Stamp Date: Sept. 28, 1998

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

ANADA 200-239

DOLOREX®

DOLOREX® (butorphanol tartrate) is indicated for the relief of pain associated with colic in adult horses and yearlings. Clinical studies in horses have shown that butorphanol tartrate alleviates abdominal pain associated with torsion, impaction, intussusception, spasmodic and tympanic colic, and postpartum pain.

Sponsored by:

Intervet Inc.
405 State Street
P.O. Box 318
Millsboro, Delaware 19966-0318

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION

ANADA Number:	200-239
Sponsor:	Intervet Inc. 405 State Street P.O. Box 318 Millsboro, Delaware 19966-0318
Generic Name:	butorphanol tartrate
Trade Name:	Dolorex®
How Dispensed:	Rx
Amount of Active Ingredients:	10 mg butorphanol base (as butorphanol tartrate, USP) per mL
Route of Administration:	Intravenous injection
Species:	Horses
Pioneer Product:	Torbugesic® (butorphanol tartrate) NADA 135-780, Fort Dodge Animal Health
Labeled Dosage/ Indications for Use:	DOLOREX® (butorphanol tartrate) is indicated for the relief of pain associated with colic in adult horses and yearlings. Clinical studies in horses have shown that butorphanol tartrate alleviates abdominal pain associated with torsion, impaction, intussusception, spasmodic and tympanic colic, and postpartum pain.

The recommended dosage in horses is 0.1 mg of butorphanol per kilogram body weight (0.05 mg/lb) given by intravenous injection. This is equivalent to 5 mL of DOLOREX® for each 1000 lb body weight. The dose may be repeated within 3 to 4 hours but treatment should not exceed 48 hours. Preclinical model studies and clinical field trials in horses demonstrate that analgesic effects of butorphanol are seen within 15 minutes following injection and persist for about 4 hours.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness and human food safety data in the pioneer's new animal drug application. Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an in vivo bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, April 1990).

Based upon the formulation characteristics of the generic product, Intervet Inc. was granted a waiver from conducting an in vivo bioequivalence study for DOLOREX® (butorphanol tartrate). The generic product is administered as an injectable solution. It contains the same active ingredient and drug concentration as the pioneer product. It is the same dosage form as the pioneer and contains no inactive ingredients that may significantly affect absorption of the active ingredient.

3. HUMAN FOOD SAFETY:

Human safety relative to food consumption, possession, handling and administration:

Labeling contains adequate caution/warning statements.

Regarding consumption of drug residues in food, human safety data were not required for approval of this ANADA. The drug is for use in horses which are non-food animals. The following warning statement is found on the label:

WARNING

FOR USE IN HORSES ONLY. NOT FOR USE IN HORSES INTENDED FOR FOOD.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that when butorphanol tartrate is used under the proposed conditions of use, it is safe and effective for its labeled indications.

Attachments:
generic product labeling
pioneer product labeling