Date of Approval: May 16, 2024

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-781

Flunine™

(flunixin meglumine injection)

Injectable solution

Horses, beef cattle, and dairy cattle (excluding dry dairy cows)

Horse: Flunine™ (flunixin meglumine injection) is recommended for the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse. It is also recommended for the alleviation of visceral pain associated with colic in the horse.

Cattle: Flunine™ (flunixin meglumine injection) is indicated for the control of pyrexia associated with bovine respiratory disease, endotoxemia and acute bovine mastitis. Flunine™ is also indicated for the control of inflammation in endotoxemia.

Sponsored by:

Cronus Pharma Specialities India Private Ltd

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I. GENERAL INFORMATION

A. File Number

ANADA 200-781

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

Flunine™

D. Drug Product Established Name

flunixin meglumine injection

E. Pharmacological Category

Non-steroidal anti-inflammatory drug (NSAID), antipyretic, and analgesic

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

50 mg/mL

H. How Supplied

100 mL, 250 mL, and 500 mL multi-dose vials

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Horse: The recommended dose for musculoskeletal disorders is 0.5 mg per pound (1 mL/100 lbs) of body weight once daily. Treatment may be given by intravenous or intramuscular injection and repeated for up to 5 days. The recommended dose for the alleviation of pain associated with equine colic is 0.5 mg per pound of body weight. Intravenous administration is recommended for prompt relief. Treatment may be repeated when signs of colic recur.

Cattle: The recommended dose for control of pyrexia associated with bovine respiratory disease and endotoxemia and control of inflammation in endotoxemia, is

1.1 to 2.2 mg/kg (0.5 to 1 mg/lb; 1 to 2 mL per 100 lbs) of body weight given by slow intravenous administration either once a day as a single dose or divided into two doses administered at 12-hour intervals for up to 3 days. The total daily dose should not exceed 2.2 mg/kg (1.0 mg/lb) of body weight. Avoid rapid intravenous administration of the drug. The recommended dose for acute bovine mastitis is 2.2 mg/kg (1 mg/lb; 2 mL per 100 lbs) of body weight given once by intravenous administration.

K. Route of Administration

Horse: Intravenous or intramuscular injection
Cattle: Intravenous injection

L. Species/Class

Horses, beef cattle, and dairy cattle (excluding dry dairy cows)

M. Indications

Horse: Flunine™ (flunixin meglumine injection) is recommended for the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse. It is also recommended for the alleviation of visceral pain associated with colic in the horse.

Cattle: Flunine™ (flunixin meglumine injection) is indicated for the control of pyrexia associated with bovine respiratory disease, endotoxemia and acute bovine mastitis. Flunine™ is also indicated for the control of inflammation in endotoxemia.

N. Reference Listed New Animal Drug (RLNAD)

Banamine®; flunixin meglumine injection; NADA 101-479; Intervet, 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 Flunine™ (flunixin meglumine injection). 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 Banamine® (flunixin meglumine injection), sponsored by

Intervet, Inc., under NADA 101-479, and was approved for use in horses on August 2, 1977, for use in beef cattle and non-lactating dairy cattle on May 6, 1998, and for use in lactating dairy cows on August 19, 2004.

III. HUMAN FOOD SAFETY

The product labeling contains the following Warning statement: Not for use in horses intended for food.

The tolerances for residues and the withdrawal period and milk discard time established for the RLNAD apply to the generic product. The following are assigned to this product for cattle:

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) for total residues of flunixin is 0.72 µg/kg of body weight *per* day. The tolerances established for the RLNAD apply to the generic product. A tolerance of 125 parts per billion (ppb) is established for flunixin free acid (the marker residue) in liver (the target tissue) and 25 ppb in muscle. A tolerance of 2 ppb is established for 5-hydroxy flunixin (the marker residue) in milk, under 21 CFR 556.286.

B. Withdrawal Period and Milk Discard Time

Because a biowaiver was granted, the withdrawal period and milk discard time are those previously assigned to the RLNAD product. A withdrawal period of 4 days and a milk discard time of 36 hours have been established for flunixin meglumine injection in cattle.

C. Analytical Method for Residues

The validated analytical method for analysis of residues of flunixin 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 request to: https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm.

IV. 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 Flunine™, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.

Additionally, data demonstrate that residues in food products derived from beef cattle and dairy cattle (excluding dry dairy cows) treated with Flunine™ will not represent a public health concern when the product is used according to the label.