BAYTRIL® 100
(enrofloxacin) 100 mg/mL Antimicrobial Injectable Solution

Bayer Animal Health
For Subcutaneous use in Beef Cattle, Non-Lactating Dairy Cattle and Swine Only
Not For Use In Female Dairy Cattle 20 Months of Age or Older Or In Calves To Be Processed For Veal

CAUTION:
Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.
Federal (U.S.A.) law prohibits the extra-label use of this drug in food-producing animals.

PRODUCT DESCRIPTION:
Baytril® 100 is a sterile, ready-to-use injectable antimicrobial solution that contains enrofloxacin, a broad-spectrum fluoroquinolone antimicrobial agent.

Each mL of Baytril® 100 contains 100 mg of enrofloxacin. Excipients are L-arginine base 200 mg, n-butyl alcohol 30 mg, benzyl alcohol (as a preservative) 20 mg and water for injection q.s.

CHEMICAL NOMENCLATURE AND STRUCTURE:
1-cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid.

INDICATIONS:
Cattle - Single-Dose Therapy: Baytril® 100 is indicated for the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, Histophilus somni and Mycoplasma bovis in beef and non-lactating dairy cattle.

Cattle - Multiple-Day Therapy: Baytril® 100 is indicated for the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida and Histophilus somni (previously Haemophilus somnus) in beef and non-lactating dairy cattle.

Swine: Baytril® 100 is indicated for the treatment and control of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis and Streptococcus suis.

DOSEAGE AND ADMINISTRATION:
Baytril® 100 provides flexible dosages and durations of therapy.

Baytril® 100 may be administered as a single dose for one day (cattle and swine) or for multiple days (cattle) of therapy. Selection of the appropriate dose and duration of therapy should be based on an assessment of the severity of disease, pathogen susceptibility and clinical response.

Cattle:
Single-Dose Therapy: Administer once, a subcutaneous dose of 7.5 - 12.5 mg/kg of body weight (3.4 - 5.7 mL/100 lb).
Multiple-Day Therapy: Administer daily, a subcutaneous dose of 2.5 - 5.0 mg/kg of body weight (1.1 - 2.3 mL/100 lb). Treatment should be repeated at 24-hour intervals for three days. Additional treatments may be given on Days 4 and 5 to animals that have shown clinical improvement but not total recovery.

Administered dose volume should not exceed 20 mL per injection site.

Table 1 - Baytril® 100 Dose and Treatment Schedule for Cattle*

<table>
<thead>
<tr>
<th>WEIGHT (lb)</th>
<th>Single-Dose Therapy 7.5-12.5 mg/kg Dose Volume (mL)</th>
<th>Multiple-Day Therapy 2.5-5.0 mg/kg Dose Volume (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>3.5 - 5.5</td>
<td>1.5 - 2.0</td>
</tr>
<tr>
<td>200</td>
<td>7.0 - 11.0</td>
<td>2.5 - 4.5</td>
</tr>
<tr>
<td>300</td>
<td>10.5 - 17.0</td>
<td>3.5 - 6.5</td>
</tr>
<tr>
<td>400</td>
<td>14.0 - 22.5</td>
<td>4.5 - 9.0</td>
</tr>
<tr>
<td>500</td>
<td>17.0 - 28.5</td>
<td>5.5 - 11.5</td>
</tr>
<tr>
<td>600</td>
<td>20.5 - 34.0</td>
<td>7.0 - 13.5</td>
</tr>
<tr>
<td>700</td>
<td>24.0 - 39.5</td>
<td>8.0 - 16.0</td>
</tr>
<tr>
<td>800</td>
<td>27.5 - 45.5</td>
<td>9.0 - 18.0</td>
</tr>
<tr>
<td>900</td>
<td>31.0 - 51.0</td>
<td>10.0 - 20.5</td>
</tr>
<tr>
<td>1000</td>
<td>34.0 - 57.0</td>
<td>11.0 - 23.0</td>
</tr>
</tbody>
</table>
Enrofloxacin is bactericidal and exerts its antibacterial effect by inhibiting bacterial DNA gyrase (a type II topoisomerase) thereby preventing DNA supercoiling and replication which leads to cell death. Enrofloxacin is active against Gram-negative and Gram-positive bacteria.

