

Date of Approval: March 11, 2021

FREEDOM OF INFORMATION SUMMARY
ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-699

Dexmedetomidine Hydrochloride Injection

(dexmedetomidine hydrochloride)

Injectable Solution

Dogs and cats

Dexmedetomidine Hydrochloride Injection is indicated for use as a sedative and analgesic in dogs and cats to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures. Dexmedetomidine Hydrochloride Injection is also indicated for use as a preanesthetic to general anesthesia in dogs and cats.

Sponsored by:

Akorn Operating Company LLC (dba Akorn Animal Health Inc.)

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I. GENERAL INFORMATION

A. File Number

ANADA 200-699

B. Sponsor

Akorn Operating Company LLC (dba Akorn Animal Health Inc.)
1925 West Field Ct.
suite 300
Lake Forest, IL 60045

Drug Labeler Code: 059399

C. Proprietary Name

Dexmedetomidine Hydrochloride Injection

D. Drug Product Established Name

dexmedetomidine hydrochloride

E. Pharmacological Category

Alpha₂-adrenoreceptor agonist

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

0.5 mg/mL

H. How Supplied

10 mL multi-dose vials

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Dogs: Sedation and Analgesia: 500 mcg/m² intramuscularly (IM) or 375 mcg/m² intravenously (IV). Preanesthesia: 125 or 375 mcg/m² IM.

Cats: Sedation, Analgesia and Preanesthesia: 40 mcg/kg intramuscularly (IM).

K. Route of Administration

Intramuscular injection (dogs and cats) and intravenous injection (dogs)

L. Species/Class

Dogs and cats

M. Indications

Dexmedetomidine Hydrochloride Injection is indicated for use as a sedative and analgesic in dogs and cats to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures. Dexmedetomidine Hydrochloride Injection is also indicated for use as a preanesthetic to general anesthesia in dogs and cats.

N. Reference Listed New Animal Drug (RLNAD)

DEXDOMITOR®; dexmedetomidine hydrochloride; NADA 141-267; 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, Akorn Operating Company LLC (dba Akorn Animal Health Inc.), was granted a biowaiver for the generic product Dexmedetomidine Hydrochloride 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 DEXDOMITOR® (dexmedetomidine hydrochloride) Sterile Injectable Solution, sponsored by Orion Corp., under NADA 141-267, and was approved for use in dogs on December 1, 2006 and approved for use in cats on September 7, 2007.

III. HUMAN FOOD SAFETY

This drug is intended for use in dogs and cats. 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 Dexmedetomidine Hydrochloride Injection:

Human safety: Not for human use. Keep out of reach of children.

Dexmedetomidine hydrochloride can be absorbed following direct exposure to skin, eyes, or mouth, and may cause irritation. 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.

Appropriate precautions should be taken while handling and using filled syringes. Accidental topical (including ocular) exposure, oral exposure, or exposure by injection could cause adverse reactions, including sedation, hypotension, and bradycardia. Seek medical attention immediately.

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

Caution should be exercised when handling sedated animals. Handling or any other sudden stimuli, including noise, may cause a defense reaction in an animal that appears to be heavily sedated.

The safety data sheet (SDS) contains more detailed occupational safety information. To report adverse reactions in users or to obtain a copy of the SDS for this product call 1-800-932-5676.

Note to physician: This product contains an alpha₂-adrenergic agonist.

V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the Federal Food, Drug, and Cosmetic Act. The data demonstrate that Dexmedetomidine Hydrochloride Injection, when used according to the label, is safe and effective.