

**OroCAM®**

(meloxicam)

Transmucosal Oral Spray

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

OroCAM™ Transmucosal Oral Spray is used for the control of pain and inflammation due to osteoarthritis in dogs.

This summary contains important information about OroCAM. You should read this information before you start giving your dog OroCAM 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 OroCAM.

**What Is OroCAM?**

OroCAM is a veterinary prescription non-steroidal anti-inflammatory drug (NSAID) that is used to control pain and inflammation 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 or run, or difficulty in performing these activities)
- Stiffness or decreased movement of joints

OroCAM is given to dogs by mouth. **Do not use OroCAM Transmucosal Oral Spray 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 OroCAM for osteoarthritis?**

While OroCAM is not a cure for osteoarthritis, it can control the pain and inflammation of osteoarthritis and improve your dog’s mobility.

- Response varies from dog to dog but can be quite dramatic
- In most dogs, improvement can be seen within days
- If OroCAM is discontinued, or not given as directed, your dog’s pain and inflammation may return

**Which dogs should not take OroCAM?**

Your dog should not be given OroCAM if he/she:

- Has had an allergic reaction to meloxicam, the active ingredient of OroCAM
- Has had an allergic reaction (such as hives, facial swelling, or red or itchy skin) to aspirin or other NSAIDs
- Is presently taking aspirin, other NSAIDs, or corticosteroids
- Is under 5.5 pounds in body weight

**OroCAM Should Only Be Given To Dogs. Do Not Give To Cats.**

**People should not take OroCAM. Keep OroCAM and all medications out of reach of children.** Call your physician immediately if you accidentally take OroCAM.

**What to tell/ask your veterinarian before giving OroCAM.**

Tell your veterinarian if your dog is currently experiencing or has ever had the following medical problems:

- Any side effects from taking OroCAM or other NSAIDs, such as aspirin
- Any digestive upset (vomiting and/or diarrhea)
- Any kidney disease
- Any liver disease

Talk to your veterinarian about:

- The signs of osteoarthritis you have observed in your dog, such as limping or stiffness
- The importance of weight control in the management of osteoarthritis
- What tests might be done before OroCAM is prescribed
- How often your dog may need to be examined by your veterinarian
- The risks and benefits of using OroCAM.

Serious adverse reactions associated with this drug class can occur without warning and in rare situations result in death

Tell your veterinarian about:

- Any other medical problems or allergies that your dog has now, or has had in the past
- All medicines that you are giving or plan to give your dog, including those you can get without a prescription and any dietary supplements

Tell your veterinarian if your dog:

- Is under 6 months of age
- Is pregnant, nursing or if you plan to breed your dog

**How to give OroCAM to your dog.**

OroCAM should be given according to your veterinarian’s instructions. Do not change the way you give OroCAM to your dog without first speaking with your veterinarian. Your veterinarian will tell you what amount of OroCAM is right for your dog and for how long it should be given. Your veterinarian will assemble the spray bottle/pump prior to dispensing it to you. Follow the illustrated instructions below for how to give OroCAM to your dog.



Gently shake bottle.



Spray OroCAM into dog’s cheek space.



Wipe pump with tissue to prevent clogging.

**Directions for Administration.**

Prior to each use, shake the bottle gently. If OroCAM is not used for two days or more, re-prime with one spray into an absorbent material, or until a fine spray appears. In case of pump failure, wipe nozzle and then re-prime the pump. If a partial dose has been administered to the pet due to pump failure, do not redose; wait until the next dosing time to administer OroCAM. The contents of the bottle should be discarded 6 months after assembly.

## **Particular care should be given with regard to the accuracy of dosing.**

To administer OroCAM® (meloxicam) Transmucosal Oral Spray, grasp the corner of your dog's mouth and gently pull it away from the gums, opening the cheek space. Place the tip of the applicator just inside the cheek space directed towards the back of the cheek space. Holding the bottle and pump upright, fully depress the spray head taking special care to ensure no spray escapes from the mouth. Allow the pump to fully reflate before administering consecutive sprays (if necessary).

Immediately after administration of the spray, use a moist paper towel or tissue to clean the tip of the pump. Wash hands after administration of the product.

## **When do I need a new bottle?**

The end of the center tube should be covered by the fluid level. Once fluid falls below the level of the center tube, sprays will not be adequate and the bottle should be replaced. There is a residual volume of fluid at the bottom of the bottle which cannot be used. Each bottle should not be used longer than 6 months after it is first assembled by your veterinarian.

## **What do I do if the pump clogs?**

In case of pump failure, wipe nozzle and then re-prime the pump. If the pump clogs while dosing your dog, do not re-administer that spray. Do not redose if pump failure occurs; wait until the next dosing time to administer OroCAM.

## **What are the possible side effects that may occur in my dog during OroCAM therapy?**

OroCAM, like other NSAIDs, may cause some side effects. Serious side effects associated with NSAID therapy in dogs can occur with or without warning, and, in rare situations, result in death. The most common side effects associated with OroCAM therapy involve the digestive tract (vomiting and decreased food consumption). Liver and kidney problems have also been reported with NSAIDs. Look for the following side effects that may indicate your dog is having a problem with OroCAM:

- Decrease or increase in appetite
- Vomiting
- Change in bowel movements (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, or amount consumed)
- Change in urination habits (frequency, color, or smell)
- Change in skin (redness, scabs, or scratching)
- Unexpected weight loss

It is important to stop the medication and contact your veterinarian immediately if you think your dog has a medical problem or side effect while taking OroCAM. If you have additional questions about possible side effects, talk with your veterinarian or call (888) 299-7416.

## **Can OroCAM be given with other medications?**

OroCAM should not be given with other NSAIDs (for example, aspirin, carprofen, etodolac, deracoxib, tepoxalin, or other meloxicam products) or corticosteroids (for example, prednisone, cortisone, dexamethasone, or triamcinolone).

Tell your veterinarian about all medications that you have given your dog in the past, and any medications you are planning to give with OroCAM. This should include other medicines that you can get without a prescription or any dietary supplements. Your veterinarian may want to check that all of your dog's medicines can be given together.

## **What do I do in case my dog ingests more than the prescribed amount of OroCAM?**

Consult your veterinarian immediately if your dog ingests more than the prescribed amount of OroCAM.

## **What else should I know about OroCAM?**

- This sheet provides a summary of information about OroCAM Transmucosal Oral Spray. If you have any questions or concerns about OroCAM, or osteoarthritis pain, talk with your veterinarian.
- As with all prescribed medicines, OroCAM should only be given to the dog for which it is prescribed. It should be given to your dog only for the condition for which it was prescribed, at the prescribed dose.
- **OroCAM is for use in dogs only. Do not give OroCAM to cats.**
- It is important to periodically discuss your dog's response to OroCAM with your veterinarian. Your veterinarian will determine if your dog is responding as expected and if your dog should continue receiving OroCAM.

## **What should I do if I come into contact with OroCAM?**

Wash hands after administration of the product. Consult a physician in case of accidental ingestion by humans or contact with mucous membranes. Direct contact with skin, eyes, and mucous membranes should be avoided. If contact occurs with skin, the area should be washed immediately with soap and water for at least 20 seconds. In case of contact with eyes, flush immediately with water. Women in late pregnancy should avoid contact with this product.

**To report suspected adverse events, for technical assistance or to obtain a copy of the MSDS, contact Abbott Animal Health at (888) 299-7416.**

For additional information about adverse drug experience reporting for animal drugs, contact the FDA at 1-888-FDA-VETS or online at <http://www.fda.gov/AnimalVeterinary/SafetyHealth>

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