Package Insert for Dogs

Metacam®

(meloxicam)

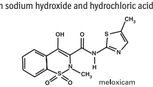
5 mg/mL Solution for Injection

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 oxicam class. Each mL of this sterile product for injection contains meloxicam 5.0 mg, alcohol 15%, glycofurol 10%, poloxamer 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.



meloxicam

Indications: Dogs: METACAM Injection is indicated in dogs for the control of pain and inflammation associated with osteoarthritis.

Dosage and Administration: Carefully consider the potential benefits and risk of METACAM and other treatment options before deciding to use METACAM. Use the lowest effective dose for the shortest duration consistent with individual response.

Dogs: METACAM Injection should be administered initially as a single dose at 0.09 mg/lb (0.2 mg/kg) body weight intravenously (IV) or subcutaneously (SQ), followed, after 24 hours, by METACAM Oral Suspension at the daily dose of 0.045 mg/lb (0.1 mg/kg) body weight, either mixed with food or placed directly in the mouth.

Contraindications: Dogs with known hypersensitivity to meloxicam should not receive METACAM Injection.

Warnings: Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion by humans. For IV or SQ injectable use in dogs. All dogs should undergo a thorough history and physical examination before administering any NSAID. Appropriate laboratory testing to establish hematological and serum biochemical baseline data is recommended prior to, and periodically during use of any NSAID in dogs.

Owner should be advised to observe their dogs for signs of potential drug toxicity.

Precautions: The safe use of METACAM Injection in dogs younger than 6 months of age, dogs used for breeding, or in pregnant or lactating bitches has not been evaluated. Meloxicam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders. Safety has not been established for intramuscular (IM) administration in dogs. When administering METACAM Injection, use a syringe of appropriate size to ensure precise dosing. As a class, cyclo-oxygenase inhibitory NSAIDs may be associated with gastrointestinal, renal and hepatic toxicity. Sensitivity to drug-associated adverse events varies with the individual patient. Dogs that have experienced adverse reactions from one NSAID may experience adverse reactions from another NSAID. Patients at greatest risk for renal toxicity are those that are dehydrated, on concomitant diuretic therapy, or those with existing renal, cardiovascular, and/or hepatic dysfunction. Concurrent administration of potentially nephrotoxic drugs should be carefully approached. NSAIDs may inhibit the prostaglandins that maintain normal homeostatic function. Such anti-prostaglandin effects may result in clinically significant disease in patients with underlying or preexisting disease that has not been previously diagnosed. Since NSAIDs possess the potential to induce gastrointestinal ulcerations and/or perforations, concomitant use with other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be avoided. If additional pain medication is needed after the administration of the total daily dose of METACAM Oral Suspension, a non-NSAID or noncorticosteriod class of analgesia should be considered. The use of another NSAID is not recommended. Consider appropriate washout times when switching from corticosteroid use or from one NSAID to another in dogs. The use of concomitantly protein-bound drugs with METACAM Injection has not been studied in dogs. Commonly used protein-bound drugs include cardiac, anticonvulsant and behavioral medications. The influence of concomitant drugs that may inhibit metabolism of METACAM Injection has not been evaluated. Drug compatibility should be monitored in patients requiring adjunctive therapy. The effect of cyclo-oxygenase inhibition and the potential for thromboembolic occurrence or a hypercoagulable state has not been studied.

Adverse Reactions: Dogs: A field study involving 224 dogs was conducted. Based on the results of this study, GI abnormalities (vomiting, soft stools, diarrhea, and inappetence) were the most common adverse reactions associated with the administration of meloxicam. The following table lists adverse reactions and the numbers of dogs that experienced them during the study. Dogs may have experienced more than one episode of the adverse reaction during the study.

