

## Veterinary Package Insert

### TP-MECOTIL 300 SOL TILMICOSIN PHOSPHATE 300MG/ML SOLUTION

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#### PRODUCT DESCRIPTION

Light brown to brown colour liquid, which contains 30% of tilmicosin phosphate in 250ml bottle.

#### PHARMACODYNAMICS & PHARMACOKINETICS

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.

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.

#### INDICATION

##### 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.

#### RECOMMENDED DOSAGE AND ADMINISTRATION

It is to be given orally. The recommended dosage is as following:

##### Chickens:

15-20 mg tilmicosin per kg body weight for 3 days, i.e. 5.5 - 7.5 ml of product for 100kg body weight corresponding to 28 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. 3.8 - 10 ml of product for 100kg body weight corresponding to 28 ml of product per 100 litres of drinking water for 3 days.

##### Pigs:

15-20 mg tilmicosin per kg body weight for 5 days, i.e. 5.5 - 7.5 ml of product for 100 kg body weight corresponding to 74 ml of product per 100 litres of drinking water for 5 days.

#### CONTRAINDICATIONS

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

#### WARNINGS & PRECAUTIONS.

##### 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.

##### 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.

Special precautions to be taken by the person administering the 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.

Wash hands after use.

#### INTERACTIONS WITH OTHER MEDICATIONS

Cross resistance between tilmicosin and other macrolide antibiotics and lincosamides has been observed.

Tilmicosin may lessen the antibacterial activity of  $\beta$ -lactam antibiotics

#### PREGNANCY AND LACTATION

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.

#### ADVERSE EFFECTS

None known.

#### OVERDOSE & TREATMENT

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.

#### WITHDRAWAL PERIOD

Meat and offal: Pigs: 14 days

Broilers: 12 days

Turkeys: 19 days

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

#### MAXIMUM RESIDUAL LIMIT (MRL)

| Substance  | Food                          | Maximum Residue Limits (MRLs) in food $\mu\text{g/kg}$ |
|------------|-------------------------------|--------------------------------------------------------|
| Tilmicosin | Muscle, fat (poultry and pig) | 100                                                    |
|            | Liver (pig)                   | 1500                                                   |

#### STORAGE CONDITION

Store below 30°C. Protect from direct sunlight.

#### SHELF LIFE

2 years.

After 1st opening, reconstitution or dilution, use within 24 hours.

#### THYE PHARMA SDN. BHD.

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