Date of Approval: March 28, 2022

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-688

Tenotryl™

(enrofloxacin)

Injectable Solution

Beef cattle, non-lactating dairy cattle, and swine

Cattle – 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*.
Cattle – 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.
Swine: Tenotryl™ 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*. Tenotryl™ is indicated for the control of colibacillosis in groups or pens of weaned pigs where colibacillosis associated with *Escherichia coli* has been diagnosed.

Sponsored by:

Virbac AH, Inc.

Table of Contents

I. GENERAL INFORMATION

A. File Number

ANADA 200-688

B. Sponsor

Virbac AH, Inc.
PO Box 162059
Fort Worth, TX 76161

Drug Labeler Code: 051311

C. Proprietary Name

Tenotryl™

D. Drug Product Established Name

enrofloxacin

E. Pharmacological Category

Antimicrobial

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

100 mg/mL

H. How Supplied

100 mL, 250 mL, and 500 mL bottles

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Tenotryl™ 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).

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/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).

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/100 lb). 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.

K. Route of Administration

Subcutaneous injection in beef and non-lactating dairy cattle
Intramuscular or subcutaneous (behind the ear) injection in swine

L. Species/Class

Beef cattle, non-lactating dairy cattle, and swine

M. Indications

Cattle – 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*.

Cattle – 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.

Swine: Tenotryl™ 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*. Tenotryl™ is indicated for the control of colibacillosis in groups or pens of weaned pigs where colibacillosis associated with *Escherichia coli* has been diagnosed.

N. Reference Listed New Animal Drug (RLNAD)

Baytril® 100; enrofloxacin; NADA 141-068; 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, Virbac AH, Inc., was granted a biowaiver for the generic product Tenotryl™ (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® 100 (enrofloxacin) injectable solution, sponsored by Elanco US Inc., under NADA 141-068, and was approved for use in cattle on July 24, 1998, and for use in swine on March 14, 2008.

III. HUMAN FOOD SAFETY

The tolerances for residues and withdrawal periods established for the RLNAD apply to the generic product. The following are assigned to this product for beef cattle, non-lactating dairy cattle, and swine:

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) for total residues of enrofloxacin is 3 µg/kg of body weight per day. The tolerances established for the RLNAD apply to the generic product. A tolerance of 0.1 part per million (ppm) is established for desethylene ciprofloxacin (the marker residue) in liver (the target tissue) of cattle, and a tolerance of 0.5 ppm is established for enrofloxacin (the marker residue) in liver (the target tissue) of swine, under 21 CFR 556.226.

B. Withdrawal Periods

Because a biowaiver was granted, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of 28 days has been established for enrofloxacin in beef cattle and non-lactating dairy cattle. A withdrawal period of 5 days has been established for enrofloxacin in swine.

C. Analytical Methods for Residues

The validated analytical methods for analysis of residues of enrofloxacin are on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855. To obtain a copy of the analytical methods, please submit a Freedom of Information request to: https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm.

IV. USER SAFETY

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

Not for use in humans. 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 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. 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 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 Tenotryl™, when used according to the label, is safe and effective for the indications listed in Section I.M. above.

Additionally, data demonstrate that residues in food products derived from beef cattle, non-lactating dairy cattle, and swine treated with Tenotryl™ will not represent a public health concern when the product is used according to the label.