil G100 Premix for Medicated Feedingstuff

2. STATEMENT OF ACTIVE SUBSTANCES

Pulmotil G100 Premix is a yellowish tan to reddish tan free-flowing granular material containing tilmicosin (as phosphate) 100-g/kg.

Tilmicosin (as phosphate) 100 g/kg

3. PHARMACEUTICAL FORM

Premix for Medicated Feedingstuff

4. PACKAGE SIZE

Net weight 2 kg

5. TARGET SPECIES

For use in pigs and rabbits

6. INDICATION(S)

Pigs: Prevention and treatment of respiratory disease caused by *Actinobacillus pleuropneumoniae, Mycoplasma hyopneumoniae, Pasteurella multocida* and other organisms sensitive to tilmicosin.

Rabbits: Prevention and treatment of respiratory disease caused by *Pasteurella multocida* and *Bordetella bronchiseptica*, susceptible to tilmicosin.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For in-feed use.
Read reverse of the bag before use.

The uptake of medicated feed depends on the clinical condition of the animals. In order to obtain a correct dosage the concentration of tilmicosin has to be adjusted accordingly.

Use the following formula:

$$\text{Kg Premix/tonne feed} = \frac{\text{Dose rate (mg/kg bodyweight) x bodyweight (kg)}}{\text{Daily feed intake (kg) x premix strength (g/kg)}}$$

Pigs
Administer in the feed at a dose of 8 to 16 mg/kg body weight/day of tilmicosin activity (equivalent to 200 to 400 ppm in the feed) for a period of 15 to 21 days.

Indication	Dose of tilmicosin	Duration of treatment	Inclusion rate in feed
Prevention and treatment of respiratory disease	8-16 mg/kg bodyweight /day	15 to 21 days	2-4 kg Pulmotil G100 Premix/tonne

Rabbits
Administer in the feed at 12.5 mg/kg body weight/day of tilmicosin (equivalent to 200 ppm in the feed) for 7 days.

Indication	Dose of tilmicosin	Duration of treatment	Inclusion rate in feed
Prevention and treatment of respiratory disease	12.5 mg/kg bodyweight /day	7 days	2 kg Pulmotil G100 Premix/tonne

Not to be incorporated into feeds containing Bentonite.
To ensure thorough dispersion of the product, it should first be mixed with a suitable quantity of feed ingredients (20 to 50 kg) before incorporation into the finished feed.
This product can be incorporated into pelleted feed, preconditioned for the minimum time-period at a temperature not exceeding 75°C.
Inappropriate use of the product may increase the prevalence of bacteria resistant to tilmicosin and may decrease the effectiveness of treatment with tilmicosin related substances.
Official, national and regional antimicrobial policies should be taken into account when the product is used.
Due to the likely variability (time, geographical) in the occurrences of the resistance of bacteria for tilmicosin, bacteriological sampling and susceptibility testing are recommended.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Pigs: 21 days
Rabbits: 4 days

9. SPECIAL WARNING(S), IF NECESSARY

Special warning
When mixing the veterinary medicinal product and handling the medicated feed, direct contact with eyes, skin and mucous membranes should be avoided. Personal protective equipment should be worn.
In case of accidental ingestion seek medical advice immediately and show the label to the physician.
See back of pack for full operator warnings.

Under practical conditions, the management of respiratory disease outbreaks recognises that acutely ill animals are inappetant and require parenteral therapy. The safety of tilmicosin has not been established in boars used for breeding purposes. No symptoms of overdose have been seen in pigs fed a ration containing levels of tilmicosin up to 10 times the recommended dose for 15 days.

For the user:
- Tilmicosin may induce irritation. Macrolides, such as tilmicosin, may also cause hypersensitivity (allergy) following injection, inhalation, ingestion or contact with skin or eye. Hypersensitivity to tilmicosin 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. Do not eat, drink or smoke when handling this product. Wash hands after use.
- In the case of accidental ingestion, wash out mouth immediately with water and seek medical advice. 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 after 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.

Adverse reactions
In very rare cases, feed intake may decrease (including feed refusal) in animals receiving medicated feed. This effect is transient.
If you notice any serious effects or other effects not mentioned, please inform your veterinary surgeon.
Contraindications:
Horses or other Equidae must not be allowed access to feeds containing tilmicosin. Horses fed with tilmicosin medicated feeds may present signs of toxicity with lethargy, anorexia, reduction of feed consumption, loose stools, colic, distension of the abdomen and death.
Do not use in case of hypersensitivity to tilmicosin or to any of the excipients.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Once opened, use within 3 months
Once incorporated into meal or pelleted feed, use within 3 months
Store in a dry place.
Do not store above 25°C.
Protect from direct sunlight.
Do not use after the expiry date which is stated on the label after ‘EXP’.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with national requirements.
Pig manure should not to be spread onto grass land and when spread onto arable land should be ploughed to a depth of 30-cm.

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.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

Ireland only:
Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Ireland only:
Marketing Authorisation Number VPA22020/012/001

UK only:
Marketing Authorisation Number Vm 00879/4169

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

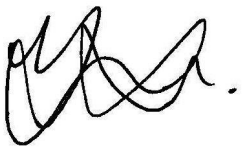
OTHER INFORMATION

Pulmotil G100 Premix is available in bags containing 2-kg, 5 kg or 10-kg.
Not all pack sizes may be marketed.

Manufacturer for the batch release:
Elanco UK AH Limited
Elanco Speke Operations, Fleming Road, Speke, Liverpool,
L24 9LN UK

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

Date on which the information was last approved: September 2020



Approved: 24 September 2020