

**Baytril® 100 (enrofloxacin) is
approved for use in dairy replacement heifers
less than 20 months of age!**



Injectable
Baytril® 100
(enrofloxacin)
Right the first time®



IT'S ABOUT TIME.

It's about time dairy-heifer producers count on the same performance beef-cattle producers trust to fight bovine respiratory disease (BRD). For years, Baytril® 100 (enrofloxacin) Injectable Solution has proven to quickly kill the bacteria that cause BRD. That performance is now approved for dairy replacement heifers less than 20 months of age.

It's about time to recognize the impact of BRD in dairy replacement heifers.

How important are dairy replacement heifers to an operation? Consider this:

- The cost of replacement heifers is second only to feed costs in most dairy operations.
- The cost of replacement heifers has increased considerably in the last few years, reaching approximately \$2,000 in summer 2007.



Dairy replacement heifers are not just a financial investment: they represent the future of your operation. Keeping them healthy can't be an afterthought — it's imperative. And risking them to BRD just isn't an option.

When BRD hits a dairy replacement heifer, it attacks fast and hard.

- BRD will rob a calf of healthy lung tissue each day it goes untreated.
- Lung damage from BRD is permanent, seriously threatening the health and long-term earning potential as a replacement animal.

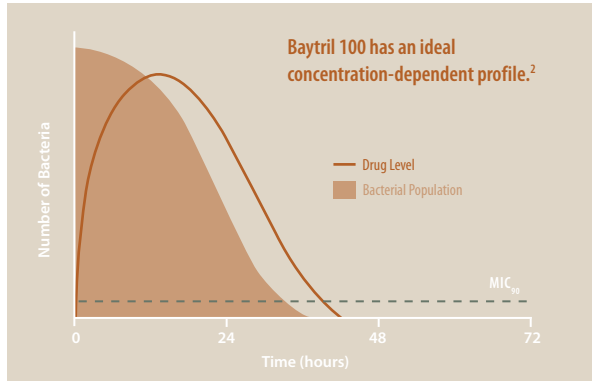
Baytril® 100 (enrofloxacin) goes directly to the site of the infection and starts killing BRD-causing bacteria in minutes, not days.¹

Federal law restricts this drug to use by or on the order of a licensed veterinarian. Extra-label use of this product in food-producing animals is prohibited.



Because BRD moves fast, you need an antibiotic that works fast.

Baytril® 100 (enrofloxacin): concentration-dependent to start working in minutes.²



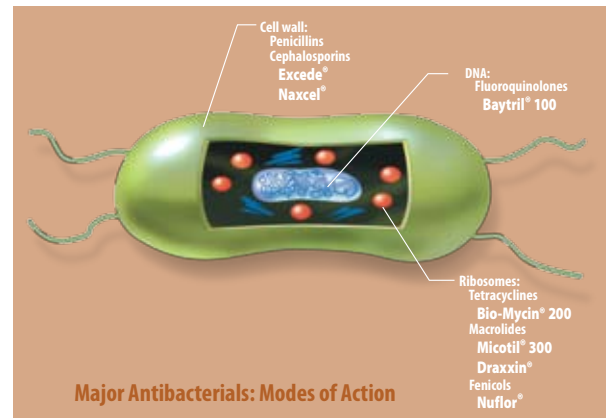
Baytril 100 is concentration-dependent: it achieves high drug levels at the site of infection to quickly kill bacteria.

- Some BRD treatments are time-dependent, so they need to be at therapeutic levels at the site of the infection for a long period of time to be effective.
- Baytril 100 is concentration-dependent, not time-dependent. It goes directly to the site of infection and starts killing BRD-causing bacteria in minutes, not days.^{1,2}



Baytril® 100 (enrofloxacin) is built to kill the “heart” of BRD-causing bacteria.

- Many antibiotics are bacteriostatic. They do not kill bacteria immediately; they inhibit bacterial growth.
- Baytril® 100 is bactericidal. Its unique mode of action allows it to penetrate the bacterial cell wall, disrupt the DNA and kill BRD-causing bacteria fast.
- Baytril 100 kills bacteria in both the resting and growth phases of development.



Were food-safety questions addressed regarding the use of Baytril 100 in dairy replacement heifers?

Yes. The safety of Baytril 100 is well documented and food-safety questions were recently addressed through a Risk Assessment that estimated the potential risk to public health to be at or near zero.

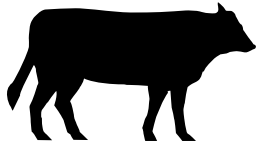
Baytril 100 is an effective, lifesaving tool for the producer and veterinarian.

Injectable
Baytril® 100
(enrofloxacin)
Right the first time®



Baytril® 100

(enrofloxacin)



100 mg/mL Antimicrobial Injectable Solution

For Subcutaneous Use in Beef and Non-Lactating Dairy Cattle 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:

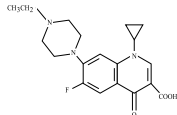
Baytril® 100 is a sterile, ready-to-use injectable antimicrobial solution that contains enrofloxacin, a broad-spectrum fluoroquinolone antimicrobial agent.

Therapeutic treatment with Baytril® 100 may be administered as a single-dose or as a multiple-day therapy.

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.



INDICATION:

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.

DOSAGE AND ADMINISTRATION:

Baytril® 100 provides flexible dosages and durations of therapy.
Baytril® 100 may be administered as a single dose for one day or for multiple days 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.

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.

Baytril® 100 Dose and Treatment Schedule for Cattle*

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

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

RESIDUE WARNINGS:

Animals intended for human consumption must not be slaughtered within 28 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. Use of enrofloxacin in this class of cattle may cause milk residues. 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:

For use in animals only. Keep out of the 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 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.

PRECAUTIONS:

The effects of enrofloxacin on cattle reproductive performance, pregnancy and lactation have not been adequately determined.

Subcutaneous injection 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.

MICROBIOLOGY:

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.¹ Enrofloxacin is active against Gram-negative and Gram-positive bacteria.

EFFECTIVENESS:

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.

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:

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, inappetence and incoordination 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 stifle joints from animals administered 25 mg/kg for 15 days.

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 stifle 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.

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:
Code: 08711170-023699 100 mg/mL 100 mL Bottle
Code: 08711278-032199 100 mg/mL 250 mL Bottle

REFERENCES:

- Hooper, D. C., Wolfson, J. S., *Quinolone Antimicrobial Agents*, 2nd ed, 59 - 75, 1993.
U.S. Patent No. 4,670,444

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.

December, 2007
80908653, R.0
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BR022808
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NADA 141-068, Approved by FDA



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Shawnee Mission, Kansas 66201 U.S.A.

- A study to compare the Plasma Pharmacokinetics of danofloxacin and enrofloxacin in Ruminating Cattle. Bayer Report 75646 (Bayer Study 151.603). © 2003 Bayer HealthCare LLC.
- Concentration-dependent Killing Activity of Baytril® 100 (enrofloxacin). Bayer Study, BL04195. © 2004 Bayer HealthCare LLC.

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