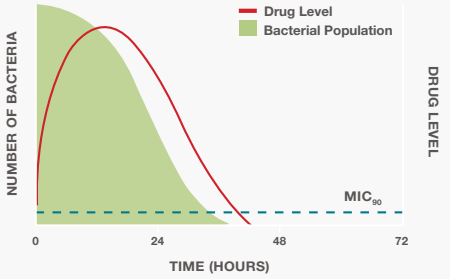
Tech Sheet

Baytril® 100
(enrofloxacin)

You can't waste time with a calf that has BRD.

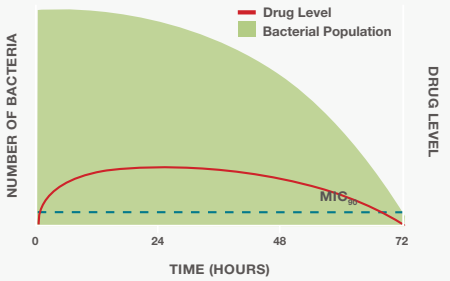
Make Baytril® 100 (enrofloxacin) injectable your first-pull treatment for BRD.

CONCENTRATION-DEPENDENT
(CONCEPT ILLUSTRATION)



The effectiveness of concentration-dependent drugs is dependent upon high drug levels that rapidly kill bacteria.

TIME-DEPENDENT
(CONCEPT ILLUSTRATION)



Time-dependent drugs inhibit bacteria's growth over time and require drug concentrations to remain above MIC (minimum inhibitory concentration) at the site of infection for as much of the dosing interval as possible.

- **First**
  Baytril 100 is the first single-dose fluoroquinolone FDA approved for the treatment of bovine respiratory disease (BRD) and the control of BRD in beef and non-lactating dairy cattle at high risk of developing BRD.
- **Four major BRD pathogens**
  Baytril 100 has bactericidal activity against the major bovine pathogens: ***Mannheimia haemolytica, Pasteurella multocida, Histophilus somni*** and ***Mycoplasma bovis.***
- **Bactericidal**
  Baytril 100 has a mode of action that actually kills the bacteria causing the infection by destroying bacterial DNA and preventing bacterial replication.
- **Concentration-dependent**
  Baytril 100 is concentration-dependent, delivering effective therapeutic drug concentrations with a single dose.
- **Effective**
  In cattle, Baytril 100 reaches therapeutic drug concentrations at the site of infection in the lung in one to two hours.[1]
- **Kills the bacteria**
  In vitro, Baytril 100 kills 97% of BRD-causing bacteria in one to two hours.*[2] And the sooner bacteria are killed, the faster a calf will feel better and get back to work eating.
- **Temperature reduction**
  In field trials, improvements in temperature and attitude scores were noted within 24 hours of treatment.[3]
- **Easy syringability**
  Baytril 100 is syringable in cold weather,[4] making it an easily stored injectable solution. Do not refrigerate and protect from freezing and exposure to direct sunlight.
- **Beef & dairy**
  Baytril 100 is approved for use in non-lactating dairy cattle, including dairy replacement heifers <20 months of age.
- **Subcutaneous**
  Single dose Baytril 100 is administered by a subcutaneous injection in compliance with BQA guidelines.
- **Available in three convenient sizes**
  Baytril 100 lets you select the bottle size that best fits your needs. Look for it in the 100 mL, 250 mL and 500 mL amber glass bottles.

* The clinical significance of *in vitro* data has not been determined.

For use by or on the order of a licensed veterinarian. Extra-label use in food-producing animals is prohibited. Cattle intended for human consumption must not be slaughtered within 28 days from the last treatment. This product is not approved for female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. The effects of enrofloxacin on cattle or swing reproductive performance, pregnancy and lactation have not been determined.

[1] Davis J. Foster D. Papich M. Pharmacokinetics and tissue distribution of enrofloxacin and its active metabolite ciprofloxacin in calves. *J. Vet. Pharmacol. Ther.* 2007. 30(6):564-571.

[2] Blondeau JM, Borsos S. Blondeau LD, Blondeau BJJ, Hesje CE Comparative minimum inhibitory and mutant prevention drug concentrations of enrofloxacin, ceftiofur, florfenicol, tilmicosin and tulathromycin against bovine clinical isolates of Mannheimia haemolytica. *Veterinary Microbiology.* 2012. 160(1-2):85-90.

[3] Freedom of Information NADA 141-068 (2012)

[4] Elanco Animal Health. Data on File.

Right for cattle. Right by you.

Elanco™

PRESCRIBING INFORMATION FOR USE IN CATTLE ONLY. SEE PRODUCT INSERT FOR COMPLETE DOSING AND ADMINISTRATION INFORMATION

Elanco™ Baytril® 100

(enrofloxacin)

100 mg/mL Antimicrobial
Injectable Solution
For Subcutaneous Use In Beef Cattle And Non-Lactating Dairy Cattle
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.

Before Using Baytril 100, please consult the complete product insert, a summary of which follows:

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; and for the control of BRD in beef and non-lactating dairy cattle at high risk of developing BRD associated with ***M. haemolytica, P. multocida, H. somni*** and ***M. bovis***.
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*** in beef and non-lactating dairy cattle.

