ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

40 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
Do not store above 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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

VM 30282/4005

17. MANUFACTURER'S BATCH NUMBER

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

B. PACKAGE LEAFLET

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

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

Marketing authorisation

Huvepharma NV, UItbreidingstraat 80, 2600 Antwerpen, Belgium

Manufacturers responsible for batch release

1. Biovet JSC, 39 Petar Rakov Str, 4550 Peshtera – Bulgaria
NI only:
2. QALIAN, 34 Rue Jean Monnet, Zone Industrielle d'Etriche, 49500 SEGRÉ, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tilmovet 40 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 40 g tilmicosin per kg

4. 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.

5. 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

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.

6. ADVERSE REACTIONS

In very rare cases (less than 1 animal in 10,000 animals*)*, 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

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:

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

Pigs
Administer in the feed at a dose of 8 to 16 mg/kg body weight/day of tilmicosin (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	5-10 kg 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
Prevention and treatment of respiratory disease	12 mg/kg bodyweight/day	7 days	5 kg 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 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. Medicated feed may be pelleted using a pre-conditioning step for 5 minutes at a temperature not exceeding 75°C.

10. WITHDRAWAL PERIOD

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 after the expiry date stated on the label.

12. SPECIAL WARNING(S)

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

Special precautions for use in animals

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.

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

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, national and regional 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.

Special precautions for the person administering the veterinary medicinal product to animals

- 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.

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.

Fertility
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 product is safe in sows whatever the pregnancy stages.
The safety of the veterinary medicinal product has not been established in boars used for breeding purposes.

Overdose (symptoms, emergency procedures, antidotes

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.

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

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

September 2022

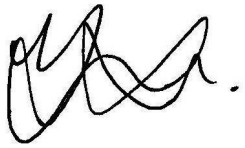
15. OTHER INFORMATION

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
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: 18 January 2023