

Date of Approval: May 25, 2017

FREEDOM OF INFORMATION SUMMARY
ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-610

Medetomidine Hydrochloride
(medetomidine hydrochloride)
Sterile Injectable Solution

Dogs

For use as a sedative and analgesic in dogs over 12 weeks of age to facilitate clinical examinations, clinical procedures, minor surgical procedures not requiring muscle relaxation, and minor dental procedures not requiring intubation. The intravenous route of administration is more efficacious for dental care.

Sponsored by:

Modern Veterinary Therapeutics, LLC

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-610

B. Sponsor

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

Drug Labeler Code: 015914

C. Proprietary Name

Medetomidine Hydrochloride

D. Product Established Name

medetomidine hydrochloride

E. Pharmacological Category

Alpha₂-adrenoreceptor agonist

F. Dosage Form

Sterile injectable solution

G. Amount of Active Ingredient

1 mg/mL

H. How Supplied

10 mL vial

I. Dispensing Status

Rx

J. Dosage Regimen

Medetomidine Hydrochloride should be administered at the rate of 750 mcg IV or 1000 mcg IM per square meter of body surface. Use the table below to determine the correct dosage on the basis of body weight.

Table I.1. Dosage and Administration

Body Weight (lb) - IV Administration	Injection Volume (mL)	Body Weight (lb) - IM Administration
3-4	0.1	N/A
5-7	0.15	4-5
8-11	0.2	6-7

Body Weight (lb) - IV Administration	Injection Volume (mL)	Body Weight (lb) - IM Administration
12-15	0.25	8-9
16-21	0.3	10-14
22-31	0.4	15-20
32-43	0.5	21-27
44-55	0.6	28-35
56-68	0.7	36-44
69-82	0.8	45-53
83-97	0.9	54-63
98-121	1.0	64-78
122-156	1.2	79-101
157-194	1.4	102-126
195+	1.6	127-165
N/A	2.0	166+

Following injection of Medetomidine Hydrochloride, the dog should be allowed to rest quietly for 15 minutes.

K. Route of Administration

Intravenous or intramuscular injection

L. Species/Class

Dogs

M. Indication

Medetomidine Hydrochloride is indicated for use as a sedative and analgesic in dogs over 12 weeks of age to facilitate clinical examinations, clinical procedures, minor surgical procedures not requiring muscle relaxation, and minor dental procedures not requiring intubation. The intravenous route of administration is more efficacious for dental care.

N. Reference Listed New Animal Drug

Domitor®; (medetomidine hydrochloride); NADA 140-999; Orion Corp.

II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (reference listed new animal drug (RLNAD)). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, 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. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal period for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the

requirement of demonstrating bioequivalence (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 waiver from the requirement to demonstrate bioequivalence for the generic product Medetomidine Hydrochloride (medetomidine hydrochloride) Sterile Injectable Solution. 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 Domitor® (medetomidine hydrochloride) Sterile Injectable Solution, sponsored by Orion Corp., under NADA 140-999 and, was approved for use in dogs on May 9, 1996.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this approval.

V. HUMAN FOOD SAFETY:

Data on human food safety, pertaining to drug residues in food, were not required for approval of this application. This drug is approved for use in dogs, which are not food producing animals.

VI. USER SAFETY:

CVM did not require user safety studies for this approval.

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

"For use in dogs only," "Federal law restricts this drug to use by or on the order of a licensed veterinarian," "Keep out of reach of children," "Not for use in humans," "Medetomidine 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 (e.g., sedation, hypotension, bradycardia), seek medical attention. In case of accidental oral exposure or injection, seek medical attention. Precaution should be used while handling and using filled syringes. Users with cardiovascular disease (e.g., hypertension or ischemic heart disease) should take special precautions to avoid any exposure to this product. The safety data sheet (SDS) contains more detailed occupational safety information."

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that Medetomidine Hydrochloride, when used according to the label, is safe and effective.