Adverse Reactions Observed During Field Study

Clinical Observation	Meloxicam (n=109)	Placebo (n=115)
Vomiting	31	15
Diarrhea/Soft Stool	15	11
Inappetence	3	0
Bloody Stool	1	0

In foreign suspected adverse drug reaction (SADR) reporting, adverse reactions related to meloxicam administration included: auto-immune hemolytic anemia (1 dog), thrombocytopenia (1 dog), polyarthritis (1 dog), nursing puppy lethargy (1 dog), and pyoderma (1 dog).

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.**

To report suspected 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. Drug bioavailability, volume of distribution, and total systemic clearance remain constant up to 5 times the recommended dose for use in dogs. However, there is some evidence of enhanced drug accumulation and terminal elimination half-life prolongation when dogs are dosed for 45 days or longer.

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 upon intravenous administration in Beagle dogs, the meloxicam volume of distribution in dogs (Vdλ) is approximately 0.32 L/kg and the total systemic clearance is 0.01 L/hr/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 METACAM 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 3 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 control group, 2 of 6 dogs in the 1X 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 mL/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, 68-77°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 0010-6013-01 - 10 mL

Approved by FDA under NADA # 141-219

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

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Revised 03/2023
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Boehringer Ingelheim

Metacam®

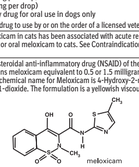
(meloxicam oral suspension)

1.5 mg/mL (equivalent to 0.05 mg per drop)
0.5 mg/mL (equivalent to 0.02 mg per drop)
Non-steroidal anti-inflammatory drug for oral use in dogs 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 oxicam class. Each milliliter of METACAM Oral Suspension contains meloxicam equivalent to 0.5 or 1.5 milligrams and sodium benzoate (1.5 milligrams) as a preservative. The chemical name for Meloxicam is 4-Hydroxy-2-methyl-N-(5-methyl-2-thiazolyl)-2H-1,2-benzothiazine-3-carboxamide-1, 1-dioxide. The formulation is a yellowish viscous suspension with the odor of honey.



meloxicam

Indications: METACAM Oral Suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Dosage and Administration: Always provide client information sheet with prescription. Carefully consider the potential benefits and risk of METACAM and other treatment options before deciding to use METACAM. Use the lowest effective dose for the shortest duration consistent with individual response. METACAM Oral Suspension should be administered initially at 0.09 mg/lb (0.2 mg/kg) body weight only on the first day of treatment. For all treatments after day 1, METACAM Oral Suspension should be administered once daily at a dose of 0.045 mg/lb (0.1 mg/kg). The syringe is calibrated to deliver the daily maintenance dose in pounds.

Directions for Administration (1.5 mg/mL strength):
Dogs under 10 pounds (4.5 kg)
Shake well before use, then remove cap. Particular care should be given with regard to the accuracy of dosing. **To prevent accidental overdosing of small dogs, administer drops on food only, never directly into the mouth.** Carefully measure suspension onto food to assure that the correct dose is given before presentation of the food to the dog. The syringe provided with the meloxicam concentration of 1.5 mg/mL cannot be used to measure doses for dogs weighing less than 5 lbs (2.3 kg).
For dogs less than 5 lbs (2.3 kg), METACAM Oral Suspension can be given using the dropper bottle: one drop for each pound of body weight for the 1.5 mg/mL concentration (two drops for each kilogram of body weight), dropped directly onto the food.
For dogs between 5-10 pounds, METACAM Oral Suspension can be given by drops or by using the measuring syringe provided in the package (see dosing procedure below). The syringe fits on to the bottle and has a scale beginning at 5 lbs, designed to deliver the daily maintenance dose (0.05 mg/lb or 0.1 mg/kg). When using the syringe, the dog's weight should be rounded down to the nearest 5 pound increment. Replace and tighten cap after use.
Dogs over 10 pounds (4.5 kg)
Shake well before use then remove cap. METACAM Oral Suspension may be either mixed with food or placed directly into the mouth. Particular care should be given with regard to the accuracy of dosing. METACAM Oral Suspension can be given using the measuring syringe provided in the package (see dosing procedure below). The syringe fits on to the bottle and has a scale in pounds designed to deliver the daily maintenance dose (0.05 mg/lb or 0.1 mg/kg). When using the syringe, the dog's weight should be rounded down to the nearest 1 pound increment. Alternatively, METACAM Oral Suspension can be given using the dropper bottle: two drops for each pound of body weight for the 0.5 mg/mL concentration (five drops for each kilogram of body weight). Replace and tighten cap after use.

