Date of Approval: January 11, 2023

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-611

DetomiSed™

(detomidine hydrochloride)

Injectable solution

Horses

DetomiSed™ is indicated for use as a sedative and analgesic to facilitate minor surgical and diagnostic procedures in mature horses and yearlings.

Sponsored by:

Akorn Operating Company LLC

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I. GENERAL INFORMATION

A. File Number

ANADA 200-611

B. Sponsor

Akorn Operating Company LLC
5605 Centerpoint Court
Suite A
Gurnee, IL 60031

Drug Labeler Code: 059399

C. Proprietary Name

DetomiSed™

D. Drug Product Established Name

detomidine hydrochloride

E. Pharmacological Category

Alpha$_2$-adrenoreceptor agonist

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

10 mg/mL

H. How Supplied

5 mL and 20 mL multi-dose vials

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

For Sedation: Administer DetomiSed™ IV or IM at the rates of 20 or 40 mcg detomidine hydrochloride per kg of body weight (0.2 or 0.4 mL of DetomiSed™ per 100 kg or 220 lb), depending on the depth and duration of sedation required. Onset of sedative effects should be reached within 2 to 4 minutes after IV administration and 3 to 5 minutes after IM administration. Twenty mcg/kg will provide 30 to 90 minutes of sedation and 40 mcg/kg will provide approximately 90 minutes to 2 hours of sedation.

For Analgesia: Administer DetomiSed™ IV at the rates of 20 or 40 mcg detomidine hydrochloride per kg of body weight (0.2 or 0.4 mL of DetomiSed™ per 100 kg or 220 lb), depending on the depth and duration of analgesia required.

Twenty mcg/kg will usually begin to take effect in 2 to 4 minutes and provide 30 to 45 minutes of analgesia. The 40 mcg/kg dose will also begin to take effect in 2 to 4 minutes and provide 45 to 75 minutes of analgesia.

For Both Sedation and Analgesia: Administer DetomiSed™ IV at the rates of 20 or 40 mcg detomidine hydrochloride per kg of body weight (0.2 or 0.4 mL of DetomiSed™ per 100 kg or 220 lb), depending on the depth and duration of sedation and analgesia required.

Before and after injection, the animal should be allowed to rest quietly.

K. Route of Administration

For Sedation: Intravenous and intramuscular injection

For Analgesia: Intravenous injection

For Both Sedation and Analgesia: Intravenous injection

L. Species/Class

Horses

M. Indications

DetomiSed™ is indicated for use as a sedative and analgesic to facilitate minor surgical and diagnostic procedures in mature horses and yearlings.

N. Reference Listed New Animal Drug (RLNAD)

DORMOSEDAN®; detomidine hydrochloride; NADA140-862; 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, was granted a biowaiver for the generic product DetomiSed™ (detomidine hydrochloride) sterile 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 DORMOSEDAN® (detomidine

hydrochloride) sterile solution, sponsored by Orion Corp., under NADA 140-862, and was approved for use in horses on December 6, 1989.

III. HUMAN FOOD SAFETY

This drug is intended for use in horses. 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.

The product labeling contains the following Warning statement: Do not use in horses intended for human consumption.

IV. USER SAFETY

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

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

HUMAN SAFETY INFORMATION: Care should be taken to assure that detomidine hydrochloride is not inadvertently ingested as safety studies have indicated that the drug is well absorbed when administered orally. Standard ocular irritation tests in rabbits using the proposed market formulation have shown detomidine hydrochloride to be nonirritating to eyes. Primary dermal irritation tests in guinea pigs using up to 5 times the proposed market concentration of detomidine hydrochloride on intact and abraded skin have demonstrated that the drug is nonirritating to skin and is apparently poorly absorbed dermally. However, in accordance with prudent clinical procedures, exposure of eyes or skin should be avoided and affected areas should be washed immediately if exposure does occur. As with all injectable drugs causing profound physiological effects, routine precautions should be employed by practitioners when handling and using loaded syringes to prevent accidental self-injection.

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