

KETOMED- ketoprofen injection, solution
Bimeda, Inc.

KetoMed™

KetoMed™
(ketoprofen)

Sterile Solution, 100 mg/mL

For intravenous use in horses only.

CAUTION

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

Ketoprofen is a non-steroidal anti-inflammatory agent of the propionic acid class that includes ibuprofen, naproxen, and fenoprofen. Each mL of KetoMed (ketoprofen) contains 100 mg of ketoprofen in an aqueous formulation containing: L-Arginine, 70 mg; citric acid (to adjust pH); benzyl alcohol, 0.025 g (as preservative).

It is packaged in a multiple dose bottle.

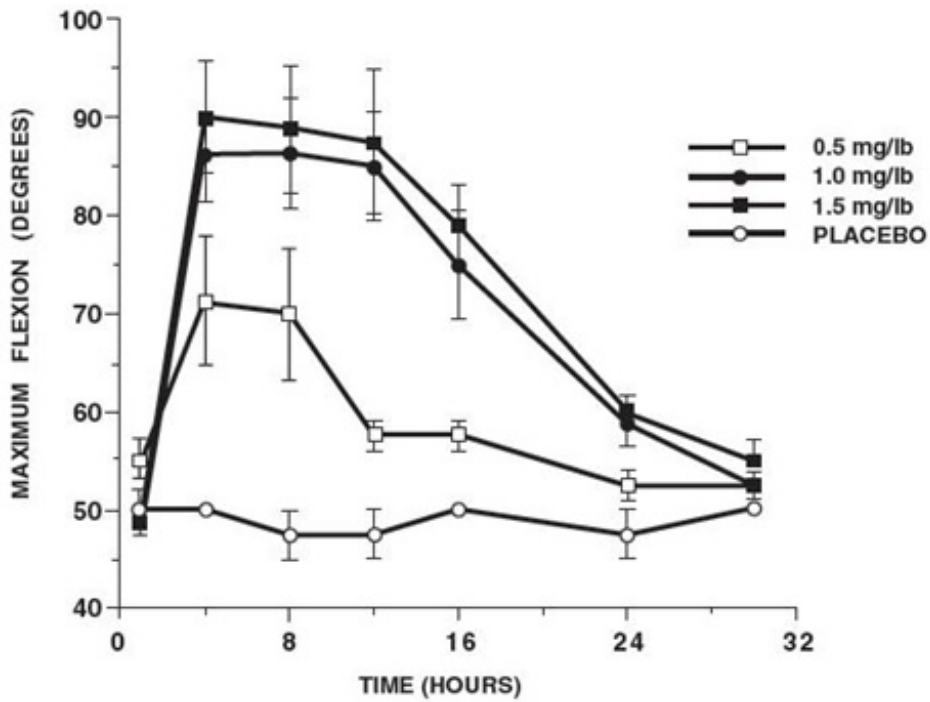
PHARMACOLOGY

KetoMed is a non-narcotic, non-steroidal anti-inflammatory agent with analgesic and antipyretic properties.

In horses, intravenous dosages of ketoprofen ranging from 0.5 to 1.5 mg/lb resulted in dosage dependent anti-inflammatory effects in the chronic adjuvant carpal model as depicted in the following graph.

MAXIMUM FLEXION

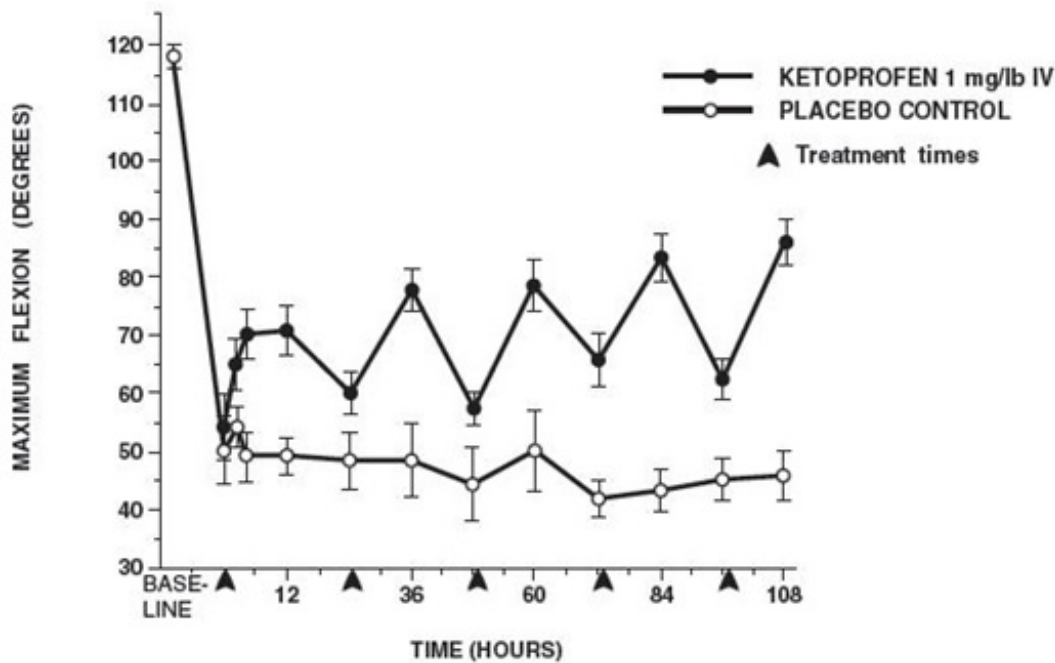
(intravenous ketoprofen, mean \pm sem, n = 4)*



*sem = standard error of the mean
n = number of animals

Additional studies using the same model in horses have shown that the effects of ketoprofen are maximal by 12 hours and still measurable at 24 hours after each dosage as depicted in the following graph.

