Non-steroidal anti-inflammatory drug for oral use in dogs only

**Metacam®**

**Description:** Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the sacchromal class. Each milliliter of Metacam Oral Suspension contains meloxicam equivalent to 0.5 or 1.5 milligrams and sodium benzoate (1.5 milligrams). The chemical name for Meloxicam is 4-Hydroxy-2-methyl-6-(4-fluorophenyl)-4H-2,3- benzoazinone. The formulation is a yellowish viscous suspension with the odor of honey. The active ingredient is meloxicam (meloxicam hydrochloride).

**Uses:** Meloxicam is indicated for the control of pain and inflammation associated with acute and chronic osteoarthritis.

**Dosage and Administration:** The supplier information sheet with prescription. Carefully consider the potential benefits and risks 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 at least 0.5 to 0.75 mg/kg body weight only on the first day of treatment. For all treatments after the first day of treatment, Metacam Oral Suspension should be administered at a dose of at least 0.5 mg/kg body weight only on the first day. The calibration is calibrated to deliver the daily maintenance dose in pounds.

**Directions for Administration:**

- **For Dogs less than 1 lb (0.45 kg):** Metacam Oral Suspension can be given using the dropper bottle: one drop for each pound of body weight for the 0.5 mg/mL concentration (two drops for each kilogram of body weight). When using the syringe, the dog's weight should be rounded down to the nearest 0.5 pound increment. Replace and tighten cap after use.

- **For 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. For dogs over 10 pounds (4.5 kg), the syrup may be given using the measuring syringe provided in the package (see dosing procedure below). The syringe fits to the bottle and has a scale that begins at 1/2 oz (15 ml) and has a scale beyond the 1/2 oz (15 ml) mark. It is calibrated 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 0.5 pound increment. Replace and tighten cap after use.

- **For Dogs 10 to 20 pounds (4.5 to 9.1 kg):** For dogs between 1-10 pounds (0.45 to 4.5 kg), Metacam Oral Suspension can be given by feeding the dogs using a dropper bottle: one drop for each pound of body weight for the 0.5 mg/mL concentration (two drops for each kilogram of body weight). When using the syringe, the dog's weight should be rounded down to the nearest 0.5 pound increment. Replace and tighten cap after use.

- **For Dogs 20 pounds (9.1 kg) or greater:** Shake well before use then remove cap. Metacam Oral Suspension may be either mixed with food or placed directly into the mouth. For dogs 20 pounds (9.1 kg) or greater, the syrup may be given using the measuring syringe provided in the package (see dosing procedure below). The syringe fits to the bottle and has a scale that begins at 1/2 oz (15 ml) and has a scale beyond the 1/2 oz (15 ml) mark. It is calibrated 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 0.5 pound increment. Alternatively, Metacam Oral Suspension can be given using the measuring syringe provided in the package (see dosing procedure below). The syringe fits to the bottle and has a scale that begins at 1/2 oz (15 ml) and has a scale beyond the 1/2 oz (15 ml) mark. When using the syringe, the dog's weight should be rounded down to the nearest 0.5 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 (two drops for each kilogram of body weight). When using the syringe, the dog's weight should be rounded down to the nearest 0.5 pound increment. Replace and tighten cap after use.

**Contraindications:** Dogs with drug-induced hyperglycemia should not be treated with Metacam Oral Suspension.

**Warnings:** Not for use in humans. Keep this and all medications out of reach of children. Consult a veterinarian in case of oral ingestion by humans. For oral use in dogs only.

**Precautions:** Use in cats is not recommended. Use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders. As a class, cyclooxygenase (COX) inhibitors have been associated with gastrointestinal ulcerations, hemorrhage, and erosions, and the potential for nephrotoxicity. Use with caution in dogs with gastrointestinal disease, or during administration of drugs that may alter gastrointestinal pH. Use with caution in dogs with an increased risk of bleeding, such as those with a history of gastrointestinal ulceration, platelet abnormalities, or during administration of drugs that may affect coagulation. Use with caution in dogs with anemia, pre-existing renal disease, heart failure, or hepatic disease. Use with caution in pregnant or lactating bitches, or in bitches in heat. Use with caution in breeding dogs, or in dogs that may be pregnant. Use with caution in dogs with a history of renal or hepatic disease, or in dogs receiving other drugs that alter renal function or hepatic function. Use with caution in dogs receiving anticoagulant or antiplatelet drugs. Use with caution in dogs with a history of gastrointestinal ulceration. The influence of concomitant drugs on drug pharmacokinetics, drug interactions, and drug metabolism should be considered.

**Adverse Reactions Observed During Two Field Studies**

**Clinical Observations**

<table>
<thead>
<tr>
<th>Metacam (n=157)</th>
<th>Placebo (n=149)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seizures</td>
<td>62</td>
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<tr>
<td>Dystonia</td>
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<tr>
<td>Ventricular extrasystole</td>
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<tr>
<td>Etiology/Smaller Carpe</td>
<td>0</td>
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<td>Epilepsy</td>
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**Adverse Reactions**

- **In'aggressive adverse drug reaction (CADR) reporting over a year period, incidence of adverse reactions related to meloxicam administration included: auto-immune hemolytic anemia (1 dog), thrombocytopenia (1 dog), polyarthritis (1 dog), depression (1 dog), vomiting, anorexia, diarrhea, urticaria, gastrointestinal ulceration, urticaria, anemia, edema, cardiovascular, renal failure, neurological, lethargy, depression, appetite, elevated liver enzymes, dermatitis, purpura.
- **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.

**Purposes:** To report suspected adverse drug events, for technical assistance, or to obtain a copy of the MSDS, contact Boehringer Ingelheim Vetmedica, Inc. at 1-866-MELOXAM (1-866-635-6926). For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-4FDA-VETS or online at http://www.fda.gov/AnimalVeterinary/SafetyHealth/ .

**Related Information for Dog Owners:** Metacam is not available in all countries. The following adverse events are based on post-approval adverse drug experience reports involving the use of Metacam Oral Suspension in dogs. All adverse events reported are included, regardless of whether a causal relationship was thought likely or not. Adverse events are listed in decreasing order of frequency by body system. If the adverse event was associated with the medication, it was included. The severity of the adverse event was determined based on the information provided by the prescriber. Adverse events included in this section are based on post-marketing surveillance and/or marketing surveys. For additional adverse reactions not included in this section, refer to the NADA 141-213, Approved by FDA Boehringer Ingelheim Vetmedica, Inc./Merck & Co., Inc. 10413-D3/01/2408-03 Revised 08/2014.

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