

TULAXX™ INJECTION

ACTIVE CONSTITUENT: 100mg/mL TULATHROMYCIN

First line treatment for Bovine Respiratory Disease

For the treatment of respiratory infections in cattle and pigs and footrot in sheep.

- Small injection dose
- Reaches Tmax quickly
- Less tissue damage in cattle – SC injection
- Long acting
- Excellent Syringeability

	TULAXX™	DRAXXIN®
Active Constituent	100mg/mL TULATHROMYCIN	100mg/mL TULATHROMYCIN
Species	Cattle, Pigs & Sheep	Cattle, Pigs & Sheep
Dose rate	1mL/40kg bodyweight	1mL/40kg
Route of Administration	Cattle: SC Pigs: IM Sheep: IM	Cattle: SC Pigs: IM Sheep: IM
Withholding periods		
Cattle: Meat	35 days	35 days
Cattle: Milk	Only to be used in replacement dairy heifers	Only to be used in replacement dairy heifers
Pig: Meat	14 days	14 days
Sheep	28 days	28 days
ESI		
Cattle	35 days	35 days
Pig	26 days	26 days
Sheep	49 days	49 days

ABBEY ANIMAL HEALTH PTY LTD Unit 27/1 Maitland Place, Norwest NSW 2153 InfoLine (02) 8088 0720 abbeylabs.com.au

TULAXX™ INJECTION

ACTIVE CONSTITUENT: 100mg/mL TULATHROMYCIN

For the treatment of respiratory infections in cattle and pigs and footrot in sheep.

For use by or under direction of a registered veterinarian.
For subcutaneous injection in cattle, including dairy heifers up to the point of first mating, and intramuscular injection in pigs. For the treatment of early stages of foot rot in sheep.

INDICATIONS

Cattle: TULAXX™ INJECTION is indicated for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni* and *Mycoplasma bovis* sensitive to tulathromycin.
Pigs: TULAXX™ INJECTION is indicated for the treatment of swine respiratory disease (SRD) associated with *Pasteurella multocida, Mycoplasma hyopneumoniae,* and *Haemophilus parasuis* sensitive to tulathromycin.
Sheep: TULAXX™ INJECTION is indicated for the treatment of the early stages of infectious pododermatitis (foot rot) associated with virulent *Dichelobacter nodosus* requiring systemic treatment.
Tulathromycin belongs to macrolide class. Resistance may develop to any chemical.

DIRECTIONS FOR USE

Use as directed by prescribing veterinarian.

RESTRAINTS

USE ONLY in respiratory infections of cattle and swine and for early stages of footrot in sheep.
DO NOT USE in ewes and dairy cows, except replacement dairy heifers, that are producing milk or may in the future produce milk that may be used or processed for human consumption.
DO NOT USE in bobby calves.

Re-treatment Interval

DO NOT RE-TREAT cattle for 12 weeks after last treatment or pigs for 8 weeks after the last treatment or sheep for 7 weeks after the last treatment.
DO NOT RE-TREAT dairy heifers following the first mating.

PRECAUTIONS

Avoid using the product simultaneously with other macrolides or lincosamides. Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. However, the effects of TULAXX™ on bovine, ovine and porcine reproductive performance, pregnancy and lactation have not been determined.
The efficacy of antimicrobial treatment for footrot may be reduced by environmental ie. wet conditions, and management factors. Treatment of footrot should therefore be undertaken along with other flock management tools, for example providing a dry environment.
Antibiotic treatment for benign foot rot is not considered appropriate. Studies have shown limited efficacy in sheep with severe clinical signs or chronic foot rot.

SIDE EFFECTS

Subcutaneous administration to cattle frequently causes transient pain reactions, and local swellings at the injection site that can persist for up to 30 days. Pain reactions have not been observed in pigs after intramuscular administration, but local swellings at the injection site can persist for up to 30 days. These swellings may result in trim loss of edible tissue at slaughter.
In one pig field study, one out of 40 pigs exhibited mild salivation that resolved in less than four hours.
In sheep transient signs of discomfort (including walking backwards, head shaking, rubbing the injection site, lying down and getting up, and bleating) are very common after intramuscular injection. These signs usually resolve within a few minutes.

DOSAGE AND ADMINISTRATION

In use shelf life: Use within 28 days of broaching the vial.
Cattle: 1mL/40kg bodyweight (2.5mg tulathromycin/kg) by a single subcutaneous injection high on the neck. For cattle over 400kg bodyweight, divide the dose so that no more than 10mL are injected at one site.
Pigs: 1mL/40kg bodyweight (2.5mg tulathromycin/kg) by a single intramuscular injection in the neck. For pigs over 100kg bodyweight, divide the dose so that no more than 2.5mL are injected at one site.
Sheep: 1mL/40 kg bodyweight (2.5 mg tulathromycin/kg) by a single intramuscular injection in the neck.
To ensure correct dosage bodyweight should be determined as accurately as possible to avoid underdosing.

GENERAL DIRECTIONS

TULAXX™ INJECTION is a ready-to-use sterile parenteral preparation containing tulathromycin, a semi-synthetic macrolide antimicrobial agent.
Each mL of TULAXX™ contains 100mg of tulathromycin as the free base in a 50% propylene glycol vehicle with citric and hydrochloric acids added to adjust pH.

WITHHOLDING PERIODS

MEAT

Cattle: DO NOT USE less than 35 days before slaughter for human consumption.
Pigs: DO NOT USE less than 14 days before slaughter for human consumption.
Sheep: DO NOT USE less than 28 days before slaughter for human consumption.

Any variation by the prescribing veterinarian to the approved dose, frequency, duration, route, disease or target species may result in the need to extend the approved withholding period.

TRADE ADVICE

EXPORT SLAUGHTER INTERVAL (ESI)

Cattle: DO NOT USE less than 35 days before slaughter for export.
Pigs: DO NOT USE less than 26 days before slaughter for export.
Sheep: DO NOT USE less than 49 days before slaughter for export

The ESIs on this label were correct at the time of label approval. Before using this product, confirm the current ESI from Abbey Animal Health Pty Ltd on 02 8088 0720 or the APVMA website (www.apvma.gov.au/residues/).

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.

ADDITIONAL USER SAFETY INFORMATION

Tulathromycin is irritating to eyes. If accidental eye exposure occurs, flush the eyes immediately with clean water. Users should wear a face shield or goggles when administering TULAXX™, to prevent exposure from syringe or needle breakage.

Tulathromycin may cause sensitization by skin contact. If accidental skin exposure occurs, wash the skin immediately with soap and water.

In case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician.

DISPOSAL

Dispose of empty containers by wrapping with paper and putting in garbage.

STORAGE

Store below 30˚C (Room Temperature).

APVMA Approval Number: 85687/148483

For detailed information, please refer to the full product leaflet insert.

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