Directions for Administration (0.5 mg/mL strength):
Dogs under 10 pounds (4.5 kg)
Shake well before use, then remove cap. Particular care should be given with regard to the accuracy of dosing. **To prevent accidental overdosing of small dogs, administer drops on food only, never directly into the mouth.** Carefully measure suspension onto food to assure that the correct dose is given before presentation of the food to the dog. The syringe provided with the meloxicam concentration of 0.5 mg/mL cannot be used to measure doses for dogs weighing less than 2 lbs (0.90 kg).
For dogs less than 2 lbs (0.90 kg), METACAM Oral Suspension can be given using the dropper bottle: two drops for each pound of body weight for the 0.5 mg/mL concentration (five drops for each kilogram of body weight), dropped directly onto the food.
For dogs between 2 - 10 pounds, METACAM Oral Suspension can be given by drops or by using the measuring syringe provided in the package (see dosing procedure below). The syringe fits on to the bottle and has a scale beginning at 2 lbs, designed to deliver the daily maintenance dose (0.05 mg/lb or 0.1 mg/kg). When using the syringe, the dog's weight should be rounded down to the nearest 1 pound increment. Replace and tighten cap after use.
Dogs over 10 pounds (4.5 kg)
Shake well before use then remove cap. METACAM Oral Suspension may be either mixed with food or placed directly into the mouth. Particular care should be given with regard to the accuracy of dosing. METACAM Oral Suspension can be given using the measuring syringe provided in the package (see dosing procedure below). The syringe fits on to the bottle and has a scale in pounds designed to deliver the daily maintenance dose (0.05 mg/lb or 0.1 mg/kg). When using the syringe, the dog's weight should be rounded down to the nearest 1 pound increment. Alternatively, METACAM Oral Suspension can be given using the dropper bottle: two drops for each pound of body weight for the 0.5 mg/mL concentration (five drops for each kilogram of body weight). Replace and tighten cap after use.

Shake bottle well. Push down and unscrew bottle top. Attach the dosing syringe to the bottle by gently pushing the end on to the top of the bottle.

Turn the bottle/syringe upside down. Pull the plunger out until the black line on the plunger corresponds to the dog's body weight in pounds.

Turn the bottle right way up and with a twisting movement separate the dosing syringe from the bottle.

Push the plunger to empty the contents of the syringe.

