SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tilmovet 250 mg/ml Concentrate for Oral Solution (BE, BG, CZ, EL, HU, IE, NL, PL, RO, UK)
for pigs, chickens, turkeys and calves
Tilmovet 250 mg/ml Concentrado en Solución Oral (ES)
Tilmovet 250 mg/ml Concentrado Liquido per Uso Orale (IT)
Tilmovet 250 mg/ml Solution Buvable (FR)
Tilmovet 250 mg/ml Lösung (AT, DE)
Tilmovet 250 mg/ml Solução Oral (PT)
Tilmovet Vet, oral opløsnung (DK)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Tilmicosin: 250 mg per ml.
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 (except hens producing eggs for human consumption), 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 (broilers and pullets):
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)

Must be diluted in drinking water or milk replacer before administration. Protect from light after reconstitution.For oral use only. Tilmicosin should not be administered by injection to pigs. The product contains disodium edetate.

4.5 Special precautions for use

i. Special precautions for use in animals

Pigs, broilers and turkeys: Due to the administration route and as water consumption depends on the clinical condition of the animal, in order to ensure a correct dosage, the concentration of the product must be adjusted according to the water intake. If this is not possible, then an alternative medication may be required.
Animals with acute infections and severely reduced feed intake should be treated first with a suitable injectable product.

The medicated water should be prepared fresh every 24 hours.
The medicated milk replacer should be prepared fresh every 4 hours.

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. It is sound clinical practice to base treatment on susceptibility testing.

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

ii. 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. Do not use in pullets and laying hens producing eggs for human consumption.

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

4.9 Amount(s) to be administered and administration route

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 100kg 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 100kg 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.).

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.

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
Broilers: 12 days
Turkeys: 19 days

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

5. PHARMACOLOGICAL OR IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QJ01FA91

Pharmacotherapeutic group: Macrolide antibiotic

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.

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 edentate (E386)
Phosphoric acid concentrated
Purified water

6.2 Incompatibilities

None known

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 according to directions: 24 hours
Shelf life after reconstitution in milk replacer according to directions: 4 hours

6.4 Special precautions for storage

Do not store above 30°C. Protect from frost. Protect from light.

6.5 Nature and 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.

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 national requirements.

7. MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

8. MARKETING AUTHORISATION NUMBER(S)

Vm 30282/4001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28 October 2008

10. DATE OF REVISION OF THE TEXT

April 2010

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable