

Date of Approval: May 20, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY
SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION
(ANADA)

ANADA 200-625

KetoMed™

(ketoprofen)

Injectable solution

Beef heifers, beef steers, beef calves 2 months of age and older, beef
bulls, replacement dairy heifers, and dairy bulls

This approval grants the use of KetoMed™ (ketoprofen) in cattle for the following indication:

KetoMed™ (ketoprofen) is indicated for the control of pyrexia associated with Bovine Respiratory Disease (BRD) in beef heifers, beef steers, beef calves 2 months of age and older, beef bulls, replacement dairy heifers, and dairy bulls. Not for use in reproducing animals over one year of age, dairy calves, or veal calves. Not for use in lactating dairy cattle or calves <2 months old.

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 drug (NSAID)

F. Dosage Form

Injectable 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 3 mg/kg (1 mL/33.3 kg) or 1.36 mg/lb (1 mL/74 lb) of body weight. Treatment is administered by subcutaneous injection once daily and may be repeated for up to three days if pyrexia persists.

K. Route of Administration

Cattle: Subcutaneous injection

L. Species/Classes

Beef heifers, beef steers, beef calves 2 months of age and older, beef bulls, replacement dairy heifers, and dairy bulls

M. Indication

KetoMed™ (ketoprofen) is indicated for the control of pyrexia associated with Bovine Respiratory Disease (BRD) in beef heifers, beef steers, beef calves 2 months of age and older, beef bulls, replacement dairy heifers, and dairy bulls. Not for use in reproducing animals over one year of age, dairy calves, or veal calves. Not for use in lactating dairy cattle or calves <2 months old.

N. Reference Listed New Animal Drug (RLNAD)

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

O. Effect of Supplement

This supplemental approval provides for the addition of cattle as an approved species for KetoMed™ (ketoprofen) and approves the indication described in section I.M above.

II. BIOEQUIVALENCE

The Food and Drug Administration (FDA) did not require additional bioequivalence information for this supplemental approval. The FOI Summary for the original approval of ANADA 200-625, dated March 22, 2021, contains a summary of the basis for granting a biowaiver for KetoMed™ (ketoprofen) injectable solution for the cattle indications described in the General Information section above.

III. HUMAN FOOD SAFETY

The tolerance for residues and withdrawal period established for the RLNAD apply to the generic product. The following are assigned to this product for cattle:

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) for total residue of ketoprofen is 5 µg/kg of body weight per day. The tolerances established for the RLNAD apply to the generic product. A tolerance of 0.36 parts per million is established for ketoprofen (the marker residue) in kidney (the target tissue), under 21 CFR 556.345.

B. Withdrawal Period

Based on a biowaiver being granted and an evaluation of the product formulation and relevant physicochemical properties with respect to residue chemistry, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of 48 hours has been established for ketoprofen in cattle.

C. Analytical Method for Residues

The validated analytical method for analysis of residues of ketoprofen is on file at the Center for Veterinary Medicine, CPK1, 5001 Campus Drive, College Park, MD 20740. To obtain a copy of the analytical method, please submit a Freedom of Information request to: <https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm>.

IV. USER SAFETY

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

USER SAFETY WARNINGS

Not for human use. Keep this and all drugs out of the reach of children.

The Safety Data Sheet (SDS) provides more detailed occupational safety information.

V. AGENCY CONCLUSIONS

The information submitted in support of this supplemental 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 effect of supplement in the General Information Section above.

Additionally, data demonstrate that residues in food products derived from beef heifers, beef steers, beef calves 2 months of age and older, beef bulls, replacement dairy heifers, and dairy bulls treated with KetoMed™ will not represent a public health concern when the product is used according to the label.