PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Paper bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tilmovet 100 g/kg Premix for medicated feeding stuff for pigs and rabbits
Tilmicosin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

100 g tilmicosin per kg

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff

4. PACKAGE SIZE

5 kg and 20 kg

5. TARGET SPECIES

Pigs (weaned piglets and fattening pigs) and rabbits

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

To be administered orally through the medicated feed
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Pigs: meat and offal 21 days
Rabbits: meat and offal: 4 days

9. SPECIAL WARNING(S), IF NECESSARY

None

10. EXPIRY DATE

<EXP {month/year}>
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

11. SPECIAL STORAGE CONDITIONS

Store in the original container.

Store in a dry place.
Store below 30°C.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local 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
Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Huvepharma N.V.
Uitbreidingstraat 80
2600 Antwerpen
Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 30282/4004

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

B. **PACKAGE LEAFLET**

Tilmovet 100 g/kg Premix for medicated feeding stuff for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation

Huvepharma N.V, Ultbreidingstraat 80, 2600 Antwerpen, Belgium

Manufacturer responsible for batch release

Biovet JSC, 39 Petar Rakov Str, 4550 Peshtera, Bulgaria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tilmovet 100 g/kg Premix for medicated feeding stuff for pigs and rabbits
tilmicosin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

The product is a yellowish tan to reddish tan free-flowing granular material containing 100 g tilmicosin per kg

4. INDICATION(S)

The product is indicated for the treatment of pneumonia in weaned piglets and fattening pigs, caused by *Actinobacillus pleuropneumoniae, Mycoplasma hyopneumoniae, Pasteurella multocida* and other organisms sensitive to tilmicosin.

5. CONTRAINDICATIONS

Do not use in animals hypersensitive to tilmicosin and when there is resistance to tilmicosin or cross resistance to other macrolides like tylosin, erythromycin or lincomycin.
Tilmicosin is known to be toxic for horses. Do not allow horses or other equines access to feeds containing tilmicosin.

6. ADVERSE REACTIONS

Occasionally, 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 in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (weaned piglets and fattening pigs) and rabbits

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral use. Mix 16 mg/kg bodyweight, in the feed for a period of 15 days.
To avoid underdosing body weight should be determined as accurately as possible

In order to calculate the exact amount of premix to be added to the feed, use the following formula to achieve the target dose:

$$\text{Kg premix/tonne of feed} = \frac{\text{Dose rate (mg/kg body weight)} \times \text{average bodyweight (kg)}}{\text{Average Feed intake (kg)} \times \text{premix strength (g/kg)}}$$

To ensure thorough dispersion of the 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.

9. ADVICE ON CORRECT ADMINISTRATION

Animals with acute infections may have a reduced feed intake and should be treated with a suitable injectable product.
To ensure thorough dispersion of the product it should first be mixed with a suitable quantity of feed before incorporation into the finished feed.

10. WITHDRAWAL PERIOD

Pigs: meat and offal 21 days
Rabbits: meat and offal: 4 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight 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 after the expiry date stated on the label.

12. SPECIAL WARNING(S)

Do not mix into feed containing bentonite.
Do not use simultaneously with other macrolides and lincosamides.
Do not use simultaneously with bacteriostatic antimicrobials.
Tilmicosin may less the antibacterial activity of β-lactam antibiotics.
Vomiting and cardio-vascular collapse are symptoms of overdosing.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products. Do not allow horses or other equines access to feeds containing tilmicosin

The safety of tilmicosin has not been established in boars used for breeding purposes.

Cross-resistance between tilmicosin and other macrolide antibiotic has been observed .Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies. 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.

Accidental ingestion should be avoided by humans. The handling of the product in case of known hypersensitivity to macrolide antibiotics must be avoided May cause sensitisation by skin contact. May cause skin and eye irritation. Avoid direct skin contact. Wear overalls, safety glasses and impervious gloves when mixing and handling the 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

6/2013

15. OTHER INFORMATION

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

5 and 20 kg polyethylene in paper outer bag
20 kg Polyethylene/Aluminium /polyethylene terephthalate bag with venting valve
Not all pack sizes may be marketed.

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 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.

Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

Approved: 01 February 2018