For treatment and control of BRD

Tenotryl™ (enrofloxacin) injectable solution is indicated for **(single-dose therapy)** 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*.

Multiple-day therapy: For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni* in beef and non-lactating dairy cattle.

Tenotryl™ is not for use in female dairy cattle 20 months of age or older, including dry dairy cows, or in calves to be processed for veal.

Brief Summary of Prescribing Info for Cattle

Tenotryl™ (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 (USA) law restricts this drug to use by or on the order of a licensed veterinarian. Federal (USA) law prohibits the extra-label use of this drug in food-producing animals.

PRODUCT DESCRIPTION:
Tenotryl™ is a sterile, ready-to-use injectable antimicrobial solution that contains enrofloxacin, a broad-spectrum fluoroquinolone antimicrobial agent. Each mL of Tenotryl™ 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.

INDICATIONS:
Single-Dose Therapy: Tenotryl™ 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*.
Multiple-Day Therapy: Tenotryl™ 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:
Tenotryl™ provides flexible dosages and durations of therapy. Tenotryl™ may be administered as a single dose for one day for treatment and control of BRD, or for multiple days for BRD treatment. 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.
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 – Tenotryl™ 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.

Use within 30 days of first puncture and puncture a maximum of 30 times with a 16-gauge needle or smaller, or 4 times with a draw-off spike 4.75 mm or smaller. Any product remaining beyond these parameters should be discarded.

RESIDUE WARNINGS:
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. To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet, call 1-800-338-3659.

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.
Enrofloxacin injectable solution contains different excipients than other enrofloxacin products. The safety and efficacy of this formulation in species other than cattle and swine 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 cases, 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.
To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Virbac AH, Inc at 1-800-338-3659 or us.virbac.com.
For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/reportanimalae.

STORAGE CONDITIONS:
Protect from direct sunlight. Do not refrigerate or freeze.
Store at 20-30°C (68-86°F), excursions permitted between 15°C (59°F) to 40°C (104°F). Precipitation may occur due to cold temperature. To redissolve, warm and then shake the vial.

HOW SUPPLIED:
Tenotryl™ (enrofloxacin) Injectable Solution:

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

Virbac AH, Inc.
PO Box 162059
Fort Worth, TX 76161
Rev. 12/21

Approved by FDA under ANADA # 200-688

WORKS FAST
AND DELIVERS
COMBINED ACTION

Tenotryl™ (enrofloxacin) injectable solution

The full prescribing information contains complete use information, including cautions and warnings. Always read, understand and follow the labeling and use directions. See the back page for use directions and additional information.

Virbac

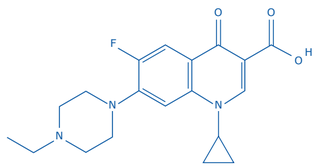
Shaping the future of animal health

Tenotryl™ (enrofloxacin) injectable solution

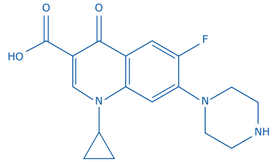
One shot, two active molecules

Enrofloxacin, the active ingredient in Tenotryl™ is an efficient, broad-spectrum antibiotic that has been trusted in the U.S. cattle industry for 25 years. Once injected into cattle, **enrofloxacin is metabolized into enrofloxacin and ciprofloxacin**.[1] These molecules deliver different modes of action for optimal efficacy. Therefore it delivers prompt, combined strengths against the primary pathogens that cause bovine respiratory disease (BRD).

Tenotryl™ works quickly at the infection site with enrofloxacin reaching peak plasma concentration in less than two hours.[1] It remains active because ciprofloxacin has a maximum residence time of 13.7 hours.[1]



Enrofloxacin molecule



Ciprofloxacin molecule

Designed to be fast and reliable

Enrofloxacin **quickly reaches peak concentrations** even in inflammatory exudates:

Time in hours to reach peak concentration (Tmax)[1]

	Plasma	Inflammatory exudate
Enrofloxacin (2.5 mg/kg)	**1.75**	**2.94**
Ciprofloxacin	3.25	5.25

Ciprofloxacin **maintains efficacy level for a longer time:**

Time in hours of maximum residence (MRT)[1]

