TILMO-X 250MG/ML ORAL SOLUTION

Tilmo-X 250mg/ml Oral Solution appears to be a yellowish brown to brown color, clear solution.

Composition

Each ml contains

Tilmicosin 250mg

Pharmacodynamics

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.

Pharmacokinetics

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.

Indications

Pigs: For the treatment and metaphylaxis of respiratory infections associated with *Mycoplasma hyopneumoniae, Pasteurella multocida and Actinobacillus pleuropneumoniae*.

Chickens & Turkey: For the treatment and prevention of respiratory infections associated with *Mycoplasma gallisepticum* and *Mycoplasma synoviae.*

Cattle (Calves): For the treatment and prevention of respiratory infections associated with *Mannheimia haemolytica, P. multocida, Mycoplasma bovis* and *M.dispar.*

The presence of the disease in the herd must be established before the veterinary medicinal product is used.

Recommended Dosage

For oral use only. The product must be diluted in drinking water or milk replacer before administration. To ensure a correct dosage, body weight should be determined as accurately as possible. The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of tilmicosin may need to be adjusted accordingly.

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 (broilers and pullets): 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 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.

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.

Contraindication

Do not administer to ruminating animals with active rumen function.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

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

Horses fed with water containing tilmicosin may present signs of toxicity with lethargy, anorexia, reduction of feed consumption, loose stools, colic, distension of the abdomen and death.

Warning and Precautions

Special warnings

The uptake of medicated water can be altered as a consequence of illness. If the uptake is insufficient alternative treatment may be required.

Repeated use of the veterinary medicinal product should be avoided by improving management practices and thorough cleansing and disinfection.

Cross-resistance has been shown between tilmicosin and other macrolides (like tylosin, erythromycin) or lincomycin. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to other macrolides or lincosamides because its effectiveness may be reduced.

Special precautions for use in the target species

Do not use when there is resistance to tilmicosin or cross resistance to other macrolides (like tylosin, erythromycin) or lincomycin.

Inappropriate use of the veterinary medicinal product may increase the prevalence of bacteria resistant to tilmicosin and may decrease the effectiveness of treatment with tilmicosin related substances.

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Special precautions to be taken by 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 sensitization by skin contact.

Avoid skin and ocular contact. Wear protective gloves and protective clothes when handling the veterinary medicinal product. Do not eat, drink or smoke when handling this 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.

Interactions with Other Medicaments

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

Do not use simultaneously with bacteriostatic antimicrobial agents.

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.

Side effects

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

Very rare (<1 animal / 10,000 animals treated, including isolated reports)	Decreased drinking

Overdose and 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 (s)

Meat and offal:

Pigs: 14 days.

Cattle (Calves): 42 days.

Chickens (broilers and pullets): 12 days.

Turkeys: 19 days.

Not for use in birds producing eggs for human consumption.

Do not use within 2 weeks before the start of the laying period.

Not authorised for use in animals producing milk for human consumption.

Storage Condition

Store below 30°C. Protect from heat and sunlight exposure.

Keep out of reach of children/ Jauhkan daripada kanak-kanak.

Unused veterinary medicinal products or residues thereof should be disposed of in accordance with local requirements.

Shelf life as packaged for sale: 3 years.

Shelf life after first open: 28 days.

Shelf life after dilution (Medicated drinking water): 24 hours.

Shelf life after dilution (Medicated milk replacer): 4 hours.

Packaging

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Product Registration Holder/Distributor

Fijiliam Enterprise Sdn. Bhd.
100 & 101, Taman A.S.T,
Jalan Sungai Ujong, 70200 Seremban,
Negeri Sembilan, Malaysia .

Manufacturer

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