TILMICOSIN 50%

WATER SOLUBLE POWDER

COMPOSITION: Contains per 500G PACK

Tilmicosin Phosphate.....250.0 g
Lactose Powder.....250.0 g

DESCRIPTION:

Tilmicosin is bacteriostatic and belongs to the macrolide antibiotic. It is used in veterinary medicine for the treatment of respiratory disease and enzootic pneumonia in poultry and cattle.

Tilmicosin 50% Water Soluble Powder is a free-flowing almost-white to pale-yellow powder which is odourless to almost odourless.

Tilmicosin 50% Water Soluble Powder is freely soluble in a 1% w/v solution and forms a clear to almost clear solution without any precipitate.

Tilmicosin 50% Water Soluble Powder has a pH range of 5.5 to 7.5 in a 1% w/v solution.

Tilmicosin 50% Water Soluble Powder contains Tilmicosin Phosphate 50.0% with lactose used as diluent.

Tilmicosin 50% Water Soluble Powder contains not less than 95.0% and not more than 105.0% of the label stated amount of Tilmicosin Phosphate.

Tilmicosin 50% Water Soluble Powder should be stored in an airtight container and protected from light and moisture.

PHARMACODYNAMICS:

Tilmicosin is a macrolide antibiotic with *in vitro* antibacterial activity primarily against Gram-positive bacteria, although certain Gram-negative bacteria are also susceptible. Macrolides interfere with bacterial protein synthesis by reversibly binding to the 50S subunit of the ribosome. They are typically regarded as being bacteriostatic, but at high concentrations can be bactericidal.

PHARMACOKINECTICS:

Tilmicosin is rapidly absorbed and slowly eliminated from the body. Tilmicosin distributes rapidly to the target tissues. Detectable levels are found in lung tissue as early as 6 hours and peak at about 5 days after the commencement of

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treatment. The relationship of serum Tilmicosin concentration to lung Tilmicosin concentration or the concentrations in bronchial secretion has not been

determined. In addition, the extent to which total lung concentrations represent free (active) drug has not been defined. Therefore, no conclusions can be made with regard to the clinical relevance of elevated Tilmicosin concentrations in the lung. Tilmicosin has been shown to concentrate within alveolar macrophages. It is also found at fairly high concentrations in liver and kidney tissue, as it is excreted both via the bile into the faeces and also via the urine.

INDICATIONS:

Tilmicosin 50% Water Soluble Powder is highly effective against C.R.D. caused by Mycoplasma, Actinobacillus, Haemophilus, Pasteurella multocida as well as for usage in secondary infections.

DOSAGE:

Prevention: Use 1g per 10 litres of drinking water for 3-5 days.
Treatment: Use 1g per 4-5 litres of drinking water for 5-7 days.

CONTRAINDICATIONS/SAFETY DATA:

Solutions of Tilmicosin salts have an acid pH and incompatibility may reasonably be expected with alkaline preparations, or with drugs unstable at low pH. The cardiovascular system is the target of toxicity and should be monitored closely. Cardiovascular toxicity may be due to calcium channel blockade. Administration of intravenous calcium offset tilmicosin-induced tachycardia and negative inotropy (decreased contractility). Dobutamine partially offset the negative inotropic effects induced by tilmicosin injection. ß-adrenergic antagonists, such as propranolol, exacerbated the negative inotropy of tilmicosin injection. Epinephrine potentiated lethality of tilmicosin. This antibiotic persists in tissues for several days.

Decreased water consumption was observed in healthy animals administered tilmicosin in target animal safety studies. Ensure that animals have continuous

access to medicated water during the treatment period. Monitor animals for signs of water refusal and dehydration while being treated. If decreased water consumption occurs, replace the medicated drinking water with fresh non-medicated water and contact your veterinarian.

INTERACTIONS WITH OTHER MEDICATIONS

Tilmicosin has neuromuscular blocking activity in high doses and may enhance the effect of other drugs with this action, with a potential danger of respiratory depression. Tilmicosin may antagonise the activity of parasympathomimetics.
Cross-resistance between Tilmicosin and other macrolides like Lincomycin has been observed.

PREGNANCY AND LACTATION

Tilmicosin 50% Water Soluble Powder should not be given to pregnant animals and lactating animals.

SIDE EFFECTS:

Tilmicosin is reported to produce diarrhoea in many animals after systemic use; in some animals, severe antibiotic-associated or pseudomembranous colitis may develop, and has proved fatal. The syndrome, which may develop during therapy or several weeks later, appears to be due to toxins produced by *Clostridium* spp., most notably *C. difficile.* It has been reported to be more frequent in females and in old animals, and may also occur rarely after topical use. Other gastrointestinal effects reported with tilmicosin include nausea, vomiting, abdominal pain or cramps, and unpleasant or metallic taste after high intravenous doses.

SYMPTOMS AND TREATMENT OF OVERDOSE

When given parenterally or in excessive oral dosage, the major adverse effects of the Tilmicosin are dose-related neurotoxicity and nephrotoxicity. Hypersensitivity reactions are rare, although rashes and fever have been reported.
Tilmicosin is potent neuromuscular blocker, and respiratory paralysis and apnoea may result, especially in animals with renal impairment or pre-existing disorders of neuromuscular transmission such as myasthenia gravis, in whom particular care is needed. Neostigmine or calcium salts may be used in reversing neuromuscular blockade and artificial ventilation may be required if it develops.
Nephrotoxicity may occur in up to 20% of animals following parenteral use and may be marked by nitrogen retention, haematuria, proteinuria, and tubular necrosis.

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Electrolyte disturbances are common. Animals with pre-existing renal impairment are at particular risk and require dosage reduction. Renal function should be monitored. Signs of increasing nitrogen retention are an indication for dosage reduction in all animals and the drugs should be withdrawn if oliguria occurs.

WITHDRAWAL TIMES:
Poultry: 7 days
Eggs: 10 days

STORAGE
Store in a cool and dry place
Store in an airtight container
For Veterinary Use Only
Keep out of the reach of children

PROPOSED SHELF LIFE:
2 years as packaged for sale

Manufactured by:
Vetpharm Lab (S) Pte Ltd
27, Tuas Ave 13, #01-25
Singapore 638993

Distributor:
ADVANCE ANIMAL SCIENCE COMPANY LTD
149-A, DIT EXTENSION ROAD
MOTIJHEEL
DHAKA 1000. BANGLADESH

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WONG MUN CHIANG, BBM
Managing Director/Pharmacist