

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet

BAG

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pulmotil G100 Premix for medicated feeding stuff

2. COMPOSITION

100 g/kg tilmicosin (as phosphate)

A yellowish tan to reddish tan free-flowing granular material.

3. PACKAGE SIZE

2 kg

5 kg

10 kg

4. TARGET SPECIES

Pigs and rabbits.

5. INDICATIONS FOR USE

Indications for use

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.

6. CONTRAINDICATIONS

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 the active substance or to any of the excipients.

7. SPECIAL WARNINGS

Special warnings

Under practical conditions, the management of respiratory disease outbreaks recognises that acutely ill animals are inappetent and require parenteral therapy.

Special precautions for safe use in the target species:

Inappropriate use of the veterinary medicinal product may increase the prevalence of bacteria resistant to tilmicosin and may decrease the effectiveness of treatment with tilmicosin related substances.

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge susceptibility of the target pathogens at farm level, or at local/regional level.

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

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

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.

Personal protective equipment consisting of overalls, safety glasses, impervious gloves and 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 should be worn when handling the veterinary medicinal product.

Do not eat, drink or smoke when handling this veterinary medicinal product. Wash hands after use.

In case of accidental ingestion, wash out mouth immediately with water and seek medical advice immediately and show the label to the physician.

In case of accidental spillage onto skin, wash thoroughly with soap and water and seek medical advice immediately and show the label to the physician.

In case of accidental eye contact, flush the eyes with plenty of clean, running water and seek medical advice immediately and show the label to the physician.

People with known hypersensitivity to tilmicosin should avoid contact with the veterinary medicinal product.

If you develop symptoms after exposure, such as skin rash, seek medical advice and show 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.

Special precautions for the protection of the environment:

Pig manure should not be spread onto grass land and when spread onto arable land should be ploughed to a depth of 30 cm.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy. Do not use in breeding animals.

Interactions with other medicinal products and other forms of interaction:

None known.

Overdose:

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.

Major incompatibilities:

Not to be incorporated into feeds containing bentonite.

8. ADVERSE EVENTS

Adverse events

Pigs and rabbits:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Reduced food intake ¹

¹Transient

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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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

Dosage for each species, routes and method of administration

In-feed use.

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

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{mg veterinary medicinal product/ kg body weight day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily feed intake (kg/animal)} \times \text{veterinary medicinal product strength (g/kg)}} = \text{kg veterinary medicinal product per tonne of feed}$$

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 rate	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 of the veterinary medicinal product/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 rate	Duration of treatment	Inclusion rate in feed
Prevention and treatment of respiratory disease	12.5 mg/kg bodyweight /day	7 days	2 kg of the veterinary medicinal product/tonne

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

To ensure thorough dispersion of the veterinary medicinal product, it should first be mixed with a suitable quantity of feed ingredients (20 to 50 kg) before incorporation into the finished feed.

This veterinary medicinal product can be incorporated into pelleted feed, preconditioned for the minimum time-period at a temperature not exceeding 75°C.

11. WITHDRAWAL PERIODS

Withdrawal periods

Pigs:

Meat and offal: 21 days

Rabbits:

Meat and offal: 4 days

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

Store in a dry place.

Do not store above 25°C.

Protect from direct sunlight

Do not use this veterinary medicinal product after the expiry date which is stated on the label after 'Exp.'. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. 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

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Vm 00879/5095

Pack sizes

10 kg polyethylene/polyamide/polyethylene (inner layer) bag.

2 kg, 5 kg or 10 kg paper/polyethylene/aluminium/polyethylene/paper bag.

Not all pack sizes may be marketed.

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

Contact details

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

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom
Tel: +44 3308221732

PV.GBR@elancoah.com

Manufacturer responsible for batch release:

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

Or

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

Or

Rumenco Limited, Trading as Nettex
Eastern Avenue
Lichfield
Staffordshire
WS13 7SE
United Kingdom

18. OTHER INFORMATION
Other information

POM-V

Veterinary medicinal product subject to prescription.

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once opened, use within 3 months.

Once incorporated into meal or pelleted feed, use within 3 months.

21. BATCH NUMBER

Lot {number}

Gavin Hall
Approved: 12 December 2025