PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

250 ml polyethylene bottle with polypropylene screw cap or polyethylene screw cap with EPE PET liner.
1000 ml polyethylene bottle with polypropylene screw cap or polyethylene screw cap with EPE PET liner..

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tilmicosol 250 mg/ml Solution for Use in Drinking Water / Milk
Tilmicosin (as phosphate)

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance: Tilmicosin (as phosphate) 250 mg/ml

3. PHARMACEUTICAL FORM

Solution for use in drinking water/ milk

4. PACKAGE SIZE

250 ml
1000 ml

5. TARGET SPECIES

Chickens, (except hens producing eggs for human consumption), turkeys, pigs, calves (pre-ruminant cattle).

6. INDICATION(S)

Pigs: For the treatment and metaphylaxis of respiratory disease in pig herds, associated with *Mycoplasma hyopneumoniae, Pasteurella multocida, Actinobacillus pleuropneumoniae* susceptible to tilmicosin.
Chickens: For the treatment and metaphylaxis of respiratory disease in chicken flocks, associated with *Mycoplasma gallisepticum* and *M. synoviae* susceptible to tilmicosin.
Turkeys: For the treatment and metaphylaxis of respiratory disease in turkey flocks, associated with *Mycoplasma gallisepticum* and *M. synoviae* susceptible to tilmicosin.
Calves: For the treatment and metaphylaxis of bovine respiratory disease, associated with *Mannheimia haemolytica, Pasteurella multocida, Mycoplasma bovis, M. dispar* susceptible to tilmicosin.

The presence of the disease in the group/flock must be established before the product is used.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet on reverse of the label before use.
In drinking water/ milk use.

8. WITHDRAWAL PERIOD(S)

Meat and offal of:
Pigs: 14 days
Chickens: 12 days
Turkeys: 19 days
Calves: 42 days
Not for use in birds producing eggs for human consumption. Do not use within 14 days of the start of the laying period. Not authorised for use in animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Important: Must be diluted before administration to animals.
For oral use only. Do not inject.
Do not allow horses and other equines access to drinking water containing tilmicosin.
Do not administer to ruminating animals with active rumen function.

User Warnings:
People with known hypersensitivity to tilmicosin should avoid contact with the product.
When mixing the veterinary medicinal product direct contact with eyes, skin and mucous membranes should be avoided. Personal protective equipment should be worn.
In case of accidental ingestion seek medical advice immediately and show the label to the physician. See package leaflet for full user warnings.

10. EXPIRY DATE

EXP {month/year}
After first opening of container: 3 months
After dilution or reconstitution in drinking water according to directions: 24 hours.
After reconstitution in milk replacer: 6 hours.
Discard date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Store in the original container in order to protect from light. Do not freeze.

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

Disposal: read 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

Lavet Pharmaceutical Ltd.
2143 Kistarcsa
Batthyány u. 6.
Hungary

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32823/4003

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Tilmicosol 250 mg/ml solution for Use in Drinking Water/Milk

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

Marketing authorisation holder and manufacturer responsible for batch release:
Lavet Pharmaceuticals Ltd
2143 Kistarcsa
Batthyány u. 6.
Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tilmicosol 250 mg/ml Solution for Use in Drinking Water/ Milk
Tilmicosin (as phosphate)

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

Active substance: Tilmicosin (as phosphate) 250 mg/ml
Clear yellow to dark yellow solution.

Excipients:
Propyl gallate (E 310)
Disodium edetate

4. INDICATION(S)

Pigs: For the treatment and metaphylaxis of respiratory disease in pig herds, associated with *Mycoplasma hyopneumoniae, Pasteurella multocida, Actinobacillus pleuropneumoniae* susceptible to tilmicosin.
Chickens: For the treatment and metaphylaxis of respiratory disease in chicken flocks, associated with *Mycoplasma gallisepticum* and *M. synoviae* susceptible to tilmicosin.
Turkeys: For the treatment and metaphylaxis of respiratory disease in turkey flocks, associated with *Mycoplasma gallisepticum* and *M. synoviae* susceptible to tilmicosin.
Calves: For the treatment and metaphylaxis of bovine respiratory disease, associated with *Mannheimia haemolytica, Pasteurella multocida, Mycoplasma bovis, M. dispar* susceptible to tilmicosin.
The presence of the disease in the group/flock must be established before the product is used.

5. CONTRAINDICATIONS

Do not allow horses and other equines access to drinking water containing tilmicosin.

Do not use in case of hypersensitivity to tilmicosin or to any of the excipients.

Do not administer to ruminating animals with active rumen function.

6. ADVERSE REACTIONS

In very rare cases (less than 1 animal in 10,000 animals, including isolated reports), a decrease in water intake has been observed.
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 inform your veterinary surgeon.
Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Chickens (except hens producing eggs for human consumption), turkeys, pigs, calves (pre-ruminant cattle).

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

In drinking water/milk use

The product must be diluted in drinking water (pigs, chickens, turkeys) or milk replacer (calves) before administration.

Calves: 12.5 mg tilmicosin/kg body weight (i.e.1 ml of product per 20 kg BW), twice daily, for 3-5 consecutive days.

Pigs: 15-20 mg tilmicosin/kg body weight/day (i.e. 6-8 ml of product per 100 kg of BW per day), for 5 consecutive days, which may be achieved by the inclusion of 150-200 mg of tilmicosin per litre (60-80 ml of product per 100 litres based on a water consumption of 10 % of bodyweight).

Chickens: 15-20 mg tilmicosin/kg body weight/day (i.e. 6-8 ml of product per 100 kg of BW per day), for 3 consecutive days, which may achieved by the inclusion of 75-100 mg of tilmicosin per litre (30-40 ml of product per 100 litres based on a water consumption of 20 % of bodyweight).

