

Date of Approval: April 27, 2020

**FREEDOM OF INFORMATION SUMMARY**  
**ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION**

**ANADA 200-674**

**Detomidine Hydrochloride**

**Injectable solution**

**Horses**

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

**Sponsored by:**

**Modern Veterinary Therapeutics, LLC**

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**I. GENERAL INFORMATION**

**A. File Number**

ANADA 200-674

**B. Sponsor**

Modern Veterinary Therapeutics, LLC  
14343 SW 119th Ave.  
Miami, FL 33186

Drug Labeler Code: 015914

**C. Proprietary Name**

Detomidine Hydrochloride

**D. Drug Product Established Name**

detomidine hydrochloride

**E. Pharmacological Category**

alpha<sub>2</sub>-adrenoreceptor agonist

**F. Dosage Form**

Injectable solution

**G. Amount of Active Ingredient**

10 mg/mL

**H. How Supplied**

5 mL and 20 mL multidose vials

**I. Dispensing Status**

Prescription (Rx)

**J. Dosage Regimen**

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

For Analgesia: Administer Detomidine Hydrochloride IV at the rates of 20 or 40 mcg detomidine hydrochloride per kg of body weight (0.2 or 0.4 mL per 100 kg or 220 pounds), depending on the depth and duration of analgesia required. Twenty mcg/kg will usually begin to take effect in 2–4 minutes and provide 30–45

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

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

**K. Route of Administration**

Intravenous or intramuscular injection

**L. Species/Class**

Horses

**M. Indications**

Detomidine Hydrochloride 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; NADA 140-862; 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, Modern Veterinary Therapeutics, LLC, was granted a biowaiver for the generic product Detomidine Hydrochloride 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 DORMOSEDAN® (detomidine hydrochloride) injectable 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 Detomidine Hydrochloride:

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

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**

This information 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 Detomidine Hydrochloride when used according to the label, is safe and effective.