Enroflox 100 – At-A-Glance

ANADA 200-495

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.

Active Ingredient – enrofloxacin is a broad-spectrum fluoroquinolone antimicrobial agent. Each mL of Enroflox 100 contains 100 mg of enrofloxacin.

Storage Conditions – Protect from direct sunlight. Do not refrigerate or freeze. Store below 77°F (25°C). Precipitation may occur due to cold temperature. To re-dissolve, warm and then shake the vial.

Broaching Statements:

100 mL vial – Use within 30 days of first puncture and puncture a maximum of 36 times. When using a needle or draw-off spike larger than 16 gauge, discard any remaining product immediately after use.

250 mL and 500 mL vials - Use within 30 days of first puncture. Puncture a maximum of 36 times with a needle or dosage delivery device 16 gauge or smaller, or 4 times with a draw-off spike 5mm or smaller. When using a needle larger than 16 gauge, or a draw-off spike larger than 5mm, discard any remaining product immediately after use.

Indications –

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

Swine: Enroflox 100 is indicated for the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis, Streptococcus suis, Bordetella bronchiseptica,* and *Mycoplasma hyopneumoniae.* Enroflox 100 is indicated for the control of colibacillosis in groups or

pens of weaned pigs where colibacillosis associated with *Escherichia coli* has been diagnosed.

To assure responsible antimicrobial use, enrofloxacin should only be used as a second-line drug for colibacillosis in swine following consideration of other therapeutic options.

Dosage and Administration

Enroflox 100 provides flexible dosages and durations of therapy. Enroflox 100 may be administered as a single dose for one day for treatment and control of BRD (cattle), for treatment and control of SRD or for control of colibacillosis (swine), 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/100Lb).

Multiple-Day Therapy (BRD Treatment): Administer daily, a subcutaneous dose of 2.5-5 mg/kg of body weight (1.1-2.3 mL/100Lb). 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/100Lb). Examples of conditions that may contribute to calves being at high risk for 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 at least 30°F during transportation.
- A temperature fluctuation of at least 30°F 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.

Swine: administer, either by intramuscular or subcutaneous (behind the ear) injection, a single dose of 7.5 mg/kg of body weight (3.4 mL/100Lb). Administered dose volume should not exceed 5 mL per injection site. For the control of colibacillosis, administration should be initiated within the first 60 days post-weaning when clinical signs are present

in at least 2% of the animals in the group. If no improvement is noted within 48 hours, the diagnosis should be reevaluated.

Differentiation – identical to the pioneer.

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

The long-term effects on articular joint cartilage have not been determined in pigs above market weight.

Subcutaneous injection in cattle or swine, or intramuscular injection in swine, can cause a transient local tissue reaction that may result in trim loss of edible tissue at slaughter.

Enroflox 100 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 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.

Warnings – Not for use in humans. Keep out of reach of children.

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 or 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. **Swine:** Animals intended for human consumption must not be slaughtered within 5 days of receiving a single-injection dose.

Presentation –

Strength	**Bottle Size**
100 mg/mL enrofloxacin	100 mL, 250 mL and 500 mL bottles
Private Label Brands*	
Covetrus - Enrofloxacin 100 Injection	100 mL and 250 mL sizes only

Competition –

Pioneer – Baytril (Elanco)	100 mL, 250 mL and 500 mL bottles

ENROFLOX 100 – Fair Balance Statement – CATTLE – I07:
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ENROFLOX 100 – Fair Balance Statement – SWINE I07:
Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals. To assure responsible antimicrobial drug use, enrofloxacin should only be used as a second-line drug for colibacillosis in swine following consideration of other therapeutic options. Swine intended for human consumption must not be slaughtered within 5 days of receiving a single-injection dose. Use with caution in animals with known or suspected CNS disorders. Observe label directions and withdrawal times. See product labeling for full product information.