Client Information Sheet for Metacam® (meloxicam)
1.5 mg/mL Oral Suspension

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

This summary contains important information about Metacam. You should read this information before you start giving your dog Metacam and read it each time the prescription is refilled. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information or if you want to know more about Metacam.

What is Metacam?
Metacam® is a prescription non-steroidal anti-inflammatory drug (NSAID) that is used to control pain and inflammation associated with osteoarthritis in dogs. Osteoarthritis (OA) is a painful condition caused by "wear and tear" of cartilage and other parts of the joints that may result in the following changes or signs in your dog: Limping or lameness, decreased activity or exercise (reluctance to stand, climb stairs, jump or run, or difficulty in performing these activities), stiffness or decreased movement of joints. Metacam is given to dogs by mouth. Do not use Metacam Oral Suspension in cats. Acute renal failure and death have been associated with the use of meloxicam in cats.

What Kind of Results Can I Expect When My Dog Is On Metacam For OA?
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 suspension 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).

Dosage and Administration:

- For dogs between 5 - 10 pounds, Metacam Oral Suspension can be given by drops or by using the measuring syringes provided in the package (see dosing procedure below). The syringe fits on to the bottle and has a scale calibrated to deliver the daily maintenance dose (0.05 mg/lb or 0.1 mg/kg). When using the syrup, the dog’s weight should be rounded down to the nearest 5 pound increment. Replace and tighten cap after use.
- For dogs over 10 pounds, Metacam Oral Suspension may be either mixed with food or placed directly into the mouth. Particular care should be given to the accuracy of dosing. Metacam Oral Suspension can be given using the measuring syringes provided in the package (see dosing procedure below). The syrup fits on to the bottle and has a scale calibrated to deliver the daily maintenance dose (0.05 mg/lb or 0.1 mg/kg). When using the syrup, the dog’s weight should be rounded down to the nearest 5 pound increment. Replace and tighten cap after use.

What Should I Do If My Dog Is Having a Bad Reaction?

- Stop giving Metacam at once. Call your veterinarian immediately if you believe your dog is having an adverse reaction.
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What Are the Possible Side Effects of Metacam?

- The actual dose to be given should be prescribed by the veterinarian.
- Dogs over 10 pounds (4.5 kg)
- Dogs between 5 - 10 pounds
- Dogs less than 5 lbs (2.3 kg)

What Are the Precautions for Metacam?

- Is presently taking aspirin, other NSAIDs, or corticosteroids (unless directed by your veterinarian).
- Has had an allergic reaction to meloxicam, the active ingredient of Metacam.

What Are the Instructions for Metacam?

- Shake bottle well. Push down and unscrew bottle cap. 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.
- Shake bottle well. Push down and unscrew bottle cap. Attach the dosing syringe to the bottle by gently pushing the end on to the top of the bottle.
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Clinical Observation Meloxicam (n=157) Placebo (n=149)

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Meloxicam</th>
<th>Placebo</th>
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</thead>
<tbody>
<tr>
<td>Limping or lameness</td>
<td>40</td>
<td>23</td>
</tr>
<tr>
<td>Decreased activity or exercise</td>
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<td>20</td>
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<tr>
<td>Stiffness or decreased movement of joints</td>
<td>25</td>
<td>15</td>
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<tr>
<td>Fever</td>
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<td>0</td>
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<tr>
<td>Epiphora</td>
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<td>6</td>
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<tr>
<td>Bleeding gums after dental procedure</td>
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<td>4</td>
</tr>
<tr>
<td>Inappetence</td>
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<td>1</td>
</tr>
<tr>
<td>Vomiting</td>
<td>40</td>
<td>23</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>30</td>
<td>20</td>
</tr>
</tbody>
</table>

What Is Metacam?
Non-steroidal anti-inflammatory drug for oral use in dogs only (meloxicam) 1.5 mg/mL Oral Suspension

Metacam
Professional Insert

NADA 141213, Approved by FDA
Metacam® (meloxicam) 1.5 mg/mL Oral Suspension (equivalent to 0.005 mg/kg per drop)

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

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

Description: Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class. Each ml of Metacam Oral Suspension contains meloxicam equivalent to 1.5 mg/ml and sodium bicarbonate (1.5 ml/mg) as a preservative. The chemical name for meloxicam is 6-methyl-2-methyl-N-15-15-methoxy-2-hydroxy-2H-1H,2-l,2-benzothiophene-3-carboxamide-1, 1-chloride. The formulation is a yellowish viscous suspension with the odor of honey.

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 of time consistent with individual response.

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 weighing between 5 and 10 lbs, Metacam Oral Suspension can be given using the dosing syringe provided in the package (see dosing procedure below). The syringe fits on to the bottle and has a scale calibrated to deliver the daily maintenance dose (0.05 mg/lb or 0.1 mg/kg). When using the syrup, the dog’s weight should be rounded down to the nearest 5 pound increment. Replace and tighten cap after use.

