KETOFEN- ketoprofen injection, solution
Zoetis Inc.

KETOFEN®
(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 KETOFEN (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).

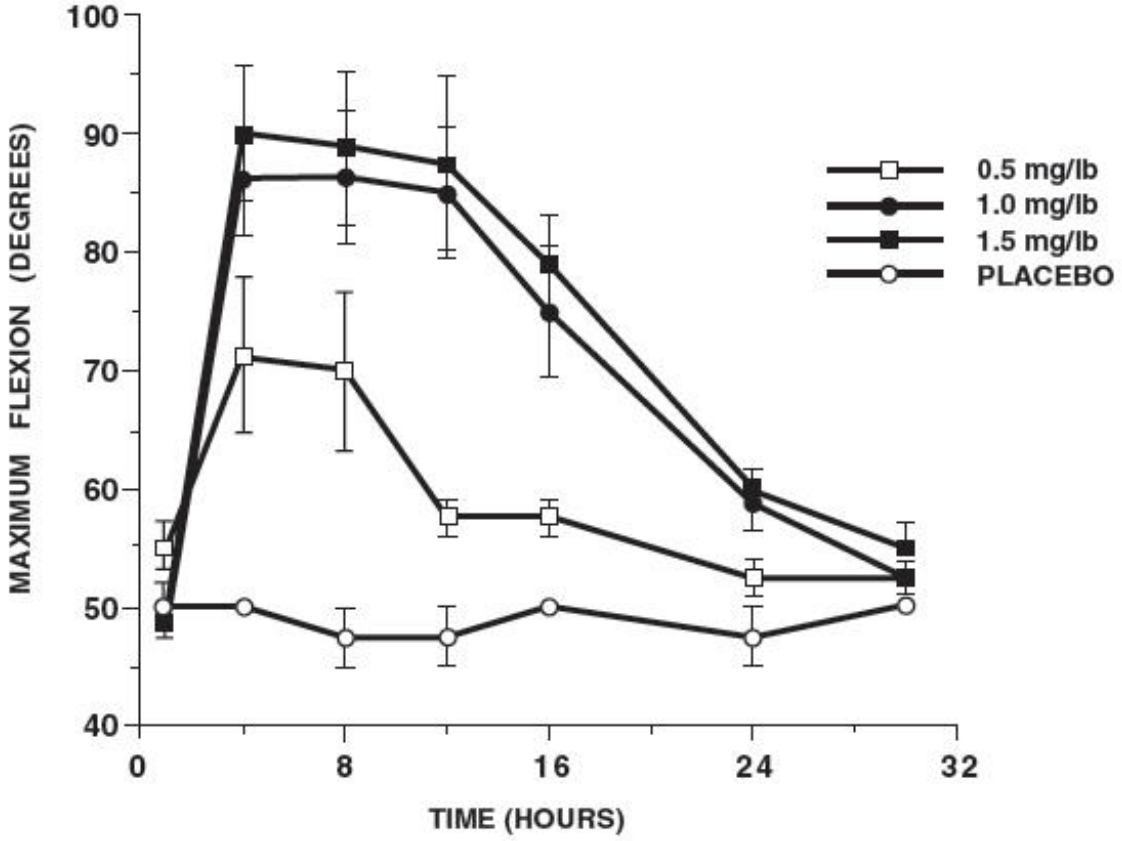
It is packaged in a multiple dose bottle.

PHARMACOLOGY

KETOFEN 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 carpitis model as depicted in the following graph.

