

KetoMed™ 100

(ketoprofen)
100 mg/mL
Sterile Solution



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.

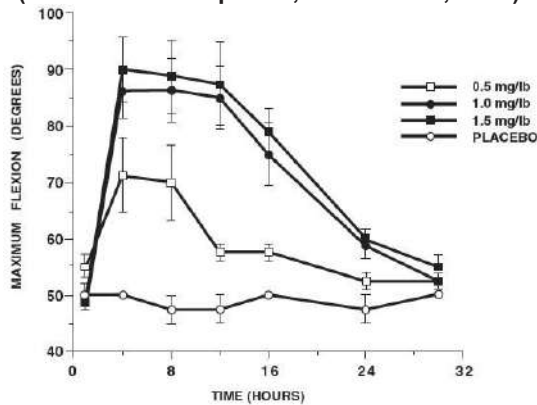
PHARMACOLOGY

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.

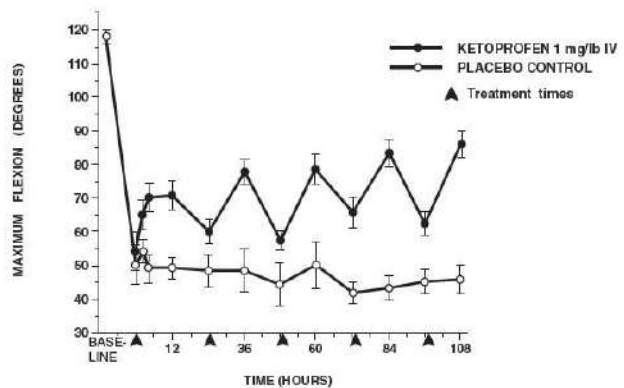
Additional studies using the same model in horses have shown that the effects of ketoprofen are maximal by 12 hours and still measurable at 24 hours after each dosage as depicted in the following graph.

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



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

MAXIMUM FLEXION
(mean \pm 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.

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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.

STORAGE

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

List Number	Pack Size	Case Size
1KET007	50 mL	12
1KET008	100 mL	12

MANUFACTURED FOR:

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