Contraindications: Dogs with known hypersensitivity to meloxicam should not receive METACAM Oral Suspension. **Do not use METACAM Oral Suspension in cats. Acute renal failure and death have been associated with the use of meloxicam in cats.**
Warnings: Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion by humans. **For oral use in dogs only.**
As with any NSAID all dogs should undergo a thorough history and physical examination before the initiation of NSAID therapy. Appropriate laboratory testing to establish hematological and serum biochemical baseline data is recommended prior to and periodically during administration. Owner should be advised to observe their dog for signs of potential drug toxicity and be given a client information sheet about METACAM.
Precautions: The safe use of METACAM Oral Suspension in dogs younger than 6 months of age, dogs used for breeding, or in pregnant or lactating dogs has not been evaluated. Meloxicam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders.
As a class, cyclo-oxygenase inhibitory NSAIDs may be associated with gastrointestinal, renal and hepatic toxicity. Sensitivity to drug-associated adverse events varies with the individual patient. Dogs that have experienced adverse reactions from one NSAID may experience adverse reactions from another NSAID. Patients at greatest risk for renal toxicity are those that are dehydrated, on concomitant diuretic therapy, or those with existing renal, cardiovascular, and/or hepatic dysfunction. Concurrent administration of potentially nephrotoxic drugs should be carefully approached. NSAIDs may inhibit the prostaglandins that maintain normal homeostatic function. Such anti-prostaglandin effects may result in clinically significant disease in patients with underlying or pre-existing disease that has not been previously diagnosed. Since NSAIDs possess the potential to induce gastrointestinal ulcerations and/or perforations, concomitant use with other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be avoided. If additional pain medication is needed after administration of the total daily dose of METACAM Oral Suspension, a non-NSAID or non-corticosteroid class of analgesia should be considered. The use of another NSAID is not recommended. Consider appropriate washout times when switching from corticosteroid use or from one NSAID to another in dogs. The use of concomitantly protein-bound drugs with METACAM Oral Suspension has not been studied in dogs. Commonly used protein-bound drugs include cardiac, anticonvulsant and behavioral medications. The influence of concomitant drugs that may inhibit metabolism of METACAM Oral Suspension has not been evaluated. Drug compatibility should be monitored in patients requiring adjunctive therapy.

Adverse Reactions: Field safety was evaluated in 306 dogs. Based on the results of two studies, GI abnormalities (vomiting, soft stools, diarrhea, and inappetence) were the most common adverse reactions associated with the administration of meloxicam. The following table lists adverse reactions and the numbers of dogs that experienced them during the studies. Dogs may have experienced more than one episode of the adverse reaction during the study.

Adverse Reactions Observed During Two Field Studies

Clinical Observation	Meloxicam (n=157)	Placebo (n=149)
Vomiting	40	23
Diarrhea/Soft Stool	19	11
Bloody Stool	1	0
Inappetence	5	1
Bleeding gums after dental procedure	1	0
Lethargy/Swollen Carpus	1	0
Epiphora	1	0

In foreign suspected adverse drug reaction (SADR) reporting over a 9 year period, incidences of adverse reactions related to meloxicam administration included: auto-immune hemolytic anemia (1 dog), thrombocytopenia (1 dog), polyarthritis (1 dog), nursing puppy lethargy (1 dog), and pyoderma (1 dog).

Post-Approval Experience (Rev. 2010): The following adverse events are based on post-approval adverse drug experience reporting. Not all adverse reactions are reported to FDA/CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data. The following adverse events are listed in decreasing order of frequency by body system.
Gastrointestinal: vomiting, anorexia, 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 use of meloxicam in cats.**
To report suspected adverse drug events, for technical assistance, or to obtain a copy of the SDS, contact Boehringer Ingelheim Animal Health USA Inc. at 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: METACAM, like other drugs of its class, 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 drug intolerance. Adverse reactions may include vomiting, diarrhea, decreased appetite, dark or tarry stools, increased water consumption, increased urination, pale gums due to anemia, yellowing of gums, skin or white of the eye due to jaundice, lethargy, incoordination, seizure, or behavioral changes. **Serious adverse reactions associated with this drug class can occur without warning and in rare situations result in death (see Adverse Reactions). Owners should be advised to discontinue METACAM and contact their veterinarian immediately if signs of intolerance are observed.**
The vast majority of patients with drug related adverse reactions have recovered when the signs are recognized, the drug is withdrawn, and veterinary care, if appropriate, is initiated. Owners should be advised of the importance of periodic follow up for all dogs during administration of any NSAID.

