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
Table of Contents

I. GENERAL INFORMATION.................................................................................. 3
II. BIOEQUIVALENCE ....................................................................................... 4
III. HUMAN FOOD SAFETY ............................................................................... 5
IV. USER SAFETY............................................................................................... 5
V. AGENCY CONCLUSIONS............................................................................... 5
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.