Client Information Sheet For Metacam® (meloxicam) 0.5 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 review 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 (swelling) due to 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 (refusal to stand, climb stairs, jump up, or run), difficulties in performing activities, stiffness or decreased movement of joints. Metacam is given by dogs by mouth.

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 1 lb (0.45 kg).

For dogs less than 1 lb (0.45 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.

Dogs over 10 pounds (4.5 kg)
Shake well before use, then remove cap. Particular care should be given with the regard to the accuracy of dosing.

Directions For Administration: Dogs under 10 pounds (4.5 kg)
Shake well before use, then remove cap. Particular care should be given with the regard to the accuracy of dosing.

Professional Insert

NDA# 411-213, Approved by FDA
Metacam® (meloxicam) 0.5 mg/mL Oral Suspension
(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.

Description: Meloxicam is a racemic mixture of (S,S)- and (R,R)-meloxicam and is classified as a non-steroidal anti-inflammatory drug (NSAID) for use in dogs.

Usage: Meloxicam is an NSAID indicated for the treatment of pain and inflammation associated with osteoarthritis in dogs.

Dosing: Meloxicam should be administered orally once daily to dogs 7 kg and larger at 0.2 mg/kg body weight. For dogs weighing less than 7 kg, the dose should be reduced to 0.1 mg/kg body weight.

Contraindications: Meloxicam is contraindicated in dogs with a history of gastrointestinal disease, liver or kidney disease, or a history of adverse reactions to meloxicam or other NSAIDs.

Warnings: Meloxicam should be used with caution in dogs with a history of allergic reactions to aspirin or other NSAIDs.

Precautions: Meloxicam should be used with caution in dogs with a history of gastrointestinal disease, liver or kidney disease.

Adverse Reactions: Meloxicam has been associated with gastrointestinal, hepatic, and renal adverse effects.

Toxicology: Meloxicam has been shown to be safe and effective in dogs.

Additional Information: Meloxicam is formulated as a liquid suspension for oral administration.

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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.
• Any other medical problems or allergies that your dog has now or has had.
• All medicines that 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 kidneys. 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, 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 (reddness, scabs, or scratching)

What To Tell Your Veterinarian About Metacam
• Any medical problems 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 If 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 side effects, 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-METACAM (1-866-638-2226).

Manufactured for:
Boehringer Ingelheim Vetmedica, Inc.
10601-417-01
Revised 01/2014

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

Post-Appearance Experience (Obs. 2010): The following adverse events are based on post-appearance adverse drug experience reporting. Net 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 exposures 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
Neuropsychiatric/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 reactions, to obtain a Material Safety Data Sheet, or for technical assistance, call 1-866-METACAM (1-866-638-2226).

Revised 01/2014

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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) included some gastrointestinal distress (diarrhea and vomiting). No treatment-related changes were observed in hematological, blood chemistry, urinalysis, urination, or buccal mucosal bleeding time.

Neutrophils included stomach mucosal polychromatophilic 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 3X dose and in one dog 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 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 atypia 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 local 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 all the recommended dose and two dogs at the 5X dose.

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