Clinical Pharmacology: Meloxicam has nearly 100% bioavailability when administered orally with food. The terminal elimination half life after a single dose is estimated to be approximately 24 hrs (+/-30%) regardless of route of administration. There is no evidence of statistically significant gender differences in drug pharmacokinetics. Drug bioavailability, volume of distribution, and total systemic clearance remain constant up to 5 times the recommended dose for use in dogs. However, there is some evidence of enhanced drug accumulation and terminal elimination half-life prolongation when dogs are dosed for 45 days or longer. Peak drug concentrations can be expected to occur within about 7.5 hrs after oral administration. Corresponding peak concentration is approximately 0.464 mcg/mL following a 0.2 mg/kg oral dose. The drug is 97% bound to canine plasma proteins.

Effectiveness: The effectiveness of meloxicam was demonstrated in two field studies involving a total of 277 dogs representing various breeds, between six months and sixteen years of age, all diagnosed with osteoarthritis. Both of the placebo-controlled, masked studies were conducted for 14 days. All dogs received 0.2 mg/kg meloxicam on day 1. All dogs were maintained on 0.1 mg/kg oral meloxicam from days 2 through 14 of both studies. Parameters evaluated by veterinarians included lameness, weight-bearing, pain on palpation, and overall improvement. Parameters assessed by owners included mobility, ability to rise, limping, and overall improvement.
In the first field study (n=109), dogs showed clinical improvement with statistical significance after 14 days of meloxicam treatment for all parameters. In the second field study (n=48), dogs receiving meloxicam showed a clinical improvement after 14 days of therapy for all parameters; however, statistical significance was demonstrated only for the overall investigator evaluation on day 7, and for the owner evaluation on day 14.
Palatability: METACAM Oral Suspension was accepted by 100% of the dogs when veterinarians administered the initial dose into the mouth. METACAM Oral Suspension was accepted by 90% of the dogs (123/136) when administered by owners. Problems associated with administration included refusal of food, resistance to swallowing and salivation.
Safety:
Six Week Study
In a six week target animal safety study, meloxicam was administered orally at 1, 3, and 5X the recommended dose with no significant clinical adverse reactions. Animals in all dose groups (control, 1, 3 and 5X the recommended dose) exhibited some gastrointestinal distress (diarrhea and vomiting). No treatment-related changes were observed in hematological, blood chemistry, urinalysis, clotting time, or buccal mucosal bleeding times. Necropsy results included stomach mucosal petechiae in one control dog, two dogs at the 3X and one dog at the 5X dose. Other macroscopic changes included areas of congestion or depression of the mucosa of the jejunum or ileum in three dogs at the 1X dose and in two dogs at the 5X dose. Similar changes were also seen in two dogs in the control group. There were no macroscopic small intestinal lesions observed in dogs receiving the 3X dose. Renal enlargement was reported during the necropsy of two dogs receiving the 3X dose and two receiving the 5X dose.
Microscopic examination of the kidneys revealed minimal degeneration or slight necrosis at the tip of the papilla in three dogs at the 5X dose. Microscopic examination of the stomach showed inflammatory mucosal lesions, epithelial regenerative hyperplasia or atrophy, and submucosal gland inflammation in two dogs at the recommended dose, three dogs at the 3X and four dogs at the 5X dose. Small intestinal microscopic changes included minimal focal mucosal erosion affecting the villi, and were sometimes associated with mucosal congestion. These lesions were observed in the ileum of one control dog and in the jejunum of one dog at the recommended dose and two dogs at the 5X dose.
Six Month Study
In a six month target animal safety study, meloxicam was administered orally at 1, 3, and 5X the recommended dose with no significant clinical adverse reactions. All animals in all dose groups (controls, 1, 3, and 5X the recommended dose) exhibited some gastrointestinal distress (diarrhea and vomiting). Treatment related changes seen in hematology and chemistry included decreased red blood cell counts in seven of 24 dogs (four 3X and three 5X dogs), decreased hematocrit in 18 of 24 dogs (including three control dogs), dose-related neutrophilia in one 1X, two 3X and three 5X dogs, evidence of regenerative anemia in two 3X and one 5X dog. Also noted were increased BUN in two 5X dogs and decreased albumin in one 5X dog.
Endoscopic changes consisted of reddening of the gastric mucosal surface covering less than 25% of the surface area. This was seen in three dogs at the recommended dose, three dogs at the 3X dose and two dogs at the 5X dose. Two control dogs exhibited reddening in conjunction with ulceration of the mucosal covering less than 25% of the surface area.
Gross gastrointestinal necropsy results observed included mild discoloration of the stomach or duodenum in one dog at the 3X and in one dog at the 5X dose. Multifocal pinpoint red foci were observed in the gastric fundic mucosa in one dog at the recommended dose, and in one dog at the 5X dose.
No macroscopic or microscopic renal changes were observed in any dogs receiving meloxicam in this six month study.
Microscopic gastrointestinal findings were limited to one dog at the recommended dose, and two dogs at the 3X dose. Mild inflammatory mucosal infiltrate was observed in the duodenum of one dog at the recommended dose. Mild congestion of the fundic mucosa and mild myositis of the outer mural musculature of the stomach were observed in two dogs receiving the 3X dose.
How Supplied:
METACAM Oral Suspension 0.5 mg/mL: 15 mL and 30 mL dropper bottles with measuring syringe.
NDC 0010-6014-01 - 0.5 mg/mL - 15 mL NDC 0010-6014-02 - 0.5 mg/mL - 30 mL
METACAM Oral Suspension 1.5 mg/mL: 10, 32, 100 and 180 mL dropper bottles with measuring syringe.
NDC 0010-6015-01 - 1.5 mg/mL - 10 mL NDC 0010-6015-02 - 1.5 mg/mL - 32 mL
NDC 0010-6015-03 - 1.5 mg/mL - 100 mL NDC 0010-6015-04 - 1.5 mg/mL - 180 mL
Storage: Store at controlled room temperature, 68-77°F (20-25°C). Excursions permitted between 59° and 86°F (15° and 30°C). Brief exposure to temperatures up to 104°F (40°C) may be tolerated provided the mean kinetic temperature does not exceed 77°F (25°C); however, such exposure should be minimized.
Approved by FDA under NADA # 141-213
Marketed by:
Boehringer Ingelheim Animal Health USA Inc.
Duluth, GA 30096
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 US-PET-0400-2021-V3

