

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {5 kg – 20 kg bag}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tilmovet 40 g/kg Premix for medicated feeding stuff

2. STATEMENT OF ACTIVE SUBSTANCES

Each kg contains:

Active substance:

40 g tilmicosin

3. PACKAGE SIZE

5 kg and 20 kg

4. TARGET SPECIES

Pigs (weaned piglets and pigs for fattening) and rabbits

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use. To be administered orally through the medicated feed.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Pigs: meat and offal: 21 days

Rabbits: meat and offal: 4 days

8. EXPIRY DATE

Exp {mm/yyyy}

Shelf-life after incorporation into meal or pelleted feed: 3 months

Shelf life after first opening of the immediate packaging: 3 months

Once broached use by

9. SPECIAL STORAGE PRECAUTIONS

Store in the original container.

Store in a dry place

Do not store above 30°C.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

14. MARKETING AUTHORISATION NUMBERS

Vm 30282/5024 (GB)

Vm 30282/3026 (NI)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Tilmovet 40 g/kg Premix for medicated feeding stuff for pigs and rabbits

2. Composition

Each kg contains:

Active substance:

40 g tilmicosin

Yellowish to reddish free-flowing granules.

3. Target species

Pigs (weaned piglets and pigs for fattening) and rabbits

4. Indications for use

Pigs:

Treatment and metaphylaxis of respiratory disease caused by *Actinobacillus pleuropneumoniae*, *Mycoplasma hyopneumoniae*, *Pasteurella multocida* and other organisms sensitive to tilmicosin

Rabbits:

Treatment and metaphylaxis of respiratory disease caused by *Pasteurella multocida* and *Bordetella bronchiseptica*, susceptible to tilmicosin.

The presence of the disease in the group must be established before the veterinary medicinal product is used.

5. Contraindications

Tilmicosin is known to be toxic for horses. Do not allow horses or other equines access to feeds containing tilmicosin. 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 cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:

With regard to the management of respiratory disease outbreaks, it should be noted that acutely ill animals are likely to be inappetent and therefore require parenteral treatment.

Repeated use of the veterinary medicinal product should be avoided by improving management practices and thorough cleansing and disinfection.

Cross-resistance has been shown between tilmicosin and other macrolides (like tylosin, erythromycin) or lincosamides. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to other macrolides or lincosamides because its effectiveness may be reduced.

Special precautions for safe use in the target species:

Due to the likely variability (time, geographical) in the occurrence of the resistance of bacteria for tilmicosin, bacteriological sampling and susceptibility testing are recommended.

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 of 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.

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.

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.

Do not use for prophylaxis.

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

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

May cause sensitisation by skin contact. May cause skin and eye irritation. Avoid direct skin contact. Personal protective equipment consisting of overalls, safety glasses and impervious gloves should be worn when handling the veterinary medicinal product. Wash affected parts if skin contact occurs. If accidental eye contact occurs, immediately rinse thoroughly with water. In case of accidental ingestion, or if you develop symptoms following exposure such as skin rash, seek medical advice immediately and show the package leaflet or the label to the

physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

If the operations involve the risk of exposure to dust, wear either a disposable filter and half mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 fitted with a filter to EN143. This warning is particularly relevant to on-farm mixing, where the risk of exposure to dust is likely to be enhanced.

Pregnancy and lactation:

Laboratory studies in rats have not produced any evidence of a teratogenic, foetotoxic/embryotoxic effect of tilmicosin, however, a maternotoxicity was observed at doses that were close to the therapeutic dosage. The veterinary medicinal product is safe in sows whatever the pregnancy stages.

Fertility:

The safety of the veterinary medicinal product has not been established in boars used for breeding purposes.

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously with other macrolides and lincosamides.

Do not use simultaneously with bacteriostatic antimicrobial agents.

Tilmicosin may less the antibacterial activity of β -lactam antibiotics.

Overdose:

No symptoms of overdose have been seen in pigs fed a ration containing levels of tilmicosin up to 80 mg/kg bodyweight (equivalent to 2000 ppm in the feed or ten times the recommended dose) for 15 days.

Special restrictions for use and special conditions for use:

This veterinary medicinal product is intended to be used for the preparation of medicated feed.

Major incompatibilities:

Do not mix into feed containing bentonite.

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Pigs and rabbits:

| | |
|--|--|
| Very rare (<1 animal / 10,000 animals treated, including isolated report(s)): | Reduced food intake, food refusal ¹ |
|--|--|

¹ this effect is transient

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, 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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, 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

8. Dosage for each species, routes and method of administration

Oral use. To be administered orally through the medicated feed.
The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of tilmicosin may need to be adjusted accordingly.
Use the following formula:

$$\frac{\text{Kg veterinary medicinal product}}{\text{tonne feed}} = \frac{\text{Dose rate (mg/kg bodyweight)} \times \text{bodyweight (kg)}}{\text{Daily feed intake (kg)} \times \text{premix strength (g/kg)}}$$

Pigs

Administer in the feed at a dose of 8 to 16 mg/kg body weight/day of tilmicosin (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 |
|---|---------------------------|-----------------------|---|
| Treatment and metaphylaxis of respiratory disease | 8-16 mg/kg bodyweight/day | 15 to 21 days | 5-10 kg veterinary medicinal product /tonne |

Rabbits

Administer in the feed at 12 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 |
|---|-------------------------|-----------------------|--|
| Treatment and metaphylaxis of respiratory disease | 12 mg/kg bodyweight/day | 7 days | 5 kg veterinary medicinal product /tonne |

9. Advice on correct administration

Animals with acute infections may have a reduced feed intake and should be treated with a suitable injectable veterinary medicinal product.

To ensure thorough dispersion of the veterinary medicinal product it should first be mixed with a suitable quantity of feed before incorporation into the finished feed. Medicated feed may be pelleted using a pre-conditioning step for 5 minutes at a temperature not exceeding 75°C.

10. Withdrawal periods

Pigs: meat and offal: 21 days

Rabbits: meat and offal: 4 days

11. Special storage precautions

Keep out of sight and reach of children.
Store in a dry place.
Do not store above 30°C.
Store in the original container.

Shelf-life after incorporation into meal or pelleted feed: 3 months
Shelf life after first opening of the immediate packaging: 3 months
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.

12. 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 30282/5024 (GB)

Vm 30282/3026 (NI)

5 and 20 kg polyethylene in paper outer bag
Not all pack sizes may be marketed.

15. 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.

16. Contact details

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

Huvepharma NV

Uitbreidingstraat 80

2600 Antwerpen

Belgium

+32 3 288 18 49

pharmacovigilance@huvepharma.com

Manufacturer responsible for batch release

Biovet JSC

39 Petar Rakov Str

4550 Peshtera

Bulgaria

17. Other information

POM-V

When the bag is broached for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any veterinary medicinal product remaining in the bag should be discarded should be worked out. This discard date should be written in the space provided on the label.

Gavin Hall

Approved: 19 March 2025