

Date of Approval: March 22, 2021

FREEDOM OF INFORMATION SUMMARY
ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-625

KetoMed™

(ketoprofen)

sterile solution

Horses

KetoMed™ (ketoprofen) is recommended for the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse.

Sponsored by:

Bimeda Animal Health Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-625

B. Sponsor

Bimeda Animal Health Ltd.
1B The Herbert Building
The Park, Carrickmines
Dublin 18, Ireland

Drug Labeler Code: 061133

U.S. Agent Name and Address:
Deb Ann Voss
Bimeda Inc.
291 Forest Prairie Road
Le Sueur, MN 56058

C. Proprietary Name

KetoMed™

D. Drug Product Established Name

ketoprofen

E. Pharmacological Category

Nonsteroidal anti-inflammatory (NSAID)

F. Dosage Form

sterile solution

G. Amount of Active Ingredient

100 mg/mL

H. How Supplied

50 mL and 100 mL multidose bottles

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

The recommended dosage is 1 mg/lb (1 mL/100 lbs) of body weight once daily. Treatment is administered by intravenous injection and may be repeated for up to five days.

K. Route of Administration

Intravenous

L. Species/Class

Horses

M. Indication

KetoMed™ (ketoprofen) is recommended for the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse.

N. Reference Listed New Animal Drug (RLNAD)

KETOFEN®; ketoprofen; NADA 140-269; Zoetis Inc.

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, Bimeda Animal Health Ltd., was granted a biowaiver for the generic product KetoMed™ (ketoprofen) sterile solution. The generic drug product is a sterile 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 KETOFEN® (ketoprofen) sterile solution, sponsored by Zoetis Inc., under NADA 140-269, and was approved for use in horses on September 26, 1990.

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 KetoMed™:

To report suspected adverse drug events, for technical assistance, or to obtain a copy of the Safety Data Sheet (SDS), contact Bimeda, Inc. at 1-888-524-6332. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

V. AGENCY CONCLUSIONS

The data 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 KetoMed™, when used according to the label, is safe and effective for the indications listed in Section I.M. above.