Turkeys: 10-27 mg tilmicosin/kg body weight/day (i.e. 4-11 ml of product per 100 kg of BW per day), for 3 consecutive days, which may achieved by the inclusion of 143-386 mg of tilmicosin per litre (57-154 ml of product per 100 litres based on a water consumption of 7 % of bodyweight).

The exact concentration of the veterinary medicinal product required can be calculated according to the following formula:

ml product per litre drinking water per day = [ml product per kg bodyweight per day x average bodyweight (kg)] / average daily water intake (litre).

Bodyweight should be determined as accurately as possible to avoid under-dosing. The required dose should be measured using suitably calibrated measuring equipment. Only sufficient medicated drinking water should be prepared to cover the daily requirements. The medicated water should be the only source of drinking water for the animals for the entire duration of the treatment period. Water intake should be monitored at frequent intervals during medication. After the end of the medication period, the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance.

Medicated drinking water should be prepared fresh every 24 hours. Medicated milk replacer should be prepared fresh every 6 hours.

The medicinal product should be diluted with water or milk replacer prior to its use. When preparing a stock solution, the maximum concentration should not exceed 200 ml of product/litre. The lowest concentrations of the product at which stability can be assured are 0.3 ml product/litre drinking water and 0.8 ml product/litre milk replacer.

The uptake of medicated drinking water/milk replacer depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of the product should be adjusted accordingly.

9. ADVICE ON CORRECT ADMINISTRATION

Medicated drinking water should be prepared fresh every 24 hours using only clean water.
Medicated milk replacer should be prepared fresh every 6 hours using only clean water.
If signs of disease do not significantly improve within 3-5 days, the diagnosis should be re-evaluated and treatment changed.
To avoid underdosing body weight should be determined as accurately as possible. The uptake of medicated water/ milk replacer depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of the product has to be adjusted accordingly.

10. WITHDRAWAL PERIOD(S)

Meat and offal of:
Pigs - 14 days
Chickens - 12 days
Turkeys - 19 days
Calves - 42 days

Not authorised for use in birds producing eggs for human consumption. Do not use within 14 days of the start of the laying period.
Not authorised for use in animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Do not store above 25°C.

Store in the original container in order to protect from light. Do not freeze.

Do not use after the expiry date stated on the label.

The expiry date refers to the last day of that month.

Shelf-life after first opening the container: 3 months.

Shelf-life after dilution or reconstitution in drinking water according to directions: 24 hours.

Shelf-life after reconstitution in milk replacer: 6 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Important: Must be diluted before administration to animals
Pigs, chickens and turkeys: Water consumption should be monitored in order to guarantee adequate dosing. In case water consumption does not match quantities for which recommended concentrations were calculated, the concentration of product has to be adapted in a way that the recommend dosage will be taken up by the animals or different medication should be considered.
The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of water or milk replacer, animals should be treated parenterally using an appropriate injectable product.

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

Special precautions for use in animals:
For oral use only. Contains disodium edetate; do not inject.
Inappropriate use of the product may increase the prevalence of bacteria resistant to tilmicosin amd may decrease the effectiveness of treatment with tilmicosin-related substances. The use of the product should be based on susceptibility tests.
Official, national and regional antimicrobial policies should be taken into account when the product is used.

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.

To avoid exposure during preparation of the medicated drinking water, wear overalls, safety glasses, and impervious gloves. Do not eat, drink or smoke when handling this product. Wash hands after use.

In the case of accidental ingestion, wash out mouth immediately with water and seek medical advice. In the event of accidental skin contact, wash thoroughly with soap and water. In case of accidental eye contact, flush the eyes with plenty of clean, running water.

Do not handle the product if you are allergic to ingredients in the product.

If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Overdose (symptoms, emergency procedures, antidotes):

When pigs are offered drinking water containing 300 or 400 mg tilmicosin/litre (equivalent to 22.5-40 mg/kg bodyweight or 1.5-2 times the recommended concentration) commonly animals exhibit a reduced water intake. Although this has a self-limiting effect on tilmicosin intake, it could, in extreme circumstances, result in dehydration. This can be corrected by the removal of the medicated drinking water and replacement with fresh unmedicated water.

No symptoms of overdose have been seen in chickens given drinking water containing levels of tilmicosin up to 375 mg/litre (equivalent to 75-100 mg/kg bodyweight or 5 times the recommended dose) for 5 days, daily treatment with 75 mg/litre (equivalent to the maximum recommended dose) for 10 days resulted in a reduction in faecal consistency.

No symptoms of overdose have been seen in turkeys given drinking water containing levels of tilmicosin up to 375 mg/litre (equivalent to 50-135 mg/kg bodyweight or 5 times the recommended dose) for 5 days, daily treatment with 75 mg/litre (equivalent to the maximum recommended dose) for 6 days also produced no symptoms of overdose.

No symptoms of overdose, with exception of a slight decrease in the milk consumption, have been seen in calves given twice daily doses 5 times the maximum recommended dose or for twice the maximum recommended duration of treatment.

Pregnancy and lactation

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Incompatibilities:

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

Other precautions: Tilmicosin is known to be toxic to aquatic organisms, including cyanobacteria, with potentially long lasting effects.

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2023

15. OTHER INFORMATION

Pack sizes:

250 ml in white high density polyethylene bottle with polypropylene screw cap or polyethylene screw cap with EPE PET liner.

1000 ml in white high density polyethylene bottle with polypropylene screw cap or polyethylene screw cap with EPE PET liner and calibrated polypropylene measuring cup.

Not all pack sizes may be marketed.

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

Approved 07 November 2023