**EFFECTIVENESS:**

- **Cattle:** A total of 845 calves with naturally-occurring BRD were treated with Baytril® 100 in eight field trials located in five cattle-feeding states. Response to treatment was compared to non-treated controls. Single-dose and multiple-day therapy regimens were evaluated. BRD and mortality were significantly reduced in enrofloxacin-treated calves. No adverse reactions were reported in treated animals. Response to treatment was compared to non-treated controls. Single-dose and multiple-day therapy regimens were evaluated. 

- **Swine:** A total of 590 pigs were treated with Baytril® 100 or saline in two separate natural infection SRD field trials. For the treatment of SRD, the success rate of enrofloxacin-treated pigs that were defined as “sick and febrile” (increased respiratory rate, labored or dyspneic breathing, depressed attitude and a rectal temperature ≥ 104.0°F) was statistically significantly greater than the success rate of saline-treated “sick and febrile” pigs. For the control of SRD, mean rectal temperature, mortality (one trial) and morbidity were statistically significantly lower for enrofloxacin-treated pigs in pens containing a percentage of “sick and febrile” pigs compared to saline-treated pigs.

- **TOXICOLOGY:**

  The oral LD50 for laboratory rats was greater than 5000 mg/kg of body weight. Ninety-day feeding studies in dogs and rats revealed no observable adverse effects at treatment rates of 3 and 40 mg/kg respectively. Chronic studies in rats and mice revealed no observable adverse effects at 5.3 and 323 mg/kg respectively. There was no evidence of carcinogenic effect in laboratory animal models. A two-generation rat reproduction study revealed no effect with 10 mg/kg treatments. No teratogenic effects were observed in rabbits at doses of 25 mg/kg or in rats at 50 mg/kg.

**ANIMAL SAFETY:**

- **Cattle:** Safety studies were conducted in feeder calves using single doses of 5, 15 and 25 mg/kg for 15 consecutive days and 50 mg/kg for 5 consecutive days. No clinical signs of toxicity were observed when a dose of 5 mg/kg was administered for 15 days. Clinical signs of depression, incoordination and muscle fasciculation were observed in calves when doses of 15 or 25 mg/kg were administered for 10 to 15 days. Clinical signs of depression, incoordination and muscle fasciculation were observed when a dose of 50 mg/kg was administered for 3 days. No drug-related abnormalities in clinical pathology parameters were identified. No articular cartilage lesions were observed after examination of stifles joints from animals administered 25 mg/kg for 15 days.

- **Swine:** A safety study was conducted in 23-day-old calves using doses of 5, 15 and 25 mg/kg for 15 consecutive days. No clinical signs of toxicity or changes in clinical pathology parameters were observed. No articular cartilage lesions were observed in the stifles joints at any dose level at 2 days and 9 days following 15 days of drug administration.

An injection site study conducted in feeder calves demonstrated that the formulation may induce a transient reaction in the subcutaneous tissue and underlying muscle. No painful responses to administration were observed.

- **Swine:** A safety study was conducted in 32 pigs weighing approximately 57 kg (125 lb) using single doses of 5, 15 or 25 mg/kg daily for 15 consecutive days. Incidental lameness of short duration was observed in all groups, including the saline-treated controls. Musculoskeletal stiffness was observed following the 15 and 25 mg/kg treatments with clinical signs appearing during the second week of treatment. Clinical signs of lameness improved after treatment ceased and most animals were clinically normal at necropsy. A second study was conducted in two pigs weighing approximately 23 kg (50 lb), treated with 50 mg/kg for 5 consecutive days. There were no clinical signs of toxicity or pathological changes. An injection site study conducted in pigs demonstrated that the formulation may induce a transient reaction in the subcutaneous tissue. No painful responses to administration were observed.
STORAGE CONDITIONS: Protect from direct sunlight. Do not refrigerate, freeze or store at or above 40°C (104°F). Precipitation may occur due to cold temperature. To redissolve, warm and then shake the vial.

HOW SUPPLIED:

Baytril® 100:

<table>
<thead>
<tr>
<th>Code</th>
<th>Concentration</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>08711170-023699</td>
<td>100 mg/mL</td>
<td>100 mL Bottle</td>
</tr>
<tr>
<td>08711278-032199</td>
<td>100 mg/mL</td>
<td>250 mL Bottle</td>
</tr>
</tbody>
</table>

REFERENCES:

2. U.S. Patent No. 5,756,506

For customer service or to obtain product information, including a Material Safety Data Sheet, call 1-800-633-3796.

For medical emergencies or to report adverse reactions, call 1-800-422-9874.

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