

Veterinary Package Insert

Product Name: **TIMICOS 250MG/ML SOLUTION**

Product Description:

Amber yellow colour solution, which contains 250mg of Tilmicosin Phosphate in 1ml.

Target Species:

Swine, Others: Pigs

Pharmacodynamics:

Tilmicosin is a semi-synthetic antibiotic of the macrolide group, and is believed to affect protein synthesis. It has bacteriostatic action but at high concentrations it may be bactericidal.

This antibacterial activity is predominantly against Gram-positive microorganism with activity against certain gram-negative ones and Mycoplasma of a bovine, porcine and avian origin. In particular, its activity has been demonstrated against the following microorganism:

Pigs: *Mycoplasma hyopneumoniae*, *Pasteurella multocida* and *Actinobacillus pleuropneumoniae*

Scientific evidence suggests that macrolides act synergistically with the host immune system. Macrolides appear to enhance phagocyte killing of bacteria. Tilmicosin has been shown to inhibit *in vitro* the replication of the Porcine Reproductive and Respiratory Syndrome virus in alveolar macrophages in a dose dependent fashion.

Cross-resistance between tilmicosin and other macrolides and lincomycin has been observed.

CLSI breakpoints for tilmicosin *	resistant	intermediate	susceptible
Porcine <i>Pasteurella multocida</i>	≥ 32 µg/ml	-	≤ 16 µg/ml
Porcine <i>Actinobacillus pleuropneumoniae</i>	≥ 32 µg/ml	-	≤ 16 µg/ml

* VET08, 4th ed. June 2018

Pharmacokinetics:

Whilst blood concentrations of tilmicosin are low, there is pH-dependent macrophage accumulation of tilmicosin in inflamed tissue.

Pigs: After oral administration of 200 mg tilmicosin/litre drinking water, the average active substance concentrations detected in lung tissue, alveolar macrophages and bronchial epithelium 5 days after the start of treatment were reported 1.44 µg/ml, 3.8 µg/ml and 7.4 µg/g respectively.

Indications:

Water medication for the treatment of pneumonia in pigs caused by *Actinobacillus pleuropneumoniae*, *Actinomyces pyogenes*, *Mycoplasma hyopneumoniae*, *Pasteurella multocida*, and other organisms sensitive to tilmicosin.

Recommended Dosage:

Prepared medicated drinking water should be used within 24 hours of mixing.

To be included in the drinking water at a dose rate of 200mg per litre (89mL Timicos 250mg/ml solution per 100L water) for five consecutive days, to provide a daily dose of 15-20mg tilmicosin per kg bodyweight.

Tilmicosin has a bitter taste. Exceeding the registered dose rate may result in reduced water intake. Monitor water intake carefully whilst medicating with Timicos 250mg/ml solution.

Environmental Properties:

Sludge from waste treatment ponds must be disposed of in approved landfills or contaminated wastes. This product may accumulate in soils. DO NOT spread effluent containing tilmicosin on the same pastures or croplands in successive years. DO NOT allow wastes from pigs treated with tilmicosin to enter waterways. These wastes contain tilmicosin which is highly toxic to algae.

Contraindications:

N/A

Warning and Precautions:**Precautions:**

Use with caution, horses or other equines should not have access to drinking water containing tilmicosin.

The safety of tilmicosin has not been established in boars intended for breeding purposes.

Any variation by the prescribing veterinarian to the approved dose, frequency, duration, route, disease or target species may require extending the approved withholding period.

Safety Directions:

Will irritate the eyes. Repeated exposure may cause allergic disorders. Avoid contact with skin and eyes. Wash hands after use. When opening the container and using the product, wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow-length PVC gloves and goggles. After each day's use, wash gloves, goggles and contaminated clothing.

Interactions with other medicaments:

Tilmicosin may lessen the antibacterial activity of beta-lactam antibiotics.

Do not use simultaneously with bacteriostatic antimicrobials.

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.

Adverse Effects:

N/A

Symptoms and Treatment of Overdose:

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.

Mode of Administration:

Oral

Withdrawal Period:

MEAT: DO NOT USE less than 7 days before slaughter for human consumption

Packaging:

Packed in 1L plastic HDPE bottle with screw cap

Storage Condition:

Store below 30°C in dry place, protected from light.

Shelf Life

Two years from date of manufacturing

To be used within 24 hours after first opening of container.

To be used within 24 hours after dilution.

Product Registration Holder
DEXCHEM INDUSTRIES SDN. BHD.

(Company No.: 555717-U)

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Manufactured by:

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