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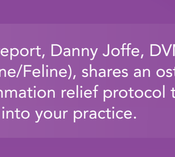
Revised 06/2022

Boehringer Ingelheim

Turn Canine Osteoarthritis (OA) Treatment Into a Win-Win-Win Situation



In this special report, Danny Joffe, DVM, DABVP Emeritus (Canine/Feline), shares an osteoarthritis pain and inflammation relief protocol that's easy to incorporate into your practice.

With this protocol, **EVERYONE** wins:

- **Dogs win** by experiencing quick and consistent ongoing relief from osteoarthritis pain and inflammation.
- **Dog owners win** with a lowest effective dose that's comfortable for their pets and their budgets, which helps reinforce the human-animal bond. This also encourages dog owners to become more actively involved as part of their dogs' healthcare team.
- **Veterinarians win** by providing a protocol that differentiates them from other clinics, offers good medicine, and helps build client loyalty and compliance.

Metacam®
(meloxicam)

The Painful-to-Playful PROTOCOL

Nonsteroidal anti-inflammatory drugs (NSAIDs) are a mainstay in managing canine osteoarthritis (OA). Adding other modalities along with an NSAID may allow us to eventually lower the NSAID dose, but in my opinion, an NSAID is indicated as soon as OA is identified.

There are multiple veterinary branded NSAIDs on the market. My go-to NSAID is METACAM® (meloxicam oral suspension). Why do I prefer METACAM® Oral Suspension over other NSAIDs? In my experience, the liquid formulation provides great dosing flexibility without compromising efficacy. Clients like using METACAM Oral Suspension, and dogs like taking METACAM Oral Suspension.