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

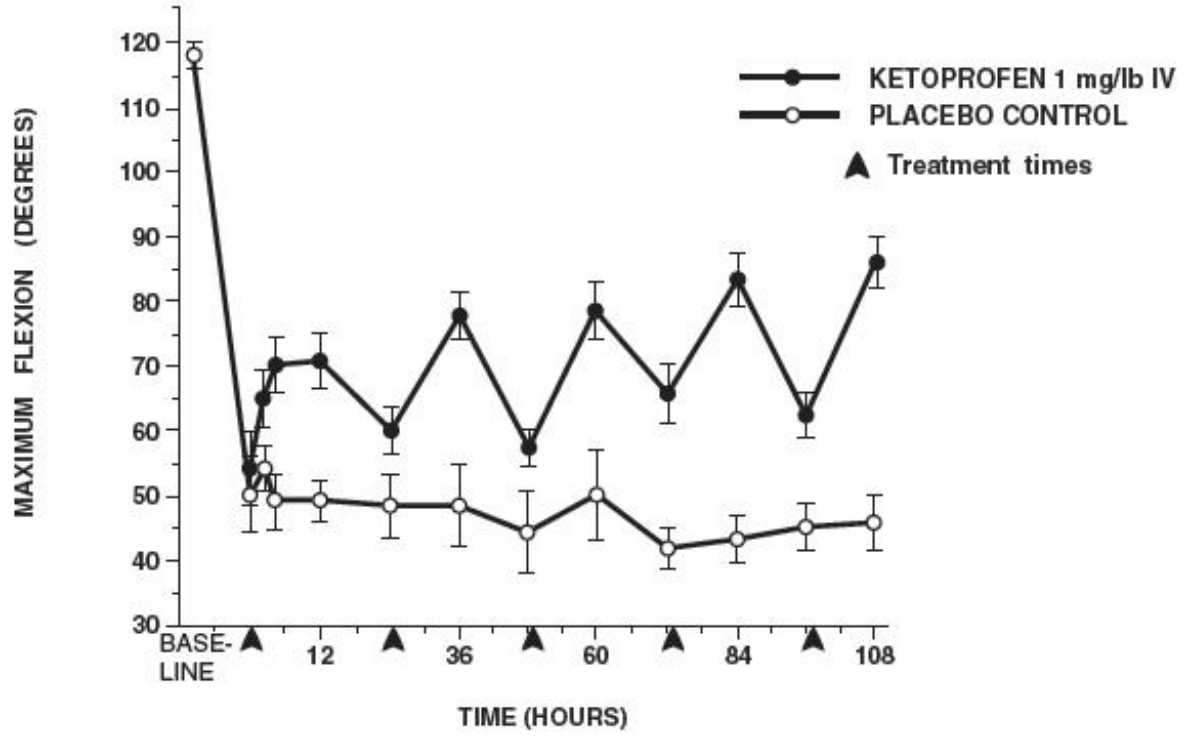


n = number of animals

* **sem = standard error of the mean**

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)*



n = number of animals

* **sem = standard error of the mean**

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

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

ADMINISTRATION AND DOSAGE

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 KETOFEN on fertility, pregnancy or fetal health in horses have not been determined.

PRECAUTIONS

Studies to determine activity of KETOFEN 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.

HOW SUPPLIED

KETOFEN (ketoprofen) Solution 100 mg/mL is available in 50 mL and 100 mL multidose bottles.

Store below 25°C (77°F), with brief excursions permitted between 0°C - 40°C (32°F - 104°F). Use contents within 4 months of first vial puncture.