DOSAGE AND ADMINISTRATION:
Baytril 100 provides flexible dosages and durations of therapy.
Baytril 100 may be administered as a single dose for one day for treatment and control of BRD (cattle), or for multiple days for BRD treatment (cattle). Selection of the appropriate dose and duration of therapy for BRD treatment in cattle should be based on an assessment of the severity of the disease, pathogen susceptibility and clinical response.
Cattle:
Single-Dose Therapy (BRD Treatment): Administer, by subcutaneous injection, a single dose of 7.5-12.5 mg/kg of body weight (3.4-5.7 mL/100 lb).
Multiple-Day Therapy (BRD Treatment): Administer daily, a subcutaneous dose of 2.5-5 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.
Single-Dose Therapy (BRD Control): Administer, by subcutaneous injection, a single dose of 7.5 mg/kg of body weight (3.4 mL/100 lb).
Examples of conditions that may contribute to calves being at high risk of developing BRD include, but are not limited to, the following:
- Transportation with animals from two or more farm origins.
- An extended transport time with few to no rest stops.
- An environmental temperature change of ≥30°F during transportation.
- A ≥30°F range in temperature fluctuation within a 24-hour period.
- Exposure to wet or cold weather conditions.
- Excessive shrink (more than would be expected with a normal load of cattle).
- Stressful arrival processing procedures (e.g., castration or dehorning).
- Exposure within the prior 72 hours to animals showing clinical signs of BRD.

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

Table 1 – Baytril 100 Dose and Treatment Schedule for Cattle*

Weight (lb)	Treatment		Control
	Single-Dose Therapy 7.5 - 12.5 mg/kg Dose Volume (mL)	Multiple-Day Therapy 2.5 - 5.0 mg/kg Dose Volume (mL)	Single-Dose Therapy 7.5 mg/kg Dose Volume (mL)
100	3.5 - 5.5	1.5 - 2.0	3.5
200	7.0 - 11.0	2.5 - 4.5	7.0
300	10.5 - 17.0	3.5 - 6.5	10.5
400	14.0 - 22.5	4.5 - 9.0	14.0
500	17.0 - 28.5	5.5 - 11.5	17.0
600	20.5 - 34.0	7.0 - 13.5	20.5
700	24.0 - 39.5	8.0 - 16.0	24.0
800	27.5 - 45.5	9.0 - 18.0	27.5
900	31.0 - 51.0	10.0 - 20.5	31.0
1000	34.0 - 57.0	11.0 - 23.0	34.0
1100	37.5 - 62.5	12.5 - 25.0	37.5

*Dose volumes have been rounded to the nearest 0.5 mL within the dose range.

See product insert for complete dosing and administration information.

Use within 30 days of first puncture and puncture a maximum of 30 times with a needle or 4 times with a dosage delivery device. Any product remaining beyond these parameters should be discarded.

RESIDUE WARNINGS:
Cattle: Animals intended for human consumption must not be slaughtered within 28 days from the last treatment. This product is not approved for female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

HUMAN WARNINGS:
Not for use in humans. Keep out of reach of children. Avoid contact with eyes. In case of contact, immediately flush eyes with copious amounts of water for 15 minutes. In case of dermal contact, wash skin with soap and water. Consult a physician if irritation persists following ocular or dermal exposures. Individuals with a history of hypersensitivity to quinolones should avoid this product. In humans, there is a risk of user photosensitization within a few hours after excessive exposure to quinolones. If excessive accidental exposure occurs, avoid direct sunlight. For product questions, to report adverse reactions, or for a copy of the Safety Data Sheet (SDS), call Elanco Product & Veterinary Support at 1-800-428-4441.

PRECAUTIONS:
The effects of enrofloxacin on cattle reproductive performance, pregnancy and lactation have not been adequately determined.
Subcutaneous injection in cattle can cause a transient local tissue reaction that may result in trim loss of edible tissue at slaughter. Baytril 100 contains different excipients than other Baytril products. The safety and efficacy of this formulation in species other than cattle have not been determined.
Quinolone-class drugs should be used with caution in animals with known or suspected Central Nervous System (CNS) disorders. In such animals, quinolones have, in rare instances, been associated with CNS stimulation which may lead to convulsive seizures. Quinolone-class drugs have been shown to produce erosions of cartilage of weight-bearing joints and other signs of arthropathy in immature animals of various species. See Animal Safety section for additional information.

ADVERSE REACTIONS:
No adverse reactions were observed during clinical trials.
For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

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.
The effectiveness of Baytril 100 for the control of respiratory disease in cattle at high risk of developing BRD was evaluated in a six-location study in the U.S. and Canada. A total of 1,150 crossbred beef calves at high risk of developing BRD were enrolled in the study. Baytril 100 (7.5 mg/kg BW) or an equivalent volume of sterile saline was administered as a single subcutaneous injection within two days after arrival. Cattle were observed daily for clinical signs of BRD and were evaluated for success on Day 14 post-treatment. Treatment success in the Baytril 100 group (497/573, 87.83%) was significantly higher ($P = 0.0013$) than success in the saline control group (455/571, 80.92%). In addition, there were more treatment successes ($n = 13$) than failures ($n = 3$) in the group of animals positive for ***M. bovis*** on Day 0 that were treated with Baytril 100. No product-related adverse reactions were reported.

STORAGE CONDITIONS: Protect from direct sunlight. Do not refrigerate or freeze. Store at 20-30ºC (68-86ºF), excursions permitted up to 40ºC (104ºF). Precipitation may occur due to cold temperature. To redissolve, warm and then shake the vial.

HOW SUPPLIED:
Baytril 100:

100 mg/mL	100 mL Bottle
100 mg/mL	250 mL Bottle
100 mg/mL	500 mL Bottle

For product questions, to report adverse reactions, or for a copy of the Safety Data Sheet (SDS), call Elanco Product & Veterinary Support at 1-800-428-4441.

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Baytril 100
Approved by FDA under NADA # 141-068
Manufactured for: Elanco US Inc.
Greenfield, IN 46140 U.S.A
Made in Germany

Elanco™