Here's an easy, 3-step protocol for METACAM® (meloxicam) I use in my practice that you can easily adopt in yours.

STEP 1: ADMINISTER THE FIRST DOSE VIA INJECTION IN THE CLINIC.

- Giving the first dose of METACAM® (meloxicam) Solution for Injection by intravenous (IV) or subcutaneous (SC) injection* allows for rapid pain relief that is quickly obvious to the client while in the clinic. It helps to set owner expectations upfront and ensure the owner is present when the dog shows signs of relief.
- The SC injection is given at a dose of 0.2 mg/kg; the product is the same viscosity as water, so the injection can be given with a 25-gauge needle, which minimizes the pain of the injection for the pet.
- Giving the first dose by injection obviates the need for a double oral dose (0.2 mg/kg) or "loading dose" on the first day.
- For patients that are markedly painful, the injection can be given IV (at the same 0.2 mg/kg dose), leading to rapid, noticeable pain relief.

*Results with IV injection will be much more rapid than SC administration; IV administration is recommended.

STEP 2: DISPENSE METACAM® ORAL SUSPENSION.

- After the injection is administered, the owner should notice their dog feeling better, which gives the veterinary team an opportunity to underscore the importance of compliance and the need to administer this level of pain and inflammation relief on a daily basis.
- To ensure continued pain relief, dispense the appropriate size of METACAM Oral Suspension in the room or at checkout, and walk the pet owner through proper at-home administration procedures.

"Using this protocol, I can decrease the patient's dose by 25% to 30% in most dogs—and even lower in some."

– Dr. Joffe

Most Dogs Can Benefit From the Lowest Effective Dose

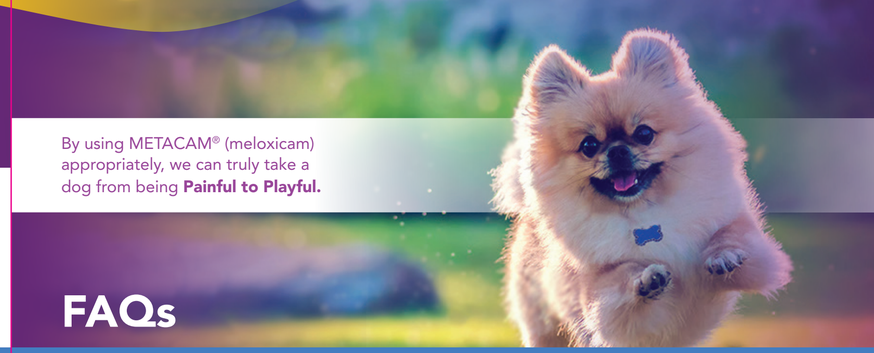
This protocol helps you follow the US Food and Drug Administration (FDA) recommendation for prescribing NSAIDs at the lowest effective dose. Some dogs need the full label dose to be comfortable, but I find that most of the time, I can significantly decrease the dose when we lower it very gradually, as per the protocol.

Painful-to-Playful PROTOCOL

- Someone from the clinic (ideally, the doctor) should call the client a few hours after the appointment to see how the pet is doing; this "check-in" will typically help make the client feel like part of the team, which really enhances compliance.
- The doctor should confirm with the client that after the product has been used at the full label dose for the first month with no side effects, we will be able to start decreasing the dose gradually each week, per the protocol in step 3. The veterinary team can explain to the owner: "Once we have maximal control of your pet's osteoarthritic pain, we can often decrease the ongoing dose by 25% to 30%—and often even more than that. Working together as a team, we will slowly lower the dose to find your pet's individual lowest effective dose."

STEP 3: SCHEDULE FOLLOW-UP APPOINTMENTS, AND TITRATE TO THE LOWEST EFFECTIVE DOSE.

