Date of Approval: March 31, 2014

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

ANADA 200-529

XYLAMED

xylazine

Injection

Horses and *Cervidae*
(Fallow Deer, Mule Deer, Sika Deer, White-Tailed Deer, and Elk)

XYLAMED should be used in horses and *Cervidae* (Fallow Deer, Mule Deer, Sika Deer, White-Tailed Deer, and Elk) when it is desirable to produce a state of sedation accompanied by a shorter period of analgesia.

Sponsored by:

Cross Vetpharm Group Ltd.

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-529

B. Sponsor

Cross Vetpharm Group Ltd.
Broomhill Rd.
Tallaght, Dublin 24, Ireland

Drug Labeler Code: 061623

US Agent:
Ms. Linda M. Duple
Bimeda Inc.
2836 Dolliver Park Avenue
Lehigh, IA 50557

C. Proprietary Name

XYLAMED

D. Established Name

xylazine

E. Pharmacological Category

Sedative and analgesic

F. Dosage Form:

Injectable solution

G. Amount of Active Ingredient

Each mL contains 100 mg xylazine hydrochloride

H. How Supplied

100 mg/mL injection for intravenous or intramuscular use is available in a 50 mL multiple dose vial

I. Dispensing Status

Rx

J. Dosage Regimen

Horses:
1. Dosage:
   Intravenously-0.5 mL/100 lbs body weight (0.5 mg/lb)
   Intramuscularly-1.0 mL/100 lbs body weight (1.0 mg/lb)

Following injection of XYLAMED, the animal should be allowed to rest quietly until the full effect has been reached.

These dosages produce sedation which is usually maintained for 1 to 2 hours, and analgesia which lasts for 15 to 30 minutes.

2. Preanesthetic to Local Anesthesia:
   XYLAMED at the recommended dosages can be used in conjunction with local anesthetics, such as procaine or lidocaine.

3. Preanesthetic to General Anesthesia:
   XYLAMED at the recommended dosage rates, produces an additive effect to central nervous system depressants such as pentobarbital sodium, thiopental sodium and thiamylal sodium. Therefore, the dosage of such compounds should be reduced and administered to the desired effect. In general, only 1/3 to 1/2 of the calculated dosage of the barbiturates will be needed to produce a surgical plane of anesthesia. Post-anesthetic or emergence excitement has not been observed in animals preanesthetized with XYLAMED.

XYLAMED has been used successfully as a preanesthetic agent for pentobarbital sodium, thiopental sodium, thiamylal sodium, nitrous oxide, ether, halothane, glyceryl guaiacolate, and methoxyflurane anesthesia.

Cervidae:
Administer intramuscularly, by either hand syringe or syringe dart, in the heavy muscles of the croup or shoulder.

Dosage Range:
Fallow Deer (*Dama dama*)-2.0 to 4.0 mL/100 lbs body weight (2.0 to 4.0 mg/lb).
Mule Deer (*Odocoileus hemionus*)-1.0 to 2.0 mL/100 lbs body weight (1.0 to 2.0 mg/lb).
Sika Deer (*Cervus nippon*)-1.0 to 2.0 mL/100 lbs body weight (1.0 to 2.0 mg/lb).
White-Tailed Deer (*Odocoileus virginianus*)-1.0 to 2.0 mL/100 lbs body weight (1.0 to 2.0 mg/lb).
Elk (*Cervus canadensis*)-0.25 to 0.5 mL/100 lbs body weight (0.25 to 0.5 mg/lb).

Following injection of XYLAMED the animal should be allowed to rest quietly until the full effect has been reached.

These dosages produce sedation which is usually maintained for 1 to 2 hours and analgesia which lasts for 15 to 30 minutes.

K. Route of Administration

Injection

L. Species/Class

Horses and *Cervidae* (Fallow Deer, Mule Deer, Sika Deer, White-Tailed Deer, and Elk).

M. Indications

XYLAMED should be used in horses and *Cervidae* (Fallow Deer, Mule Deer, Sika Deer, White-Tailed Deer, and Elk) when it is desirable to produce a state of sedation accompanied by a shorter period of analgesia.

Horses: XYLAMED has been used successfully as follows:
1. Diagnostic procedures-oral and ophthalmic examinations, abdominal palpation, rectal palpation, vaginal examination, catheterization of the bladder and radiographic examinations.
2. Orthopedic procedures, such as application of casting materials and splints.
3. Dental procedures.
4. Minor surgical procedures of short duration such as debridement, removal of cutaneous neoplasms and suturing of lacerations.
5. To calm and facilitate handling of fractious animals.
6. Therapeutic medication for sedation and relief of pain following injury or surgery.
7. Major surgical procedures:
   a. When used as a preanesthetic to general anesthesia.
   b. When used in conjunction with local anesthetics.

Cervidae: XYLAMED may be used for the following:
1. To calm and facilitate handling of fractious animals.
2. Diagnostic procedures.
3. Minor surgical procedures.
4. Therapeutic medication for sedation and relief of pain following injury or surgery.
5. As a preanesthetic to local anesthesia.

XYLAMED at the recommended dosages can be used in conjunction with local anesthetics, such as procaine or lidocaine.

N. Reference Listed New Animal Drug

ROMPUN; xylazine; NADA 047-956; Bayer Healthcare LLC, Animal Health Division

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 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). 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 reference listed new animal drug (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 time 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, Cross Vetpharm Group Ltd. was granted a waiver from the requirement to demonstrate bioequivalence for the generic product XYLAMED (xylazine) Injection. The generic product is administered as an injectable solution with the same active ingredient and excipients in the same concentration and dosage form as the RLNAD, and it contains no additional excipients or other changes in formulation from the RLNAD that may significantly affect the bioavailability of the active ingredient. The RLNAD is ROMPUN (xylazine) Injectable and was approved for use in horses and *Cervidae* (Fallow Deer, Mule Deer, Sika Deer, White-Tailed Deer, and Elk) on July 31, 1995.

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 horses and *Cervidae* (Fallow Deer, Mule Deer, Sika Deer, White-Tailed Deer, and Elk), which are not food producing animals.

VI. USER SAFETY:

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

- Keep out of reach of children. Not for human use.
- Avoid accidental administration to humans. Should such exposure occur, notify a physician immediately. Artificial respiration may be indicated.

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 XYLAMED, when used according to the label, is safe and effective.