Approved by FDA under NADA # 140-269

zoetis

Manufactured by:
Zoetis Manufacturing and Research Spain, S.L.
Girona, Spain

Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007

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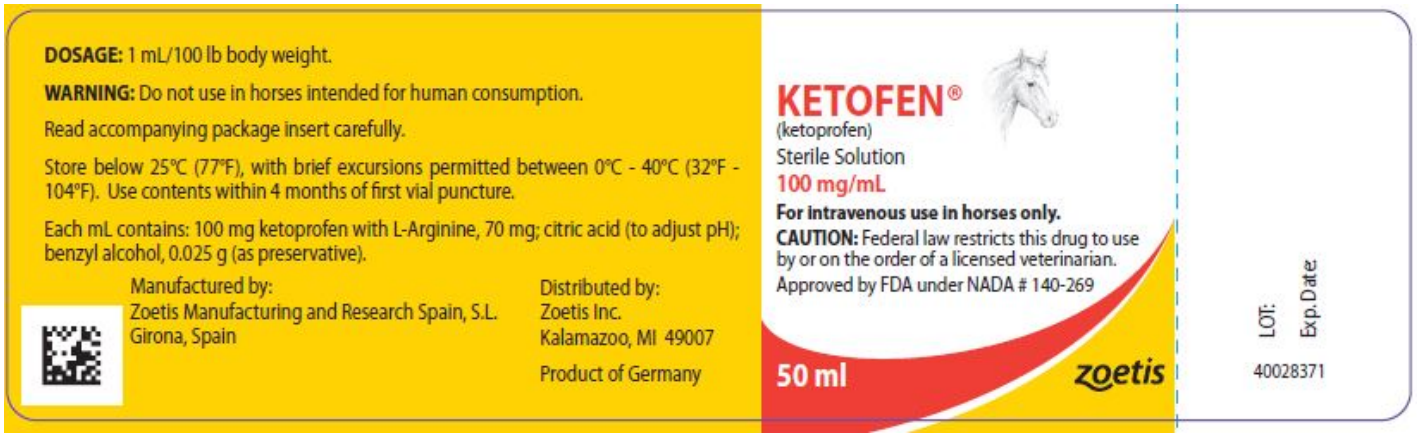
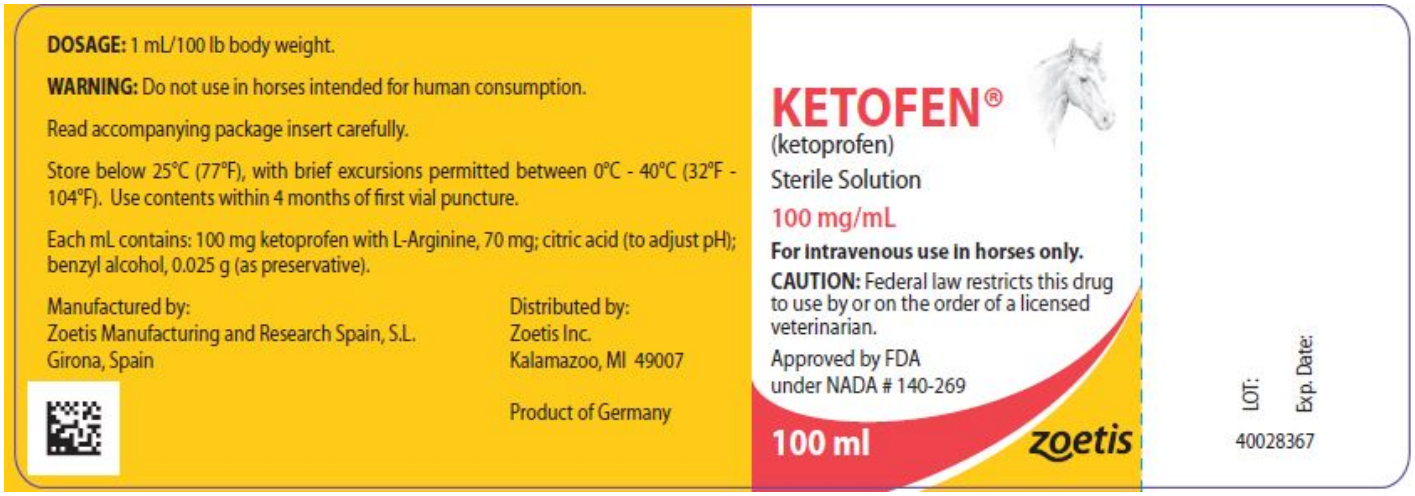
40028370

PRINCIPAL DISPLAY PANEL - 50 mL Bottle Label



PRINCIPAL DISPLAY PANEL - 100 mL Bottle Label



KETOFEN

ketoprofen injection, solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:54771-4396
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:54771-4396-1	1 in 1 CARTON		
1		50 mL in 1 BOTTLE		
2	NDC:54771-4396-2	1 in 1 CARTON		
2		100 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA140269	09/26/1990	

Labeler - Zoetis Inc. (828851555)

Revised: 3/2020 Zoetis Inc.