

Date of Approval: May 16, 2019

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-598

EnroMed™ 100

enrofloxacin

injectable solution

Beef and Non-Lactating Dairy Cattle and Swine

Cattle-Single-Dose Therapy: EnroMed™ 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: EnroMed™ 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: EnroMed™ 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*. EnroMed™ 100 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:

Bimeda Animal Health Limited

Table of Contents

I. GENERAL INFORMATION	3
II. BIOEQUIVALENCE	4
III. EFFECTIVENESS.....	5
IV. TARGET ANIMAL SAFETY.....	5
V. HUMAN FOOD SAFETY	5
VI. USER SAFETY	6
VII. AGENCY CONCLUSIONS	6

I. GENERAL INFORMATION

A. File Number

ANADA 200-598

B. Sponsor

Bimeda Animal Health Limited
1B The Herbert Building, The Park,
Carrickmines, Dublin, 18, Ireland

Drug Labeler Code: 061133

US Agent Name and Address:
Ms. Stephanie Batliner
Bimeda Inc.
One Tower Lane Suite 2250
Oakbrook Terrace, IL 60181

C. Proprietary Name

EnroMed™ 100

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 multi-dose vial

I. Dispensing Status

Rx

J. Dosage Regimen

EnroMed™ 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).

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).

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.

K. Route of Administration

Injection

Subcutaneous in beef and non-lactating dairy cattle

Subcutaneous and intramuscular in swine

L. Species/Class

Cattle (beef and non-lactating dairy)

Swine

M. Indications

Cattle-Single-Dose Therapy: EnroMed™ 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: EnroMed™ 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: EnroMed™ 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*. EnroMed™ 100 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

Baytril® 100; enrofloxacin; NADA 141-068; Bayer Healthcare LLC, Animal Health Division

II. BIOEQUIVALENCE

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTA) of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (reference listed new animal drug (RLNAD)).

New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, 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. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal period for the generic product should also be conducted. 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, Bimeda Animal Health Limited, was granted a biowaiver for the generic product EnroMed™ 100 (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 Bayer Healthcare LLC, Animal Health Division, under NADA 141-068 and, was approved for use in cattle on July 24, 1998 and in swine on March 14, 2008.

III. EFFECTIVENESS

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY

CVM did not require target animal safety studies for this approval.

V. HUMAN FOOD SAFETY

The following are assigned to this product for cattle and swine:

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) for total residues of enrofloxacin is 3 micrograms per kilogram of body weight per day (21 CFR 556.226). The tolerances established for the RLNAD apply to the generic product. A tolerance of 0.1 part per million (ppm) is established for desethylen ciprofloxacin (the marker residue) in cattle liver (the target tissue), and a tolerance of 0.5 ppm is established for enrofloxacin (the marker residue) in swine liver (the target tissue), 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 and non-lactating dairy cattle. A withdrawal period of 5 days has been established for enrofloxacin in swine.

C. Analytical Method for Residues

The validated analytical method for analysis of residues of enrofloxacin is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855. To obtain a copy of the analytical method, please submit a Freedom of Information Summary request to:

<https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm>.

VI. USER SAFETY

CVM did not require user safety studies for this approval.

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to EnroMed™ 100:

“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.”

VII. AGENCY CONCLUSIONS

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that EnroMed™ 100, when used according to the label, is safe and effective.

Additionally, data demonstrates that residues in food products derived from species treated with EnroMed™ 100 will not represent a public health concern when the product is used according to the label.