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 notice it each time the prescription isrefilled. 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 (reluctance to stand, climb stairs, jump up or down, or difficulty in performing those activities)
- stiffness or decreased movement of joints
- Melacam is given by 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 osteoarthritis, it can control the pain and inflammation of OA and improve your dog’s quality of life with OA. When given with meloxicam, the following results are expected:
- Response varies from dog to dog but can be quite dramatic.
- Pain improvement can be seen in a majority of dogs.
- If Metacam is discontinued or not given as directed, your dog’s pain and inflammation may come back.

What Dogs Should Not Take Metacam®?
Your dog should not be given Metacam if he/she:
- Has had an allergic reaction to meloxicam, the active ingredient of Metacam.
- Has had an allergic reaction (such as hives, facial swelling, and difficulty breathing) to 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)
Shake well before use, then remove cap. Particular care should be given to the accuracy of dosing.

Professional Insert

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 (meloxicam) is a 2-methyl-N-[5-methyl-2-na- cetylaminomethyl]-1,2-benzothiazole-3-carboxamide-1,1-carboxylic acid, a white to off-white, fine crystalline solid. Meloxicam is a potent inhibitor of cyclo-oxygenase enzymes. It is available in both an oral solution and a suspending agent in combi- nation that is administered orally by oral administration with food or in a liquid suspension using a dosing syringe. This combination is formulated for use in dogs weighing 1 to 45 pounds (0.45 to 20.4 kg). The combination of meloxicam and sodium benzoate (1.5 mg/mL) is available as Metacam® 0.5 mg/mL Oral Suspension.

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

Dosage And Administration: Give Metacam Oral Suspension at the dose of 0.5 mg/kg body weight every 24 hours, as directed by your veterinarian. Care should be taken to ensure that the correct dose is given. If the dose is missed, the next dose may be given at the normally scheduled time, with no weight adjustments required. If the dog’s condition worsens or if vomiting occurs, contact your veterinarian immediately. If vomiting occurs, do not give an additional dose of Metacam Oral Suspension.

Adverse Reactions Observed During Two Field Studies

Clinical Observation Meloxicam (n=157) Placebo (n=149)

Dog side effects

Vomiting 40 23
Diarrrhea 25 10
Anorexia 10 5
Epiphora 1 0
Lethargy/Swollen Carpus 1 0
Vomiting 40 23
Diarrrhea 25 10
Anorexia 10 5
Epiphora 1 0
Lethargy/Swollen Carpus 1 0

Precautions:
- Appropriate laboratory testing to establish hematological and serum biochemical baseline data is recommended prior to and periodically during administration. Owners should be advised to observe their dog for signs of potential drug toxicity and be given a client information sheet about Metacam.
- Consider appropriate washout times when switching from corticosteroid use or from one NSAID to another in dogs.
- Concurrent administration of potentially nephrotoxic drugs should be carefully approached. NSAIDs may inhibit the prostaglandins that maintain normal renal blood flow. Concurrent administration of potentially nephrotoxic drugs should be avoided. If additional pain medication is needed after administration of the total daily dose of Metacam Oral Suspension, a new NSAID or an analgesic should be used.
- Consideration should be given to patients with underlying renal, cardiovascular, and/or hepatic dysfunction. Concurrent administration of potentially nephrotoxic drugs should be avoided. If additional pain medication is needed after administration of the total daily dose of Metacam Oral Suspension, a new NSAID or an analgesic should be used.
- Non-steroidal anti-inflammatory drugs (NSAIDs) are contraindicated in pregnant or lactating dogs. In pregnant or lactating dogs, Metacam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders.
- The use of a NSAID in a dog with an existing disease that has not been previously diagnosed. Since NSAIDs possess the potential to induce gastrointestinal bleeding, NSAIDs are contraindicated in pregnant or lactating dogs. In pregnant or lactating dogs, Metacam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders.
- NSAIDs are contraindicated in pregnant or lactating dogs. In pregnant or lactating dogs, Metacam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders.
- NSAIDs are contraindicated in pregnant or lactating dogs. In pregnant or lactating dogs, Metacam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders.
- NSAIDs are contraindicated in pregnant or lactating dogs. In pregnant or lactating dogs, Metacam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders.
- NSAIDs are contraindicated in pregnant or lactating dogs. In pregnant or lactating dogs, Metacam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders.
- NSAIDs are contraindicated in pregnant or lactating dogs. In pregnant or lactating dogs, Metacam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders.
- NSAIDs are contraindicated in pregnant or lactating dogs. In pregnant or lactating dogs, Metacam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders.
- NSAIDs are contraindicated in pregnant or lactating dogs. In pregnant or lactating dogs, Metacam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders.
- NSAIDs are contraindicated in pregnant or lactating dogs. In pregnant or lactating dogs, Metacam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders.
- NSAIDs are contraindicated in pregnant or lactating dogs. In pregnant or lactating dogs, Metacam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders.
- NSAIDs are contraindicated in pregnant or lactating dogs. In pregnant or lactating dogs, Metacam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders.
- NSAIDs are contraindicated in pregnant or lactating dogs. In pregnant or lactating dogs, Metacam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders.
- NSAIDs are contraindicated in pregnant or lactating dogs. In pregnant or lactating dogs, Metacam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders.
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

