

Date of Approval: May 9, 2024

**FREEDOM OF INFORMATION SUMMARY**  
**ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION**

ANADA 200-782

EnroPro™ Silver Otic

(enrofloxacin/silver sulfadiazine)

Otic emulsion

Dogs

EnroPro™ Silver Otic is indicated as a treatment for canine otitis externa complicated by bacterial and fungal organisms susceptible to enrofloxacin and/or silver sulfadiazine.

Sponsored by:

Cronus Pharma Specialities India Private Ltd

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**I. GENERAL INFORMATION**

**A. File Number**

ANADA 200-782

**B. Sponsor**

Cronus Pharma Specialities India Private Ltd  
Plot No.9(B), Survey No. 99/1, GMR Hyderabad Aviation SEZ Ltd  
Mamidipalle Village, Balapur Mandal, Shamshabad, Rangareddy,  
Hyderabad, Telangana, 500108, India

Drug Labeler Code: 069043

**C. Proprietary Name**

EnroPro™ Silver Otic

**D. Drug Product Established Name**

enrofloxacin/silver sulfadiazine

**E. Pharmacological Category**

Antibacterial and antimycotic

**F. Dosage Form**

Otic emulsion

**G. Amount of Active Ingredient**

Each milliliter contains enrofloxacin 5 mg (0.5% w/v), silver sulfadiazine (SSD) 10 mg (1.0% w/v)

**H. How Supplied**

15 mL and 30 mL bottles with droppers

**I. Dispensing Status**

Prescription (Rx)

**J. Dosage Regimen**

As a general guide, administer 5-10 drops per treatment in dogs weighing 35 lbs. or less and 10-15 drops per treatment in dogs weighing more than 35 lbs. Following treatment, gently massage the ear so as to ensure complete and uniform distribution of the medication throughout the external ear canal. Apply twice daily for a duration of up to 14 days.

#### **K. Route of Administration**

Otic

#### **L. Species/Class**

Dogs

#### **M. Indication**

EnroPro™ Silver Otic is indicated as a treatment for canine otitis externa complicated by bacterial and fungal organisms susceptible to enrofloxacin and/or silver sulfadiazine.

#### **N. Reference Listed New Animal Drug (RLNAD)**

Baytril® Otic; enrofloxacin/silver sulfadiazine; NADA 141-176; 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, Cronus Pharma Specialities India Private Ltd, was granted a biowaiver for the generic product EnroPro™ Silver Otic (enrofloxacin/silver sulfadiazine) otic emulsion. The generic drug product is an otic emulsion, 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® Otic (enrofloxacin/silver sulfadiazine) otic emulsion, sponsored by Elanco US Inc., under NADA 141-176, and was approved for use in dogs on September 29, 2000.

### **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 EnroPro™ Silver Otic:

**HUMAN WARNINGS:**

Not for human use. 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 develops or persists following ocular or dermal exposures. Individuals with a history of hypersensitivity to quinolone compounds or antibacterials should avoid handling 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.

**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 EnroPro™ Silver Otic, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.