SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tilmovet 250 mg/ml Concentrate for Oral Solution *for pigs, chickens, turkeys and cattle (calves)*

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance
Tilmicosin: 250 mg per ml.
Excipients
For the full list of excipients: see section 6.1

3. PHARMACEUTICAL FORM

Concentrate for oral solution
Clear yellow to amber solution

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (broilers and pullets), turkeys, pigs and cattle (calves).

4.2 Indications for use, specifying the target species

Pigs: For the treatment and prevention of respiratory infections associated with Mycoplasma hyopneumoniae, Pasteurella multocida and Actinobacillus pleuropneumoniae when the disease has been diagnosed at the herd level.

Chickens:
For the treatment and prevention of respiratory infections in poultry flocks associated with Mycoplasma gallisepticum and Mycoplasma synoviae when the disease has been diagnosed at the herd level.

Turkeys: For the treatment and prevention of respiratory infections in turkey flocks associated with Mycoplasma gallisepticum and Mycoplasma synoviae when the disease has been diagnosed at the herd level.

Calves: For the treatment and prevention of respiratory infections associated with Mannheimia haemolytica, P. multocida, Mycoplasma bovis and M.dispar when the disease has been diagnosed at the herd level.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or in cases of known resistance to tilmicosin. Do not use in horses.

4.4 Special warnings (for each target species)

Tilmicosin should not be administered by injection to pigs. The product contains disodium edetate.The uptake of medicated water can be altered as a consequence of illness. If the uptake is insufficient alternative treatment may be required.

4.5 Special precautions for use

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 Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.
Do not allow horses or other equines access to drinking water containing tilmicosin.

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

People with known hypersensitivity to tilmicosin should avoid contact with the product. The veterinary medicinal product may cause irritation or sensitisation by skin contact.
Avoid skin and ocular contact. Wear protective gloves and protective clothes when handling the veterinary medicinal product.
In case of contact with skin or eyes, rinse abundantly with fresh water. If irritation persists and in case of incidental ingestion, seek immediately medical advice or call a poison center (dangers linked to disturbances in cardiac conduction).
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The safety of the product has not been established during pregnancy and lactation. Use only in accordance with risk/benefit assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Cross resistance between tilmicosin and other macrolide antibiotics and lincosamides has been observed.
Tilmicosin may lessen the antibacterial activity of β-lactam antibiotics

Do not use simultaneously with bacteriostatic antimicrobial agents.

4.9 Amount(s) to be administered and administration route

For oral use only. The product must be diluted in drinking water or milk replacer before administration.

Pigs:
15-20 mg tilmicosin per kg body weight for 5 days, i.e. 6-8 ml of product for 100 kg body weight corresponding to 80 ml of product per 100 litres of drinking water for 5 days.
Chickens:
15-20 mg tilmicosin per kg body weight for 3 days, i.e. 6-8 ml of product for 100 kg body weight corresponding to 30 ml of product per 100 litres of drinking water for 3 days.
Turkeys:
10-27 mg tilmicosin per kg body weight for 3 days, i.e. 4-11 ml of product for 100 kg body weight corresponding to 30 ml of product per 100 litres of drinking water for 3 days.
Calves:
12.5 mg tilmicosin per kg body weight two times per day for 3-5 days, i.e. 1 ml of product for 20 kg body weight two times per day for 3-5 days.

One 960 ml bottle is sufficient to medicate 1200 liters of drinking water for pigs or 3200 liters of drinking water for broilers, turkeys and pullets.
One 960 ml bottle is sufficient to medicate drinking water or milk replacer for 48 – 80 calves (40 kg b.w.).
One 240 ml bottle is sufficient to medicate drinking water or milk replacer for 8 calves (60 kg b.w.).

Medicated drinking water should be prepared fresh every 24 hours using only clean water.
Medicated milk replacer should be prepared fresh every 4 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 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
Do not administer to pigs in a wet feeding system.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Pigs drink less water when a dose of 300 to 400 mg/liter (1.5 to 2 times the recommended dose) is administered. Although this will result in less intake of tilmicosin, it might lead to dehydration of the animals. Replace with untreated water when needed.

No symptoms were seen in poultry treated at 375 mg/liter during 5 days. A dose of 75 mg/liter during 10 days resulted in less consistent faeces.

No symptoms of overdose were noticed in turkeys treated at 375 mg/liter of drinking water during 3 days. No symptoms were noticed at 75 mg/liter during 6 days.

Except for a slight decrease in milk intake, no symptoms of overdose were seen in calves treated at 5 times the recommended dose or during twice the recommended treatment period.

4.11 Withdrawal period(s)

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

Eggs: Not authorised for use in birds producing eggs for human consumption.

5. PHARMACOLOGICAL OR IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: antimicrobials for systemic use, macrolides

ATC vet code: QJ01FA91

5.1 Pharmacodynamic properties

Tilmicosin is a mainly bactericidal semi-synthetic antibiotic of the macrolide group. It is believed to affect bacterial protein synthesis.

Tilmicosin has a wide spectrum of activity against Gram-positive organisms and is particularly active against Pasteurella, Actinobacillus (Haemophilus) and Mycoplasma organisms of bovine, porcine and avian origin. Tilmicosin has some activity against certain Gram-negative micro-organisms. Cross resistance between tilmicosin and other macrolide antibiotics has been observed. Macrolides inhibit protein synthesis by reversibly binding to the 50S ribosomal subunitl. Bacterial growth is inhibited by induction of the separation of peptidyl transfer RNA from the ribosome during the elongation phase.

Ribosomal methylase, encoded by the erm gene, can precipitate resistance to macrolides by alteration of the ribosomal binding site.

The gene that encodes for an efflux mechanism, mef, also brings about a moderate degree of resistance.

Resistance is also brought about by an efflux pump that actively rids the cells of the macrolide. This efflux pump is chromosomally mediated by genes referred to as acrAB genes. Resistance of Pseudomonas species and other Gramnegative bacteria, enterococci and staphylococci may be precipitated by chromosomally controlled alteration of permeability or uptake of the drug.

5.2 Pharmacokinetic properties

When administered orally to chickens, turkeys and pigs with drinking water and to calves with milk replacer, tilmicosin is absorbed and moves rapidly out of the serum into areas of low pH. This results in very low serum concentrations, but detectable levels of tilmicosin are found in lung tissue as early as 6 hours after

starting the treatment. In chicken or turkeys, tilmicosin is also detected in pooled air sac tissue as early as 6 hours after starting the treatment. It is also known that tilmicosin is concentrated in alveolar macrophages of swine. When administered orally to calves tilmicosin is detected in lungs after 6 hours and remains at the therapeutic level up to 60 hours from the last dose.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propyl gallate (E310)
Disodium edetate
Phosphoric acid concentrated
Purified water

6.2 Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 3 months
Shelf life after dilution in drinking water: 24 hours
Shelf life after reconstitution in milk replacer: 4 hours

6.4 Special precautions for storage

As packaged for sale: Do not store above 30°C. Protect from frost. Protect from light.

After dilution in drinking water / milk replacer: Protect from light.

6.5 Nature of composition of immediate packaging

960 ml is presented in a white high density polyethylene bottle with white polypropylene or high density polyethylene, tamper-evident cap; 240 ml is presented in high density polyethylene (HDPE) bottle with a tamper-evident screw closure made of polypropylene (PP).

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 30282/4001

9. DATE OF FIRST AUTHORISATION

28 October 2008

10. DATE OF REVISION OF THE TEXT

May 2017

Approved: 04 May 2017