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 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 no 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 reported to the CVM were high. The following side effects were reported in dogs receiving Metacam or other NSAIDs. Serious side effects can occur with or without warning and in no situations result in death.

• Dehydration
• Skin problems (itching, dermatitis)
• Idiosyncratic reactions (necrosis, ulceration, pneumonia, hepatitis, or nephritis)
• Neutrophilic dermatitis

Serious but rare side effects have been reported in dogs taking NSAIDs. Serious side effects can occur with or without warning and in no situations result in death.

• Change in urination habits (frequency, color, or smell)
• Change in skin (redness, scabs, or scratching)

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 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 (for example, cortisone, prednisone, dexamethasone, triamcinolone).

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 If My Dog Eats More Than The Prescribed Amounts?

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.

Safety:

Six Month Study

The effectiveness of meloxicam was demonstrated in two field studies involving a total of 277 dogs representing a wide variety of breeds, between six months and sixteen years of age, all diagnosed with osteoarthritis. Both of the placebo-controlled, multi-site studies conducted in the United States resulted in significant clinical improvement associated with mucosal congestion. These lesions were observed in the ileum of one control dog and in the jejunum of one dog at the 3X and two dogs at the 5X dose.

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. All animals in all dose groups (controls, 1, 3, and 5X the recommended dose) exhibited some gastrointestinal (diarrhea and vomiting). No treatment-related changes were observed in hematological, blood chemistry, urinalysis, or bone marrow parameters. These changes were also seen in one dog at the lowest dose group. There were no statistically significant differences between observed changes in the control group and groups at the recommended dose level and any of the dose levels above.

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 (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), decreased neutrophil counts in 18 of 24 dogs (including three control dogs), and increased neutrophil counts in one dog at the 5X dose. These changes were also seen in one dog at the lowest dose level and in the control group. There was no statistically significant difference between observed changes in the control group and groups at the recommended dose level and any of the dose levels above.

Endocutaneous changes consisted of nodules 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 3X dose. Two control dogs exhibited reddening in conjunction with ulceration of the mucosa covering less than 25% of the surface area. Gross gastrointestinal necropsy results observed included mild to moderate ulceration of the stomach or duodenum in one dog at the 1X dose and in one dog at the 3X dose. Mild to marked hemorrhage was observed in two of 24 dogs at the 3X dose.

Most gastrointestinal findings were limited to one dog at the recommended dose, and two dogs at the 3X dose. Mild inflammatory mucosal irritation was observed in the duodenum in one dog at the recommended dose. Mild congestion of the lymph nodes and mild petechiation 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.

Manufactured for:

Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.

Boehringer Ingelheim Vetmedica, Inc.
60147-01

Revised 01/2014

Metacam is a registered trademark of Boehringer Ingelheim Vetmedica GmbH, licensed to Boehringer Ingelheim Vetmedica, Inc.

Safety:

Six Month Study

A total of 277 dogs were assigned to the following dose groups: 1X (n=48), 3X (n=48), and 5X (n=48). Treatment and placebo groups were the same as described above. Dogs were monitored for any changes in behavior, appetite, food consumption, weight, urination, defecation, mobility, and exercise. Dogs in the placebo group showed a clinical improvement after 14 days of therapy for all parameters; however, statistical significance was demonstrated only for the overall investigator assessment on day 1, and for the owner assessment on day 14.

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=60), 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 assessment on day 1, and for the owner assessment on day 14.