

Date of Approval: April 5, 2021

FREEDOM OF INFORMATION SUMMARY
ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-697
Enrofloxacin
Injectable Solution
Dogs

Enrofloxacin Injectable Solution is indicated for the management of diseases in dogs associated with bacteria susceptible to enrofloxacin.

Sponsored by:
Accord Healthcare, Inc.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-697

B. Sponsor

Accord Healthcare, Inc.
1009 Slater Rd.
suite 210-B
Durham, NC 27703

Drug Labeler Code: 016729

C. Proprietary Name

Enrofloxacin

D. Drug Product Established Name

enrofloxacin

E. Pharmacological Category

Antimicrobial

F. Dosage Form

Injectable Solution

G. Amount of Active Ingredient

22.7 mg/mL (2.27%)

H. How Supplied

20 mL vial

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Enrofloxacin Injectable Solution may be used as the initial dose at 2.5 mg/kg. It should be administered intramuscularly (IM) as a single dose, followed by initiation of enrofloxacin tablet therapy. The initial Enrofloxacin Injectable administration should be followed 12 hours later by initiation of enrofloxacin tablet therapy.

K. Route of Administration

Intramuscular (IM) injection

L. Species/Class

Dogs

M. Indication

Enrofloxacin Injectable Solution is indicated for the management of diseases in dogs associated with bacteria susceptible to enrofloxacin.

N. Reference Listed New Animal Drug (RLNAD)

Baytril®; enrofloxacin; NADA 140-913; Elanco US Inc.

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). The ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. Effectiveness, target animal safety and human food safety data (other than tissue residue data) are not required for approval of an ANADA. If bioequivalence is demonstrated through a clinical endpoint study in a food producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Accord Healthcare, Inc., was granted a biowaiver for the generic product Enrofloxacin Injectable Solution. The generic drug product is an injectable solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is Baytril® (enrofloxacin) Injectable Solution, sponsored by Elanco US Inc., under NADA 140-913, and was approved for use in dogs on May 4, 1990.

III. HUMAN FOOD SAFETY

This drug is intended for use in dogs. Because this new animal drug is not intended for use in food-producing animals, CVM did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this ANADA.

IV. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Enrofloxacin:

For use in animals only. 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 exposure. 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.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the SDS, contact Accord Healthcare Inc. at 1-866-941-7875. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>.

V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the FD&C Act. The data demonstrate that Enrofloxacin, when used according to the label, is safe and effective for the indications listed in Section I.M. above.