

# Tilmodil 300mg/ml Solution for Injection for Cattle and Sheep

## Introduction



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## Presentation

A clear, yellowish to brown-yellowish solution for injection containing 300mg of tilmosin per ml and propylene glycol.

## Uses

Indicated for:

- the treatment of pneumonia in cattle and sheep, associated with *Mannheimia haemolytica*, *Pasteurella multocida* and other microorganisms sensitive to tilmosin
- the treatment of ovine mastitis associated with *Staphylococcus aureus* and *Mycoplasma agalactiae*
- the treatment of interdigital necrobacillosis in cattle (bovine pododermatitis, foul in the foot)
- the treatment of ovine footrot

## Dosage and administration

A single subcutaneous injection of 0.5 or 1ml Tilmodil per 30kg body weight in cattle and sheep (eq. to 5 or 10mg tilmosin per kg, respectively).

**Cattle:** For pneumonia in cattle, use 10mg/kg body weight (1ml per 30kg body weight). For interdigital necrobacillosis in cattle, use 5mg/kg body weight (0.5ml per 30kg body weight).

Withdraw the required dose from the vial and remove the syringe from the needle. If a group of animals is to be treated, leave the needle in the vial as a draw-off needle for subsequent doses. Restrain the animal and insert a separate needle subcutaneously into the injection site. Injection in a fold of skin over the rib cage behind the shoulder is suggested. Connect the syringe to the needle and inject into the base of the skin fold. Do not inject more than 20ml per injection site.

**Sheep:** For pneumonia and mastitis in sheep, use 10mg/kg body weight (1ml per 30kg body weight). Do not inject lambs weighing less than 15kg, since there is a real risk of overdosage toxicity. The use of a 2ml or smaller syringe will facilitate accurate dosing. For the treatment of footrot, use 5mg/kg body weight (0.5ml per 30kg body weight). Due to the potential of inaccurate dosing leading to overdosing, this product should not be used to treat footrot in sheep weighing less than 30kg.

Withdraw the required dose from the vial and remove the syringe from the needle, leaving the needle in the vial. Restrain the sheep whilst leaning over the animal and insert a separate needle subcutaneously into the injection site, which should be in a fold of skin over the rib cage behind the shoulder. Connect the syringe to the needle and inject into the base of the skin fold. Use the same draw-off needle for the whole group to be treated.

Avoid introduction of contamination into bottle during use. Should any growth or discolouration occur the product should be discarded. Do not breach the vial more than 25 times.

If no improvement is noted within 48 hours, the diagnosis should be confirmed.

## Contra-indications, warnings, etc

Do not administer intravenously. Do not administer to pigs, horses and goats.

**Adverse reactions:** Occasionally, a soft diffuse swelling may occur at the injection site but this disappears within five to eight days. Deaths of cattle have been observed following a single intravenous dose of 5mg/kg, and following the subcutaneous injection of doses of 150mg/kg at 72 hour intervals. In pigs, intramuscular injection at 20mg/kg has caused deaths. Sheep have died following a single intravenous injection of 7.5mg/kg.

**Special warnings:** Official, national and regional antimicrobial policies should be taken into account when the product is used. In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

**Overdose:** The acute manifestations of multiple injections of large subcutaneous doses (150mg/kg) in cattle included moderate electrocardiographic changes accompanied by mild focal myocardial necrosis, marked injection site oedema, and death. Single subcutaneous injections of 30mg/kg in sheep produced increased respiration rate, and at higher levels (150mg/kg) ataxia, lethargy and drooping of the head.

**Withdrawal periods:** Cattle must not be slaughtered for human consumption for at least 60 days after treatment. Sheep must not be slaughtered for human consumption for at least 42 days after treatment. Ewe's milk must not be delivered for human consumption for at least 15 days (360 hours) after treatment. Do not use in cows producing milk for human consumption. Do not use in pregnant dairy heifers or dry dairy cows within 60 days of calving.

**User warnings:** **INJECTION OF THIS DRUG IN HUMANS CAN BE LETHAL – Exercise extreme caution to avoid accidental self-injection and follow the administration instructions and the guidance below precisely:**

- This product should only be administered by a veterinary surgeon.
- Never carry a syringe loaded with Tilmodil with the needle attached. The needle should be connected to the syringe **only** when filling the syringe or administering the injection. Keep the syringe and needle separate at all other times.
- Do not use automatic injection equipment.
- Ensure that animals are properly restrained, including those in the vicinity.
- Do not work alone when using Tilmodil.
- In case of human injection SEEK IMMEDIATE MEDICAL ATTENTION and take the vial or the package insert with you. Apply a cold pack (not ice directly) to the injection site.

Avoid contact with eyes. May cause sensitisation by skin contact. Wash hands after use.

**NOTE TO THE PHYSICIAN: Injection of tilimicosin in humans has been associated with fatalities.**

The cardiovascular system is the target of toxicity, and this toxicity may be due to calcium channel blockade. Administration of intravenous calcium chloride should only be considered if there is positive confirmation of exposure to tilimicosin. In dog studies, tilimicosin induced a negative inotropic effect with consequent tachycardia, and a reduction in systemic arterial blood pressure and arterial pulse pressure. **Do not give adrenalin or beta-adrenergic antagonists such as propranolol.** In pigs, tilimicosin-induced lethality is potentiated by adrenaline. In dogs, treatment with intravenous calcium chloride showed a positive effect on the left ventricular inotropic state and some improvements in vascular blood pressure and tachycardia. Pre-clinical data and an isolated clinical report suggest that calcium chloride infusion may help to reverse tilimicosin-induced changes in blood pressure and heart rate in humans. Administration of dobutamine should also be considered due to its positive inotropic effects although it does not influence tachycardia. As tilimicosin persists in tissues for several days, the cardiovascular system should be closely monitored and supportive treatment provided.

Physicians treating patients exposed to this compound are advised to discuss clinical management with the National Poison Information Service on: 0844 892 0111

### **Pharmaceutical precautions**

Do not store above 25°C. Protect from light. Discard unused material. Keep out of the reach and sight of children.

**Disposal:** Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

### **Legal category**

POM-V

### **Packaging Quantities**

Glass bottles with 50ml solution for injection.

### **Further information**

Following subcutaneous injection, tilimicosin is distributed throughout the body, but especially high levels are found in the lung. In calves, lung concentrations of tilimicosin remain above the MIC90 of 3.12µg/ml for *Mannheimia haemolytica* for at least 72 hours after injection. In lambs, lung concentration was found to be approximately 3.7µg/ml three days after a single subcutaneous injection of 10mg/kg. In lactating ewes, milk levels remained above the MIC90 of <1mg/ml for *Staphylococcus aureus* for at least 72 hours after injection.

### **Marketing Authorisation Holder (if different from distributor)**

Emdoka bvba, Belgium

### **Marketing authorisation number**

Vm 34534/4001.

### **Significant Changes**

### **GTIN (Global Trade Item No)**

50ml Vial:

05055037401592

