LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TILMOVET 100 mg/g oral granules for pigs
Tilmicosin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each gram contains 100 mg of Tilmicosin.

3. PHARMACEUTICAL FORM

Granules
A brown granular powder.

4. PACKAGE SIZE

0.25 kg or 1 kg

5. TARGET SPECIES

Pigs (weaned piglets and fattening pigs)

6. INDICATION(S)

Read the package leaflet Before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration only after incorporation into feed.
The product should be administered to small quantities of feed for immediate consumption by individual animals. Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal 21 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet for full user safety warnings before use of this product.

10. EXPIRY DATE

<EXP {month/year}>
Shelf life after first opening of the immediate packaging : 3 months
Once broached use by

Feed to which the oral granules has been added should be replaced if not consumed within 24 hours.

11. SPECIAL STORAGE CONDITIONS

Store in the original container in order to protect from moisture.

Do not store above 30°C.

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

Disposal: read the package leaflet.

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

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

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

PACKAGE LEAFLET

TILMOVET 100 mg/g Granules 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 holder

Huvepharma NV, UItbreidingstraat 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 mg/g Oral Granules for pigs
tilmicosin

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

Each gram contains 100 mg of Tilmicosin.
brown granulated powder

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 adverse effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (weaned piglets and fattening pigs)

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

The product should be administered to small quantities of feed for immediate consumption by individual animals. For treatment of groups of pigs, use an appropriate premix incorporated into medicated feedingstuff by an authorised feed manufacturer. Pigs to be treated should be separated and treated individually. The required quantity of the product should be thoroughly mixed into the daily ration for each individual pig. The feed containing the granules should be provided as the sole ration for the periods recommended.

Individual pigs should receive 16 mg tilmicosin per kg bodyweight, corresponding to 160 mg product, once a day during 15 days. To avoid underdosing body weight should be determined as accurately as possible and the amount of feed that the pig is likely to consume should be estimated. The correct quantity of the product should be added to the estimated quantity of daily ration for each pig, in a bucket or similar receptacle, and thoroughly mixedThe product should only be added to dry non-pelleted feed.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Meat and offal 21 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 30ºC. Store in the original container in order to protect from moisture.Shelf life after first opening of the immediate packaging: 3 months
Do not use after the expiry date stated on the label.
Feed to which the oral granules has been added should be replaced if not consumed within 24 hours.

12. SPECIAL WARNING(S)

If for an individual animal, feed intake is such that the recommended dosage is not realized, medication should be carried out by parenteral treatment.

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.

Do not use simultaneously with other macrolides and lincosamides.

Vomiting and cardio-vascular collapse are symptoms of overdosing.

Do not mix into feed containing bentonite.
Never mix with other veterinary medicinal products.

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 can be used in sows whatever the pregnancy stages

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

User safety warnings
Accidental ingestion should be avoided by humans. People with known hypersensitivity to macrolide antibiotics should avoid contact with the veterinary medicinal product.
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 materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack size:
Pack of 0.25 kg or 1 kg in a polyethylene-lined 3-ply paper bag
Not all pack sizes may be marketed

For animal treatment only.
To be supplied only on veterinary prescription.

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