**COMPOSITION**

<table>
<thead>
<tr>
<th>Content</th>
<th>Tilmovet® 250</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tilmicosin</td>
<td>250 mg</td>
</tr>
<tr>
<td>Excipients: propyl gallate (E310), disodium edetate, phosphoric acid concentrated, purified water</td>
<td>Up to 1 ml</td>
</tr>
</tbody>
</table>

**PHARMACOLOGICAL ACTION**

Tilmicosin is a mainly bacteriostatic semi-synthetic antibiotic of the macrolide group. It affects 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 activity against certain Gram-negative micro-organisms. Cross-resistance between tilmicosin and other macrolide antibiotics has been observed. 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 chickens 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 swines. 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.

**INDICATIONS**

**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, Pasteurella multocida, Mycoplasma bovis* and *Mycoplasma dispar* when the disease has been diagnosed at the herd level.

**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. Do not administer to pigs in a wet feeding system. 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.
MODE OF ADMINISTRATION

Orally, must be diluted in drinking water or milk replacer before administration. Protect from light after reconstitution. Tilmicosin should not be administered by injection to pigs. The product contains disodium edetate.

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. 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.

TARGET SPECIES

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

DOSAGE

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.). 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.

SIDE EFFECTS

None known. Except for a slight decrease in milk intake, no symptoms of overdose are seen in calves treated at 5 times the recommended dose or during twice the recommended treatment period.

WITHDRAWAL PERIOD

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.

STORAGE

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

960 ml is presented in a white high density polyethylene bottle with white polypropylene or high density polyethylene, tamper-evident cap.

WARNING

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