Non-steroidal anti-inflammatory drug for use in dogs and cats only

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

Warning: Repeated use of meloxicam in cats has been associated with acute renal failure and death. Do not administer additional injectable or oral meloxicam to cats.

See Contraindications, Warnings, and Precautions for detailed information.

Description: Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxazol class. Each ml of this sterile product for injection contains meloxicam 5.0 mg, alcohol 15%, glycerol 10%, polysorbate 188 5%, sodium chloride 0.6%, glycine 0.5% and meglumine 0.3%, in water for injection, pH adjusted with sodium hydroxide and hydrochloric acid.

Inappetence 3 0

Diarrhea/Soft Stool 15 11

Bloody Stool 1 0

Post-Approval Experience (Rev. 2009): The following adverse reactions are based on post-approval adverse drug event reporting. The categories are listed in decreasing order of frequency by body system:

- Gastrointestinal: vomiting, diarrhea, melena, gastrointestinal ulceration
- Urinary: azotemia, elevated creatinine, renal failure
- Neurological/Behavioral: lethargy, depression
- Hepatic: elevated liver enzymes
- Dermatologic: pruritus

Death has been reported as an outcome of the adverse events listed above. Acute renal failure and death have been associated with the use of meloxicam in cats.

For reported adverse events, for technical assistance or to obtain a copy of the SDS, contact Boehringer Ingelheim Animal Health USA Inc., 1-888-637-4251. 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.

Information For Dog Owners: Meloxicam, like other NSAIDs, is not free from adverse reactions. Owners should be advised of the potential for adverse reactions and be informed of the clinical signs associated with NSAID Intolerance. Adverse reactions may include vomiting, diarrhea, lethargy, decreased appetite and behavioral changes. Dog owners should be advised when their pet has received a meloxicam injection. Dog owners should contact their veterinarian immediately if possible adverse reactions are observed, and dog owners should be advised to discontinue METACAM therapy.

Clinical Pharmacology: Meloxicam has nearly 100% bioavailability when administered orally or after subcutaneous injection in dogs. The terminal elimination half life after a single dose is estimated to be approximately 24 hrs (+/- 30%) in dogs regardless of route of administration.

Peak drug concentrations of 0.734 mcg/ml can be expected to occur within 2.5 hours following a 0.2 mg/kg subcutaneous injection in dogs. Based on intravenous administration in Beagle dogs, the meloxicam volume of distribution in dogs (Vd) is approximately 0.2 l/kg and the total systemic clearance is 0.01 l/h/kg. The drug is 97% bound to canine plasma proteins.

Effectiveness: Dogs: The effectiveness of METACAM Injection was demonstrated in a field study involving a total of 224 dogs representing various breeds, all diagnosed with osteoarthritis. This placebo-controlled, masked study was conducted for 14 days. Dogs received a subcutaneous injection of 0.2 mg/kg meloxicam Injection on day 1. The dogs were maintained on 0.1 mg/kg oral meloxicam from days 2 through 14. Variables evaluated by veterinarians included lameness, weight-bearing, pain on palpation, and overall improvement. Variables assessed by owners included mobility, ability to rise, limping, and overall improvement. In this field study, dogs showed clinical improvement with statistical significance after 14 days of meloxicam treatment for all variables.

Animal Safety: Dogs: 3 Day Target Animal Safety Study - In a three day safety study, METACAM Injection was administered intravenously to Beagle dogs at 1, 3, and 5 times the recommended dose (0.2, 0.6 and 1.0 mg/kg) for three consecutive days. Vomiting occurred in 1 of 6 dogs in the 5X group. Fecal occult blood was detected in 3 of 6 dogs in the 5X group. No clinically significant hematologic changes were seen, but serum chemistry changes were observed. Serum alkaline phosphatase (ALP) was significantly increased in one 1X dog and two of the 5X dogs. One dog in the 5X group had a steadily increasing GGT over 4 days, although the values remained within the reference range. Decreases in total protein and albumin occurred in 2 of 6 dogs in the 3X group and 2 of 6 dogs in the 5X group. Increases in blood urea nitrogen (BUN) occurred in 3 of 6 dogs in the 1X group, 2 of 6 dogs in the 3X group and 2 of 6 dogs in the 5X group. Increased creatinine occurred in 2 dogs in the 5X group. Increased urine protein excretion was noted in 2 of 6 dogs in the 5X group. 2 of 6 dogs in the 3X group, 2 of 6 dogs in the 3X group, and 5 of 6 dogs in the 5X group. Two dogs in the 5X group developed acute renal failure by Day 4. Bicarbonate levels were at or above normal levels in 1 of the 3X dogs and 2 of the 5X dogs.

Histological examination revealed gastrointestinal lesions ranging from superficial mucosal hemorrhages and congestion to erosions. Mesenteric lymphadenopathy was identified in 2 of 6 dogs in the 1X group, 4 of 6 dogs in the 3X group, and 5 of 6 dogs in the 5X group. Renal changes ranged from dilated medullary and cortical tubules and inflammation of the interstitium, to necrosis of the tip of the papilla in 2 of 6 dogs in the 1X group, 2 of 6 dogs in the 3X group, and 4 of 6 dogs in the 5X group.

Injection Site Tolerance - METACAM Injection was administered once subcutaneously to Beagle dogs at the recommended dose of 0.2 mg/kg and was well-tolerated by the dogs. Pain upon injection was observed in one of eight dogs treated with meloxicam. No pain or inflammation was observed post-injection. Long term use of METACAM Injection in dogs has not been evaluated.

Effect on Buccal Mucosal Bleeding Time (BMBT) - METACAM Injection (0.2 mg/kg) and placebo (0.4 mg/kg) were administered as single intravenous injections to 8 female and 16 male Beagle dogs. There was no statistically significant difference (p>0.05) in the average BMBT between the two groups.

Storage Information: Store at controlled room temperature, 58-78°F (20–25°C). When used as labeled, there is no limit on the number of punctures throughout the full expiry period.

How Supplied: METACAM 5 mg/mL Solution for Injection: 10 mL vial, NDC 0010-6001-10 - 10 mL

Approved by FDA under NADA # 141-219

Marketed by: Boehringer Ingelheim Animal Health USA Inc. Duluth, GA 30096

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Metacam® (meloxicam)

5 mg/mL Solution for Injection

Adverse Reactions Observed During Field Study

Clinical Observation Meloxicam (n=129) Placebo (n=115)

Vomiting 31 15

Diarrhea/Soft Stool 15 11

Inappetence 3 0

Bloody Stool 1 0

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