Date of Approval: July 11, 2023

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-753

Cropamezole™

(atipamezole hydrochloride)

Sterile injectable solution

Dogs

Cropamezole™ is indicated for the reversal of the sedative and analgesic effects of dexmedetomidine hydrochloride, and medetomidine hydrochloride in dogs.

Sponsored by:

Cronus Pharma Specialities India Private Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-753

B. Sponsor

Cronus Pharma Specialities India Private Ltd.,
Sy No-99/1, M/s GMR Hyderabad Aviation SEZ Ltd.,
Mamidipalli Village, Shamshabad Mandal,
Ranga Reddy, Hyderabad, Telangana, 501218, India

Drug Labeler Code: 069043

C. Proprietary Name

Cropamezole™

D. Drug Product Established Name

atipamezole hydrochloride

E. Pharmacological Category

Alpha$_2$-adrenoreceptor antagonist

F. Dosage Form

Sterile injectable solution

G. Amount of Active Ingredient

5 mg/mL

H. How Supplied

10 mL multidose vials

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Cropamezole™ is administered intramuscularly (IM) for reversal of sedation and analgesia regardless of the route used for dexmedetomidine hydrochloride or medetomidine hydrochloride. The atipamezole dose for the reversal of intravenous dexmedetomidine hydrochloride or medetomidine hydrochloride is 3750 mcg/m^2. The atipamezole dose for the reversal of IM dexmedetomidine hydrochloride or medetomidine hydrochloride is 5000 mcg/m^2.

K. Route of Administration

Intramuscular injection

L. Species/Class

Dogs

M. Indication

Cropamezole™ is indicated for the reversal of the sedative and analgesic effects of dexmedetomidine hydrochloride, and medetomidine hydrochloride in dogs.

N. Reference Listed New Animal Drug (RLNAD)

ANTISEDAN®; atipamezole hydrochloride; NADA 141-033; Orion Corp.

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 Cropamezole™ (atipamezole hydrochloride) sterile 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 ANTISEDAN® (atipamezole hydrochloride) sterile injectable solution, sponsored by Orion Corp., under NADA 141-033, and was approved for use in dogs on August 6, 1996.

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 Cropamezole™:

HUMAN WARNINGS

Not for human use. Keep out of reach of children.

Atipamezole hydrochloride can be absorbed and may cause irritation following direct exposure to skin, eyes, or mouth. In case of accidental eye exposure, flush with water for 15 minutes. In case of accidental skin exposure, wash with soap and water. Remove contaminated clothing.

If irritation or other adverse reaction occurs (for example, increased heart rate, tremor, muscle cramps), seek medical attention.

In case of accidental oral exposure or injection, seek medical attention. Caution should be used while handling and using filled syringes.

Users with cardiovascular disease (for example, hypertension or ischemic heart disease) should take special precautions to avoid any exposure to this product.

Note to Physician: This product contains an alpha$_2$-adrenergic antagonist.

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 Cropamezole™, when used according to the label, is safe and effective for the indications listed in Section I.M. above.