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 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 intolerance 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?

While Metacam is not a cure for OA, it can control the pain and inflammation associated with your dog's OA and improve your dog's mobility and quality of life.

• Response varies from dog to dog but can be quite dramatic.
• Most dogs, improvement can be seen in a matter of days.
• If Metacam is discontinued or not given as directed, your dog's pain and inflammation may come back.

What Drugs Should Not Take Metacam?

Your dog should not be given Metacam if:

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

Metacam Should Only Be Given To Dogs

People should not take Metacam. Keep Metacam and all medication out of reach of children. Call your physician immediately if you accidentally take Metacam.

How To Give Metacam To Your Dog.

The actual dose to be given should be prescribed by your veterinarian.

Directions For Administration: Dogs under 10 pounds (4.5 kg)

Shakes well before use, then remove cap. Particular care should be given with regard to the accuracy of dosing. 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 (2.3 - 4.5 kg), 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 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.

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 provides the meloxicam concentration of 1.5 mg/mL and cannot be used to measure doses for dogs weighing less than 5 lbs (2.3 kg).

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 onto the food. Particular care should be given with regard to the accuracy of dosing. Metacam Oral Suspension can be given using the measuring syringes 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 should be considered. The use of another NSAID is not recommended. Consider appropriate washout times when switching from one NSAID to another.

Gastrointestinal/Intestinal:

• Vomiting
• Diarrhea
• Nausea

Hepatic:

• Anorexia
• Inappetence
• Abdominal pain

Renal:

• Lethargy
• Swollen Carp

Inflammation (soreness) 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 intolerance 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.
Post-Approval Experience (Rev. 2010):

In foreign suspected adverse drug reaction (SADR) reporting over a 9 year period, incidences of adverse reactions related to:

• Change in skin (redness, scabs, or scratching)
• Yellowing of gums, skin, or whites of the eyes (jaundice)
• Vomiting

...are the most common NSAID-related side effects generally involve the stomach and liver or kidney problems. Look for:

• 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)

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• Vomiting

Serious side effects can occur with or without warning and in rare situations result in death.

What Are The Possible Side Effects That May Occur In My Dog During Metacam Therapy?

• Pregnant, nursing or if you plan to breed your dog.
• Any change in your dog’s behavior.
• Any change in your dog’s appetite.
• Any change in your dog’s body weight.
• Any change in your dog’s breathing or difficulty breathing.
• Any change in the color of your dog’s gums.
• Any change in the color or consistency of your dog’s stool.
• Any increased signs of bleeding or bruising.
• Any infections, including fever.
• Any unusual change in your dog’s behavior or appearance.

Tell your veterinarian:

• 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:

• Pregnant, nursing or if you plan to breed your dog.
• You give your dog Metacam with or without food.

What Can I Do If My Dog Eats More Than The Prescribed Amount?

Contact your veterinarian immediately if you think your dog has a medical problem or side effect from Metacam therapy 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.

Safety:

Six Study

To report suspected adverse reactions, to obtain a Material Safety Data Sheet, or for technical assistance, call 1-866-METACAM

Information for Dog Owners:

http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm055394.htm

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Six Month Study

In foreign suspected adverse drug reaction (SADR) reporting over a 9 year period, incidences of adverse reactions related to meloxicam administration included:

Appearance of anemia in 2 dogs receiving 0.2 mg/kg. The dogs were treated and recovered.

Gastrointestinal bleeding was observed in one dog at the 3X dose. No macroscopic or microscopic renal changes were observed in any dogs receiving meloxicam in this six month study.

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 both the rostral and caudal portions of the stomach. 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.

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