	Plasma	Inflammatory exudate
Enrofloxacin (2.5 mg/kg)	5.52	8.88
Ciprofloxacin	**10.62**	**13.74**

A single injection of enrofloxacin has a relatively brief period of effect. After a single subcutaneous injection of 12.5 mg/kg, the combined, unbound concentrations of enrofloxacin and ciprofloxacin are below the minimal inhibitory count (MIC) for 90% of *Mannheimia haemolytica* isolates in plasma and tissue fluids by 48 hours.[2] Do not exceed a 20 mL dose per injection site. Subcutaneous injection in cattle can cause a transient local tissue reaction and may result in trim loss of edible tissue at slaughter.

Designed to deliver broad spectrum efficacy

Enrofloxacin is a broad-spectrum antibiotic with low minimal inhibitory concentration on the primary agents of bovine respiratory disease. Its bactericidal effects are concentration and time dependent.[3]

	Pasteurella multocida	*Mannheimia haemolytica*	*Histophilus somni*	*Mycoplasma bovis*
Mechanism of action	Bactericidal Concentration dependent	Bactericidal Concentration dependent	Bactericidal Concentration dependent	Bactericidal Time dependent
MIC (enrofloxacin)	0.06 - 0.13 µg/mL[4]	0.7 - 1.2 µg/mL[4]	MIC 90 = 1.0 µg/mL[5]	0.2 - 1.3 µg/mL[4]

Adaptable for field conditions

Tenotryl™ is convenient to use and adaptable to field conditions because it can be given once or over multiple days, depending on the challenge. U.S. federal law restricts this drug to use by or on the order of a licensed veterinarian and prohibits the extra-label use of this drug in food producing animals.

Tenotryl™ (enrofloxacin) Dose and Treatment Schedule for Cattle*

Weight (lb)	Treatment: Single-Dose Therapy 7.5-12.5 mg/kg Dose Volume (mL)	Treatment: Multiple-Day Therapy 2.5-5.0 mg/kg Dose Volume (mL)	Control: 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
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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.*

Tenotryl™ injectable solution delivers:

Fast acting

Combined strengths of enrofloxacin and ciprofloxacin[1]

Control and treatment of BRD

Convenience of single or multiple doses

Adaptable injection supports judicious use of antibiotics

IMPORTANT SAFETY INFORMATION

Tenotryl™ (enrofloxacin) 100 mg/ml injectable solution: Animals intended for human consumption must not be slaughtered within 28 days from the last treatment. This product is not approved for use in 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 the calves born to these cows. A withdrawal period has not been established for this product in pre-ruminating calves. Federal (USA) law prohibits the extra-label use of this drug in food producing animals.

Learn more about Tenotryl™ and other products for the treatment of BRD at **https://vet-us.virbac.com/cattle**

[1] *McKellar, Q., Gibson, I., Monteiro, A., Bregante, M. 1999. Pharmacokinetics of Enrofloxacin and Danofloxacin in Plasma, Inflammatory Exudate, and Bronchial Secretions of Calves following Subcutaneous Administration. ANTIMICROBIAL AGENTS AND CHEMOTHERAPY, Aug. 1999, p. 1988–1992.*

[2] *Apley, Michael D., DVM, Ph.D. 2015. Treatment of Calves with Bovine Respiratory Disease; Duration of Therapy and Posttreatment Intervals - Vet Clin Food Anim 31 (2015) 441–453.*

[3] *Giguére, S.; Prescot, J.F.; Dowling, P.M. 2013. Antimicrobial Therapy in Veterinary Medicine, Fifth Edition.*

[4] *Stanford, et al. Antimicrobial Resistance in Members of the Bacterial Bovine Respiratory Disease Complex Isolated from Lung Tissue of Cattle Mortalities Managed with or without the Use of Antimicrobials. Microorganisms 2020, 8, 288.*

[5] *Portis, et al. A ten-year (2000–2009) study of antimicrobial susceptibility of bacteria that cause bovine respiratory disease complex—Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni—in the United States and Canada. Journal of Veterinary Diagnostic Investigation 24(5) 932–944.*