ATLAS VETERINAIRE

BRONCHOTIL

INJECTABLE SOLUTION

COMPOSITION

Tilmicosin (sf phosphate) …….. 30 g

Excipient qs…….. . 100ml

PHARMACEUTICAL PROPERTIES **Tilmicosin**

is an essentially bactericidal semi-synthetic antibiotic belonging to the group of macrolides. It affects protein synthesis. This antibacterial activity is directed predominantly against Gram-positive microorganisms, certain Gram-negative bacteria and mycoplasmas of bovine or ovine origin. Its activity has been demonstrated in particular against the following microorganisms: *Mannheimia, Pasteurella, Actinomyces (Corynebacterium), Fusobacterium, Dichelobacter, Staphylococcus,* as well as mycoplasmas of bovine or ovine origin.

After subcutaneous injection of **tilmicosin,** it distributes throughout the body with particularly high levels in the lungs. Several metabolites are formed following administration of **tilmicosin,** but the predominant metabolite is (N-desmethyl tilmicosin). However, most of it is eliminated without modification. Tilmicosin is excreted mainly **via** the bile in the faeces, but a small proportion is excreted in the urine. The half-life following subcutaneous injection in cattle is 2-3 days.

The primary target organ for toxicity following oral or parenteral administration of **tilmicosin** is the heart. The main cardiac effects are increased heart rate (tachycardia) and decreased contractility (negative inotropic effect). Cardiovascular toxicity can result from blockage of calcium channels.

TARGET SPECIES

Cattle and Sheep.

INDICATIONS

Treatment of respiratory diseases caused by *Mannheimia haemolytica* and *Pasteurella multocida* in cattle and sheep.

ADMINISTRATION AND DOSAGE

Dose : 10 mg of Tilmicosin/kg BW corresponding to 1 ml of the product/30 kg BW.

Route: Subcutaneous.

Method of administration :

- ***Cattle :***
  - ÿ Withdraw the required dose from the vial and remove the needle from the syringe, leaving the needle in the vial. When it is necessary to treat a group of animals, leave the needle in the vial to withdraw the necessary doses. Immobilize the animal by leaning over it and insert a separate needle **subcutaneously** at the injection site, preferably in a fold of skin at the level of the rib cage behind the shoulder. Fit the syringe to the needle and inject at the base of the skin fold.
  - ÿ Do not inject more than 20 ml per injection site.
- ***Sheep :***
  - ÿ Withdraw the required dose from the vial and remove the needle from the syringe, leaving the needle in the vial. When treating a group of animals, leave the needle in the vial to withdraw subsequent doses. Immobilize the animal by leaning over it and insert a separate needle subcutaneously at the injection site, preferably in a fold of skin at the level of the rib cage behind the shoulder. Fit the syringe to the needle and inject at the base of the skin fold.
  - ÿ Do not inject more than 2 ml per injection site.
  - ÿ It is important to weigh lambs accurately to avoid overdosing. Use of a 2ml or smaller syringe improves dosing accuracy Accurate weighing of lambs is important to avoid overdosing. Using a 2ml or smaller syringe improves dosing accuracy

- If there is no improvement within 48 hours, then the diagnosis must be confirmed.
- Avoid contamination of the bottle during use. The vial should be visually inspected for any foreign particles and/or abnormal physical appearance. If either is detected, discard the vial.

CONTRAINDICATIONS AND INTERACTIONS

- Do not administer intravenously.
- Do not administer intramuscularly.
- Do not administer to lambs weighing less than 15 kg.
- Do not administer to primates.
- Do not administer to pigs.
- Do not administer to horses and donkeys.
- Do not administer to goats.
- Do not administer in case of hypersensitivity to the active ingredient or to any of the excipients.
- The safety of this veterinary medicinal product has not been established in the event of pregnancy. To be used only on the basis of a benefit/risk assessment by the veterinarian.
- Interactions between macrolides and ionophores can be observed in some species.

SIDE EFFECTS

- Occasionally, slight, diffuse swelling may occur at the injection site, but this disappears within five to eight days.

