Date of Approval: February 6, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-838

Atipamezole Hydrochloride Injection

(atipamezole hydrochloride)

Sterile Injectable Solution

Dogs

For the reversal of the sedative and analgesic effects of dexmedetomidine hydrochloride, and medetomidine hydrochloride in dogs.

Sponsored by:

Felix Pharmaceuticals Pvt. Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-838

B. Sponsor

Felix Pharmaceuticals Pvt. Ltd.
25-28 North Wall Quay
Dublin 1, Ireland

Drug Labeler Code: 086101

U.S. Agent Name and Address:

Sreejith Kurup
Felixvet Inc.
1300 NW Briarcliff Parkway
Suite 100
Kansas City, MO 64150

C. Proprietary Name

Atipamezole Hydrochloride Injection

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

5.0 mg atipamezole hydrochloride/mL

H. How Supplied

10 mL multidose vials

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Atipamezole Hydrochloride Injection 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 (IV) 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.

The dosage of Atipamezole Hydrochloride Injection is calculated based on body surface area.

K. Route of Administration

Intramuscular injection

L. Species

Dogs

M. Indication

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 Corporation

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, Felix Pharmaceuticals Pvt. Ltd., was granted a biowaiver for the generic product Atipamezole Hydrochloride Injection (atipamezole hydrochloride). The generic drug product is a sterile 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), 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, the Food and Drug Administration (FDA) 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 Atipamezole Injectable Solution:

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 Atipamezole Hydrochloride Injection, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.