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Draxxin

100 mg/ml
Injectable Solution Veterinary

Veterinary medicine package leaflet
This medicine is dispensed with a veterinarian's prescription only
For use in animals only

1. NAME, FORM AND STRENGTH OF THE VETERINARY MEDICINE
Draxxin 100 mg/ml Injectable Solution Veterinary

2. ACTIVE INGREDIENT
Tulathromycin 100 mg/ml
List of the inactive ingredients in section 13.

3. WHAT IS THIS MEDICINE INTENDED FOR
Cattle:
Treatment and prevention of bovine respiratory disease associated with *Mannheimia (pasteurella) haemolytica*, *Pasteurella multocida, Haemophilus somnus* and *Mycoplasma bovis* sensitive to tulathromycin. The presence of the disease in the herd should be established before preventative treatment.
Pigs:
Treatment of swine respiratory disease associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida* and *Mycoplasma hyopneumoniae* sensitive to tulathromycin.

4. CONTRAINDICATIONS
Do not use in cases of hypersensitivity to macrolide antibiotics in the animal.

5. SIDE EFFECTS
Subcutaneous administration of the medicinal product to cattle very commonly causes transient pain reactions and local swelling at the injection site that can persist for up to 30 days. No such reaction has been observed in pigs after intramuscular administration. Pathomorphological injection site reactions (including reversible changes of congestion, oedema, fibrosis (thickening and scarring of the connective tissue) and haemorrhage) are very common for approximately 30 days after injection in both species.
If you notice any side effects, which may not already be listed in this leaflet or you think that the medicine has not worked, please inform the treating veterinarian. You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects.
You can also use this link:
https://sideeffects.health.gov.il

6. TARGET ANIMALS
Cattle, pigs

7. METHOD OF ADMINISTRATION AND DOSAGE
Injectable solution.
Cattle (treatment and metaphylaxis):
Subcutaneous administration.
A single subcutaneous injection, with a dosage of 2.5 mg tulathromycin/kg bodyweight (equivalent to 1 ml/40 kg bodyweight). For cattle over 300 kg bodyweight, divide the dose so that no more than 7.5 ml are injected at the same site.
Pigs:
Intramuscular administration.
A single intramuscular injection, with a dosage of 2.5 mg tulathromycin/kg bodyweight (equivalent to 1 ml/40 kg bodyweight) in the neck. For treatment of pigs over 80 kg bodyweight, divide the dose so that no more than 2 ml are injected at the same site.

8. HOW TO USE THIS MEDICINE
For any respiratory disease, it is recommended to treat animals in the early stages of the disease and to evaluate the response to treatment within 48 hours after injection.
If clinical signs of respiratory disease persist or worsen, or if relapse occurs, treatment should be changed, using another antibiotic, until clinical signs have resolved.

To ensure correct dosage, the weight of the animal should be determined as accurately as possible to avoid underdosing.
For multiple vial entry, an aspirating needle or multi-dose syringe is recommended to avoid excessive broaching of the stopper.

9. WITHDRAWAL PERIOD
Cattle: 22 days.
Pigs: 13 days.
Do not use in cattle producing milk for human consumption.
Do not use in pregnant animals, which are intended to produce milk for human consumption, within 2 months of expected parturition.

10. WARNINGS
- Special warnings about use of the medicine in all target animals
  Cross-resistance occurs with other macrolides. Do not administer concomitantly with other macrolides or lincosamide antibiotics.
- Special warnings about the safety of using this medicine in animals
  Use of the product should be based on susceptibility testing of the bacteria isolated from the animal.
  If a hypersensitivity reaction occurs, appropriate treatment should be administered without delay.
- Special safety precautions for the person administering the medicine
  Tulathromycin is irritating to eyes. In case of contact with the eyes, flush them immediately with clean water.
  Tulathromycin may cause sensitisation by skin contact, e.g. reddening of the skin (erythema) and/or dermatitis. In case of exposure, wash the affected area immediately with soap and water.
  Wash hands after use.
  In case of accidental injection, seek medical attention immediately and show the package or package leaflet to the doctor.
  If there is suspicion of a hypersensitivity reaction following accidental exposure (expressed as itching, difficulty in breathing, hives, swelling of the face, nausea, vomiting) appropriate treatment should be administered. Contact a physician immediately and show him the package leaflet or the package.
- Pregnancy and lactation
  Laboratory studies in rats and rabbits have not demonstrated teratogenic, foetotoxic or maternotoxic effects.
  The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
  Use only according to the benefit/ risk assessment by the responsible veterinarian.
- Interactions with other medicines and other forms of interaction
  None known.
- Overdose
  In cattle, in administration of 3, 5 or 10 times the recommended dose, transient signs attributed to injection site discomfort were observed and included restlessness, headshaking, pawing the ground, and brief decrease in feed intake. Mild myocardial degeneration has been observed in cattle receiving 5-6 times the recommended dosage.
  In young pigs weighing approximately 10 kg given 3 or 5 times the therapeutic dose transient signs attributed to injection site discomfort were observed, including excessive vocalisation and restlessness.
  Lameness was observed when the hind leg was used as the injection site.
- Incompatibility
  Given that compatibility studies have not been conducted, do not mix Draxxin with other veterinary medicinal products.

11. STORAGE INSTRUCTIONS
Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants.
Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Storage conditions
  Store below 30°C
- Shelf-life after opening the bottle
  28 days.

12. INSTRUCTIONS FOR THE DISPOSAL OF THE UNUSED PRODUCT OR WASTE MATERIALS
Dispose of any remaining veterinary medicine or waste obtained from using a veterinary medicine in the same manner as toxic waste; do not discard into a sewer.

13. ADDITIONAL INFORMATION
- **In addition to the active ingredient, this medicine also contains**
  Citric Acid, anhydrous
  Hydrochloric Acid (for pH adjustment)
  Sodium Hydroxide (for pH adjustment)
  Propylene Glycol
  Monothioglycerol
  Water for Injections
- **What the medicine looks like and contents of the pack**
  A vial with a clear, colourless to yellowish solution.
- **Pack sizes**
  Glass vial with volume of 20, 50, 100, 250 and 500 ml.
  Not all volumes may be marketed.
  The 500 ml vials must not be used for pigs.
- **Registration holder**
  Zoetis Israel Holding B.V.,
  5 Atir Yeda Street, Kfar Saba
- **Manufacturer's name**
  FAREVA AMBOISE, FRANCE,
  POCE-SUR-CISSE, FRANCE
  or
  ZOETIS MANUFACTURING & RESEARCH SPAIN, S.L, SPAIN
  or
  INOVAT INDUSTRIA FARMACEUTICA LTDA, BRAZIL
- **Revised in September 2021 according to MOH guidelines.**
- **Registration number of the medicine in the Ministry of Health's National Drug Registry:**
  083-76-92398-00
  083-76-92398-01
  083-76-92398-02