- In rare cases, recumbency, incoordination and convulsions have been observed.
- Cases of mortality have been observed in cattle following the administration of a single intravenous dose of 5 mg/kg body weight, and following the subcutaneous injection of doses of 150 mg/kg body weight at 72 hour intervals. In pigs, intramuscular injection of a dose of 20 mg/kg body weight caused death. Sheep have died following a single intravenous injection of 7.5 mg/kg body weight.

SPECIFIC WARNINGS FOR EACH TARGET SPECIES

In sheep:

- Do not administer to lambs weighing less than 15 kg due to a risk of toxicity linked to an overdose.
- It is important to accurately weigh the lambs in order to avoid overdosing. The use of a syringe 2ml or smaller size makes it easier to dose accurately.
- Clinical trials have not shown bacteriological cure in sheep with acute mastitis caused by *Staphyloccocus aureus* and *Mycoplasma agalactiae.*
- The use of the specialty should only be made after checking the sensitivity of the strains and should take into account the recommendations for antibiotic therapy.
- Respect the recommended dosage.
- Avoid handling the product in case of known allergy to tetracyclines.
- In case of accidental contact with skin or eyes, rinse immediately with plenty of water.

PRECAUTIONS FOR USE

Precautions for use in animals:

- The safety of this veterinary medicinal product has not been established in the event of pregnancy. To be used only on the basis of a benefit/risk assessment by the veterinarian.
- Official antimicrobial policies should be considered when using this product.
- Do not use an automatic injection device to avoid any risk of self-injection.
- Where possible, use of this product should be based on susceptibility testing.

Precautions to be taken by the person administering the veterinary medicinal product to animals:

Injection of tilmicosin can be fatal in humans. Take extreme care to avoid accidental self-injection and follow the administration instructions and advice below precisely:

ÿ This product should only be administered by a veterinarian.
ÿ Never transport a filled syringe with the needle attached. The needle should be fitted to the syringe only when filling the syringe or injecting. In all other circumstances, the syringe and needle should be kept separate.
ÿ Do not use an automatic injection device.
ÿ Ensure animals are properly restrained, including nearby ones.
ÿ Do not work alone when BRANCHOTIL 300 is used.
ÿ In the event of self-injection, consult a doctor immediately and show him the vial or the product leaflet.
ÿ Apply a cold compress (not ice) to the injection site.
ÿ Avoid contact with skin and eyes. Rinse immediately with water any splashes on the skin or the eyes.
ÿ May cause sensitization in case of skin contact. Hands should be washed after use.

Note to Physician:

- Injection of Tilmicosin in humans has been associated with death.
- The cardiovascular system is the target of toxicity, which can result from the blockage of the channels calcium.
- In studies in dogs, Tilmicosin induced a negative inotropic effect with subsequent tachycardia, and a reduction in systemic blood pressure and pulse blood pressure. In dogs, treatment with intravenous calcium chloride showed a positive effect on the inotropic state of the left ventricle and some improvement in vascular blood pressure and tachycardia.
- Preclinical data and an isolated clinical report suggest that calcium chloride infusion may reverse Tilmicosin-induced changes in blood pressure and heart rate in humans.

- Do not administer adrenaline or beta-adrenergic antagonists such as propranolol.
- Intravenous administration of calcium chloride should only be considered if exposure to Tilmicosin is confirmed.
- The administration of dobutamine should also be considered due to its positive inotropic effects, although it does not influence tachycardia.
- As Tilmicosin persists for several days in the tissues, the cardiovascular system must be closely monitored and supportive treatment given.
- Physicians treating patients exposed to this product are recommended to discuss management clinic with the country's poison control centre.

WITHDRAWAL PERIOD

Cattle:

- **Meat and offal:** 70 days.
- **Milk:** 36 days.
- If the product is administered to cows during the dry period or to pregnant dairy heifers, the milk should not be used for human consumption until 36 days after calving.

Sheep:

- **Meat and offal:** 42 days.
- **Milk:** 18 days.
- If the product is administered to ewes during the dry period or to pregnant ewes, the milk should not be used for human consumption until 18 days after lambing.

STORAGE CONDITIONS

- **Unopened container:** Keep the product in the original packaging, protected from light and at a temperature ÿ 25°C.
- **After opening the bottle:** 4 weeks.

PHARMACEUTICAL FORM AND PRESENTATION

Solution for injection.

Bottles of 20, 50, 100 and 250 ml.