See package insert for complete product information. For swine and bovine respiratory disease.

Inject intramuscularly as a single dose in the neck at a dosage of 2.5 mg/kg (1 mL/22 lb) body weight. For swine and bovine respiratory disease, inject subcutaneously as a single dose in the neck at a dosage of 2.5 mg/kg (1 mL/22 lb) body weight.

FOR USE IN

Injectable Solution

Swine

Antibiotic

25 mg of tulathromycin/mL

STORAGE CONDITIONS:

Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Injector Solution

Swine

DRAXXIN 25 Injectable Solution is indicated for the treatment of swine respiratory disease (SRD) caused by Actinobacillus pleuropneumoniae, Mycoplasma hyopneumoniae; and for the control of Mycoplasma bovis.

DOSAGE AND ADMINISTRATION

For swine with swine respiratory disease (SRD) caused by Actinobacillus pleuropneumoniae, Mycoplasma hyopneumoniae; and for the control of Mycoplasma bovis.

| Pounds (lbs) | mL/
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>0.7</td>
</tr>
<tr>
<td>22</td>
<td>1.0</td>
</tr>
<tr>
<td>50</td>
<td>2.3</td>
</tr>
<tr>
<td>90</td>
<td>4.0</td>
</tr>
<tr>
<td>200</td>
<td>9.0</td>
</tr>
</tbody>
</table>

WARNINGS

FOR USE IN ANIMALS ONLY. NOT FOR HUMAN USE.

KEEP OUT OF REACH OF CHILDREN. NOT FOR USE IN CHICKENS OR TURKEYS.

ANIMAL SAFETY

A safety study was conducted in feeder calves receiving DRAXXIN Injectable Solution (100 mg/mL) as a single subcutaneous injection at a dosage of 2.5 mg/kg BW. When calves became pyrexic and had abnormal respiration scores, they were treated with either DRAXXIN (2.5 mg/kg BW) or a saline solution. The results showed that 11.3% of DRAXXIN-treated calves compared with 28.9% of saline-treated calves (P = 0.0001) and 15.0% of DRAXXIN-treated calves compared with 30.7% of saline-treated calves (P < 0.0001).

Mycoplasma bovis.

 Injectable Solution (100 mg/mL) against pathogens. When acting as a cidal compound, they tend to exhibit concentration independent activity.

1 Markedly higher tulathromycin concentrations are achieved following intramuscular injection, compared with subcutaneous injection.

27

A total of 166 calves were inoculated intratracheally with field strains of Mycoplasma bovis. Following intramuscular (IM) administration to feeder pigs at a dosage of 2.5 mg/kg BW, tulathromycin is nearly completely absorbed, with peak plasma concentrations achieved within ~0.25 hr. The volume of distribution exceeds 11 L/kg of body weight. Drugs administered by subcutaneous or intravenous injection are absorbed more slowly, with peak concentrations achieved after 2 to 4 hr.

DRAXXIN Injectable Solution (100 mg/mL) and DRAXXIN 25 Injectable Solution (25 mg/mL) contain the same active ingredient, tulathromycin, and are bioequivalent. The MICs of tulathromycin against indicated pathogens isolated from field studies evaluating SRD in the U.S. and Canada.

Calves intended for human consumption must not be slaughtered within 22 days from the last treatment with DRAXXIN 25 Injectable Solution. This drug is not for use in cattle intended for human consumption. The effects of Draxxin 25 Injectable Solution on porcine reproductive performance, pregnancy, and lactation have not been determined.

In one field study, one out of 40 pigs treated with DRAXXIN Injectable Solution (100 mg/mL) at 2.5 mg/kg BW exhibited mild salivation that resolved in less than four hours.

A safety study was conducted in preruminant calves 13 to 27 days of age receiving DRAXXIN Injectable Solution (100 mg/mL) as a single subcutaneous injection at a dosage of 2.5 mg/kg BW. A total of 72 calves were treated with either DRAXXIN or saline. The injection site was examined macroscopically and microscopically. No drug-related lesions were observed.

Store at or below 25°C (77°F). Use within 90 days of first vial puncture.

HOW SUPPLIED

DRAXXIN 25 Injectable Solution is available in the following package sizes: 50 mL vial, 100 mL vial, 250 mL vial.

Approved by FDA under NADA # 141-349

Distributed by:

Zoetis Inc.
Kalamazoo, MI 49007

To report a suspected adverse reaction or to request a safety data sheet call 1-888-963-8471. For additional information regarding reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/AnimalVeterinary/SafetyHealth.

Markedly higher tulathromycin concentrations are achieved following intramuscular injection, compared with subcutaneous injection.

1


Revised: March 2019