Directions for Administration: For dogs under 10 pounds (4.5 kg)

- Shake bottle well before use then remove cap. Metacam should be given with regard to the accuracy of dosing.
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- Presidents:

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What To Tell Your Veterinarian Before Giving Metacam
Talk to your veterinarian about:
• The signs of OA you have observed (for example limping, stiffness).
• The importance of weight control and exercise in the management of OA.
• What tests might be done before Metacam is prescribed.
• The risks and benefits of using Metacam.
Tell your veterinarian if your dog has ever had the following medical problems:
• Experienced side effects from Metacam or other NSAIDs, such as aspirin
• Digestive upset (vomiting and/or diarrhea)
• Liver disease
• Kidney disease
Tell your veterinarian about:
• Any other medical problems or allergies that your dog has now or has had.
• All medicines that you are giving your dog or plan to give your dog, including those you can get without a prescription.
Tell your veterinarian if your dog is:
• Pregnant, nursing or if you plan to breed your dog.

What Are The Possible Side Effects That May Occur In My Dog During Metacam Therapy?
Metacam, like other drugs, may cause some side effects. Serious but rare side effects have been reported in dogs taking NSAIDs. Serious side effects can occur with or without warning and in rare situations result in death.
The most common NSAID-related side effects generally involve the stomach and liver or kidney problems. Look for the following side effects that can indicate your dog may be having a problem with Metacam or may have another medical problem:
• Decrease or increase in appetite
• Vomiting
• Change in bowel movement (such as diarrhea, or black, tarry or bloody stools)
• Change in behavior (such as decreased or increased activity level, incoordination, seizure or aggression)
• Yellowing of gums, skin, or whites of the eyes (jaundice)
• Change in drinking habits (frequency, amount consumed)
• Change in urination habits (frequency, color, or smell)
• Change in skin (redness, scabs, or scratching)

In foreign suspected adverse drug reaction (SADR) reporting over a 9 year period, incidences of adverse reactions related to meloxicam administration included:
• Gastrointestinal: vomiting, anorexia, diarrhea, melena, gastrointestinal ulceration
• Change in urination habits (frequency, color, or smell)
• Change in drinking habits (frequency, amount consumed)
• Yellowing of gums, skin, or whites of the eyes (jaundice)
• Change in behavior (such as decreased or increased activity level, incoordination, seizure or aggression)
• Decrease or increase in appetite

It is important to stop therapy and contact your veterinarian immediately if you think your dog has a medical problem or side effect from Metacam therapy or if you have additional questions about possible side effects, talk to your veterinarian.

Can Metacam Be Given With Other Medicines?
Metacam should not be given with other NSAIDs (for example, aspirin, carprofen, etodolac, deracoxib or steroids)
Tell your veterinarian about all medicines you have given your dog in the past, and any medicines that you are planning to give with Metacam. This should include other medicines that you can get without a prescription.
Your veterinarian may want to check that all of your dog's medicines can be given together.

What Can I Do In Case My Dog Eats More Than The Prescribed Amount?
Contact your veterinarian immediately if your dog eats more than the prescribed amount of Metacam.

What Else Should I Know About Metacam?
This sheet provides a summary of information about Metacam. If you have any questions or concerns about Metacam or osteoarthritis pain, talk to your veterinarian.

As with all prescribed medicines, Metacam should only be given to the dog for which it was prescribed. Metacam Oral Suspension is for use in dogs only. Do Not give Metacam Oral Suspension to cats. It should be given to your dog only for the condition for which it was prescribed. It is important to periodically discuss your dog’s response to Metacam at regular check-ups. Your veterinarian will best determine if your dog is responding as expected and if your dog should continue receiving Metacam.

For technical assistance or to report suspected adverse reactions, call 1-866-METCAM (1-866-638-2266).
Manufactured for:
Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.
US Patent 6,184,220
Metacam is a registered trademark of Boehringer Ingelheim Vetmedica GmbH, licensed to Boehringer Ingelheim Vetmedica, Inc.
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Safety:
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. Animals in all dose groups (control, 1, 3, and 5X) exhibited some gastrointestinal distress (diarrhea and vomiting). No treatment-related changes were observed in hematological, blood chemistry, urinalysis, clinical signs, or gross necropsy findings. No macroscopic changes were noted in the stomach, small intestine, or kidneys.

Two dogs at the 5X dose showed evidence of slight myositis of the skeletal muscle. One dog at the recommended dose showed unilateral mild myositis of the quadriceps. No other changes were noted in any organ system. All dogs continued to receive meloxicam therapy without any adverse effects. No clinical evidence of organ toxicity was seen in any of the dose groups.

Clinical Pharmacology:
Metacam 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 (1-3 days) 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 cats. 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 0.46 mcg/mL following a 0.2 mg/kg oral dose. The drug is 97% bound to plasma proteins.

Effectiveness:
The effectiveness of meloxicam was demonstrated in two field studies involving a total of 217 dogs representing various breeds, between six months and thirteen years of age, all diagnosed with OA of either the coxofemur, stifle, or elbow joint. In both studies, marked improvement in mobility was noted from the initial visit to the end of the study. In the first field study (n=129), 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 improvement in pain assessment on day 7, and for the owner evaluation on day 14.

Potability: Metacam Oral Suspension was accepted by 100% of the dogs whose veterinarians administered the initial dose into the mouth. Metacam Oral Suspension was accepted by 99% of the dogs (123/133) when administered by owners. Problems associated with administration included refusal of food, resistance to swallowing and salivation.

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