

Editorial Review Board 2014

Articles in *The Bovine Practitioner* have been reviewed by two to four Editorial Review Board members. Reviewers for 2014 included:

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NOTES

Mark your calendars!

Upcoming AABP Conferences

2014

Albuquerque, New Mexico • September 18-20

2015

New Orleans, Louisiana • September 17-19

2016

Charlotte, North Carolina • September 15-17



ANADA 200-495, Approved by FDA

Enroflox 100

(enrofloxacin) 100 mg/mL Antimicrobial Injectable Solution

For Subcutaneous Use in Beef Cattle, Non-Lactating Dairy For Subcutations Ose in Dear Caute, 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.

Brief Summary: Before using Enroflox 100, consult the product insert, a summary of which follows.

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: Each mL of Enroflox 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.

INDICATIONS:

Cattle: Enroflox 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.

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

Enroflox 100 is administered as a single dose for one day (swine) or for multiple days (cattle) of therapy.

Enroflox 100 is not approved for a one-day, single dose of therapy in cattle.

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 yeal.

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

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.

PRECAUTIONS:

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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 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. been determined.

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

ANIMAL SAFETY:
In cattle safety studies, 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, inappetance and incoordination were observed when a dose of 50 mg/kg was administered for 3 days. An injection site study conducted in feeder calves demonstrated that the formulation may induce a transient reaction in the subcutaneous tissue and underlying muscle. In swine safety studies, 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. An injection site study conducted in pigs demonstrated that the formulation may induce a transient reaction in the subcutaneous tissue.

Norbrook Laboratories Limited Newry, BT35 6PU, Co. Down, Northern Ireland





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