MAXIMUM FLEXION
(mean ± sem, n = 6)*



*sem = standard error of the mean
n = number of animals

TOXICITY

Horses were found to tolerate ketoprofen given intravenously at dosages of 0, 1, 3 and 5 mg/lb once daily for 15 consecutive days (up to five times the recommended dosage for three times the usual duration) with no evidence of toxic effects. In clinical studies, intravenous injection of 1 mg/lb/day for five days resulted in no injection site irritation or other side effects.

At 15-fold overdose (15 mg/lb/day) for five days one of two horses developed severe laminitis, but no gross lesions or histologic changes were observed. The toxic effects observed in the horses given a 25-fold overdose (25 mg/lb/day) for five days included inappetence, depression, icterus, abdominal swelling and postmortem findings of gastritis, nephritis and hepatitis.

INDICATION

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

DOSAGE AND ADMINISTRATION

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. Onset of activity is within two hours with peak response by 12 hours.

CONTRAINDICATIONS

There are no known contraindications to this drug when used as directed. Intra-arterial injection should be avoided. Do not use in a horse if it has previously shown hypersensitivity to ketoprofen.

CAUTION

This product should not be used in breeding animals since the effects of KetoMed on fertility, pregnancy or fetal health in horses have not been determined.

PRECAUTIONS

Studies to determine activity of KetoMed when administered concomitantly with other drugs have not been conducted. Drug compatibility should be monitored closely in patients requiring adjunctive therapy.

WARNING

Do not use in horses intended for human consumption.

SIDE EFFECTS

During investigational studies, no significant side effects were reported.

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.

HOW SUPPLIED

KetoMed (ketoprofen) Solution 100 mg/mL is available in 50 mL and 100 mL multidose

bottles.

Store at 20°C - 25°C (68°F - 77°F); excursions permitted between 15°C - 30°C (59°F - 86°F). Do not freeze.

Use within 28 days of first puncture.

Approved by FDA under ANADA # 200-625

Manufactured for:
Bimeda, Inc.

Le Sueur, MN 56058

www.bimeda.com

12/20

<p>DOSAGE: 1 mL/100 lb body weight.</p> <p>WARNING: Do not use in horses intended for human consumption.</p> <p>Read accompanying package insert carefully.</p> <p>Store at 20°C - 25°C (68°F - 77°F); excursions permitted between 15°C - 30°C (59°F - 86°F). Do not freeze.</p> <p>Use within 28 days of first puncture.</p> <p>LOT EXP</p>	<p></p> <p>KetoMed™ (ketoprofen)</p> <p>Sterile Solution 100 mg/mL</p> <p>For intravenous use in horses only.</p> <p>CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.</p> <p>Approved by FDA under ANADA # 200-625</p> <p></p> <p>50 mL</p>	<p>Each mL contains: 100 mg keto-profen with L-Arginine, 70 mg; citric acid (to adjust pH); benzyl alcohol, 0.025 g (as preservative).</p> <p>Manufactured for: Bimeda, Inc. Le Sueur, MN 56058 www.bimeda.com</p> <p>KetoMed™ is a trademark of Bimeda, Inc.</p> <p>TAKE TIME  OBSERVE LABEL DIRECTIONS</p> <p>1KET007 BKETO09 Rev. 12/20</p>
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Each mL contains: 100 mg ketoprofen with L-Arginine, 70 mg; citric acid (to adjust pH); benzyl alcohol, 0.025 g (as preservative).

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See below for lot number and expiration date.

KetoMed™ **(ketoprofen)**

Sterile Solution
100 mg/mL

For intravenous use in horses only.
50 mL Multiple Dose Bottle

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50 mL

Bimeda

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Sterile Solution

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EXF1175



GENERAL
INFORMATION

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Bimeda

18E1007 DRCTIC R6 12/10

50 mL

KETOMED

ketoprofen injection, solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:61133-4007
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
KETOPROFEN (UNII: 90Y4QC304K) (KETOPROFEN - UNII:90Y4QC304K)	KETOPROFEN	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ARGININE (UNII: 94ZLA3W45F)	70 mg in 1 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61133-4007-1	50 mL in 1 BOTTLE		
2	NDC:61133-4007-2	100 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200625	02/08/2021	

Labeler - Bimeda, Inc. (060492923)

Establishment

Name	Address	ID/FEI	Business Operations
Bimeda- MTC		256232216	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
EUROAPI Germany GmbH		343459891	api manufacture

Revised: 1/2022

Bimeda, Inc.