125/52 mm

Pantone 227
Pantone 377

RESTRICTED VETERINARY MEDICINE
KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL TREATMENT ONLY

TilmoVet®

300 Injection
Contains tilmicosin 300 mg/mL
Net Contents 100mL
READ LABEL AND LEAFLET BEFORE USE

Indications
For use in cattle for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia (Pasteurella) haemolytica* and *Pasteurella multocida*, and other organisms sensitive to tilmicosin.
For the treatment of footrot in sheep.

Directions for use
INJECT ONLY SUBCUTANEOUSLY IN THE ANTERIOR HALF OF THE NECK.
CATTLE: For BRD, administer a single subcutaneous dose of 10 mg/kg of body weight (1mL per 30kg). Do not inject more than 15mL per injection site.
SHEEP: For footrot, administer a single subcutaneous dose of 5mg/kg of body weight (1mL per 60kg). Do not treat lambs weighing less than 15kg. If no improvement is noted within 48 hours, the diagnosis should be re-evaluated.

CAUTION: The safety of tilmicosin has not been established in pregnant cattle or in animals used for breeding purposes. Intramuscular injection will cause a local reaction that may result in trim loss.

CONTRAINDICATION: Intravenous injection in cattle may be fatal. Injection has been shown to be fatal in swine, non-human primates, goats and lambs less than 15 kg bodyweight and it may be fatal in horses.

It is an offence for users of this product to cause residues exceeding the relevant MRL in the Food Notice: Maximum Residue Levels of Agricultural Compounds.

Withholding Period:
Meat: Animals producing meat and offal for human consumption must not be slaughtered within
Cattle: 28 days of last treatment
Sheep: 42 days of last treatment
Milk: Milk intended for sale for human consumption must be discarded during treatment and for not less than 35 days following the last treatment.
Store below 25°C protected from sunlight. Store locked up. Use within 28 days of opening.

Manufactured in Europe by Huvepharma EOOD
Registered in New Zealand to AgriHealth NZ Ltd
0800 821 421
www.agrihealth.co.nz
TilmoVet is registered pursuant to the ACVM Act 1997, No. A011195.
See www.foodsafety.govt.nz for registration conditions.

WARNING
May be harmful if swallowed. Causes skin irritation. Causes eye irritation. Very toxic to aquatic life. Harmful to terrestrial vertebrates. Wear protective gloves. Take off contaminated clothing and wash before reuse. Wash hands and exposed skin thoroughly after handling. Do not eat, drink or smoke when using this product.
IF ON SKIN: wash with plenty of soap and water. If skin irritation occurs, get medical advice or attention.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If medical advice is needed, have product container or label at hand. Injection in humans has been associated with fatalities. Exercise extreme caution to avoid accidental self-injection. Do not work alone when using TilmoVet. Do not use in automatically powered injectors or syringes. Do not carry a syringe loaded with TilmoVet with the needle attached, except for filling the syringe or for administration to the animal. Remove needle at all other times. In case of human injection, consult a physician immediately and apply ice or cold pack to the injection site. Call the National Poisons Centre 0800 764 766 or a doctor/physician if exposed or you feel unwell, or in the case of self-injection. 0800 POISON (0800 764 766). Avoid release to the environment. Collect spillage.
NOTE TO PHYSICIAN:
The cardiovascular system is the target of toxicity (possibly due to calcium channel blockade) and should be monitored closely. In dogs, administration of intravenous calcium offset tilmicosin-induced tachycardia and negative inotrophy (decreased contractility). Dobutamine partially offset the negative inotrophic effects in dogs. Beta-adrenergic antagonists, such as propranolol, exacerbated the negative inotrophy of tilmicosin in dogs, and should not be used. Adrenaline potentiated lethality of tilmicosin in pigs and should not be used. Tilmicosin persists in tissues for several days. Monitor the cardiovascular system and provide supportive treatment.

AgriHealth

Batch:
Expiry:

LBB2094v2-TIL30injsol100-NZ0617

Expiry:
Batch No:
3 800043 725215 >

TilmoVet®
300 Injection
100 mL

120/150 mm leaflet insert

LfB2094v1-TIL30si-NZ0617

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TilmoVet
300 Injection
Contains tilmicosin 300 mg/mL

Indications
For use in cattle for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia (Pasteurella) haemolytica* and *Pasteurella multocida*, and other organisms sensitive to tilmicosin. For the treatment of footrot in sheep.
TilmoVet 300 Injection is a sterile solution containing 300 mg/mL tilmicosin . Tilmicosin is a semi-synthetic antibiotic of the macrolide class. It has been shown to be active *in vitro* mainly against Gram positive organisms (Streptococci, Staphylococci) and some Gram negative microorganisms (Pasteurella spp, Mannheimia haemolytica), as well as against Mycoplasma spp.

TOXICOLOGY: The heart is the target of toxicity in laboratory and domestic animals given tilmicosin by oral or parenteral routes. The primary cardiac effects are increased heart rate (tachycardia) and decreased contractility (negative inotrophy). Cardiovascular toxicity may be due to calcium channel blockade.
Upon injection subcutaneously, the acute median lethal dose (LD_{50})of tilmicosin in mice is 97 mg/kg and in rats is 185 mg/kg of bodyweight. Given orally the LD_{50} is 800 mg/kg and 2250 mg/kg in fasted and non-fasted rats respectively.
In dogs, intravenous calcium offset tilmicosin-induced tachycardia and negative inotrophy, restoring arterial pulse pressure. Dobutamine partially offset the negative inotrophic effects caused by tilmicosin in dogs. Beta-adrenergic antagonists such as propranolol exacerbated the negative inotrophy of tilmicosin in dogs. In monkeys, a single intramuscular dose of 10 mg/kg caused no signs of toxicity. A single dose of 20 mg/kg caused vomiting and 30 mg/kg caused the death of the only monkey tested.
In swine, an intramuscular injection of 10 mg/kg caused increased respiration, emesis and a convulsion. A dose of 20 mg/kg resulted in mortality in 3 of 4 pigs and 30 mg/kg caused the deaths of all 4 pigs tested. Injection of 4.5 and 5.6 mg/kg intravenously followed by 1 mL adrenaline (1:1000) intravenously 2 to 6 times, resulted in death of all pigs injected. Pigs given 4.5 mg/kg and 5.6 mg/kg intravenously with no adrenaline all survived. These results suggest intravenous adrenaline may be contraindicated.
In cattle, subcutaneous doses of TilmoVet at 10 and 20 mg/kg of body weight, each injected three times at 24 hour intervals, did not cause any deaths. Oedema at the site of injection was noted. Subcutaneous dose of 150 mg/kg injected at 72 hour intervals resulted in deaths, with marked oedema at the injection site, and minimal myocardial necrosis observed at autopsy.

PHARMACOLOGY: Tilmicosin, 20-deoxo-20-(3,5-dimethylpiperidin-1-yl)-desmycosin is a chemically modified long-acting macrolide antibiotic. A single subcutaneous dose of tilmicosin at 10 mg/kg bodyweight reached maximal blood tilmicosin levels in one hour, and maintained therapeutic concentrations in the target tissues for at least three days. It is concentrated in the lungs, penetrating intracellularly in the alveolar macrophages.

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