- Once the owner has given the 0.1 mg/kg daily dose for a month (which gives the doctor time to establish a good clinical response and ensure there are no side effects), I recommend titrating the dose down slowly to find each patient's unique "lowest effective dose" (LED).
  - For large dogs (≥20 lb), I recommend decreasing the dose (using the 5 lb increment syringe) by 5 lb each week moving forward.
  - For small dogs (<20 lb), I recommend decreasing the dose (using the 1 lb increment syringe) by 1 lb each week.
- As the dose is lowered, educate the client about signs that could indicate their pet is becoming painful again, such as limping, resisting jumping, or being slow to rise.
- If pain recurs, I recommend returning to the last dose that was given prior to the pet becoming painful again.
- Lowering the dose of METACAM Oral Suspension makes the product more cost-effective for the client and possibly reduces the risk for NSAID adverse events.
- Frequent "check-ins" with the client to assess how the patient is doing are important, help with finding the LED, and greatly enhance long-term compliance.
- I suggest explaining to the owner: "Once we know your pet's lowest effective dose, we will continue to monitor their health via regular visits to ensure that we are still doing a good job of managing pain, but also to confirm that no other health problems are sneaking up on us."



By using METACAM® (meloxicam) appropriately, we can truly take a dog from being **Painful to Playful.**

FAQs

Q: Can I alter the METACAM® (meloxicam oral suspension) dose depending on the patient's activity level?
A: Many clients become very good at determining how much METACAM Oral Suspension their pet is going to need each day depending on their pet's expected activity level (without ever going above the labeled dose). On days when the dog is quite inactive, the owner can keep the dog comfortable with 40% less than the labeled dose. When the dog is moderately active, they give 20% less than the labeled dose, and on days when the pet is super active, they may need to give the full labeled dose. The client should be reminded that the labeled dose should never be exceeded.

Q: Should blood work be performed before starting NSAIDs?
A: Ideally, we should assess blood work prior to starting NSAIDs in a canine patient to confirm that no renal or liver issues are present. Some clients will not accept the recommendation to perform blood work though, and with their consent NSAIDs can be utilized without blood work, but this is suboptimal and should be well documented in the clinician's medical record.

Q: Are there contraindications to using NSAIDs?
A: Patients should never be administered 2 NSAIDs at the same time. Dogs that are currently being treated with corticosteroids should never be given NSAIDs. Dogs with severe renal disease, gastric ulcers, or chronic gastrointestinal disease should not be given NSAIDs. The patient should also be monitored for other disease states, such as liver enzyme alterations, to ensure that the pet is still tolerating the medication.

Q: How often should I evaluate a canine patient that is being administered NSAIDs long term?
A: I like to evaluate patients on chronic NSAIDs at least twice a year and more often than that if they are still painful or if they are having other health problems.

IMPORTANT SAFETY INFORMATION

As a class, cyclooxygenase inhibitory NSAIDs may be associated with gastrointestinal, kidney, or liver side effects. The most common side effects reported in field studies were vomiting and soft stool/diarrhea. These are usually mild but may be serious. If side effects occur, pet owners should halt therapy and contact their veterinarian. Pets should be evaluated for pre-existing conditions and currently prescribed medications prior to treatment with METACAM, then monitored regularly while on treatment. Concurrent use with another NSAID, corticosteroid, or nephrotoxic medication should be avoided.

METACAM® (meloxicam oral suspension)
METACAM Oral Suspension is for use in dogs only. The safe use of METACAM Oral Suspension in dogs younger than 6 months of age, dogs used for breeding, or in pregnant or lactating dogs has not been evaluated. Please refer to the prescribing information on the reverse side for complete product information.

METACAM® (meloxicam) Solution for Injection
The safe use of METACAM Solution for Injection in dogs younger than 6 months of age, dogs used for breeding, or in pregnant or lactating dogs has not been evaluated. Please refer to the prescribing information on the reverse side for complete product information.

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 in the prescribing information for detailed information.

Metacam® (meloxicam)