

Information for Dog Owners about Firocoxib Chewable Tablets

Firocoxib chewable tablets are used for the control of pain and inflammation due to osteoarthritis or associated with soft-tissue and orthopedic surgery in your dog.

This summary contains important information about Firocoxib. You should read this information before you start giving your dog Firocoxib tablets and review it each time your 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 you want to know more about Firocoxib.

What is Firocoxib?

Firocoxib is a veterinary prescription non-steroidal anti-inflammatory drug (NSAID) used to control pain and inflammation due to osteoarthritis, or associated with soft-tissue and orthopedic surgery in dogs.

Osteoarthritis 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.

Firocoxib is indicated for the control of postoperative pain and inflammation following soft-tissue and orthopedic surgeries (e.g. spays, cruciate ligament repair). Your veterinarian may administer Firocoxib before the procedure and recommend that the dog be treated for a few days after going home.

What kind of results can I expect when my dog is on Firocoxib for osteoarthritis?

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

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

What kind of results can I expect when my dog is on Firocoxib for the control of pain and inflammation following soft-tissue and orthopedic surgery?

- Firocoxib chewable tablets allow your dog to recover more comfortably by controlling pain and inflammation following soft-tissue and orthopedic surgery.
- Control of pain and inflammation may vary from dog to dog.
- If Firocoxib chewable tablets are not given according to your veterinarian's directions, your dog's pain may return.
- Consult your veterinarian if your dog appears to be uncomfortable.

Which dogs should not take Firocoxib?

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

- Has an allergic reaction to firocoxib, the active ingredient in Firocoxib.
- 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 12.5 pounds in body weight.
- Has pre-existing kidney or liver disease.
- Has decreased appetite, vomiting or diarrhea.

Firocoxib should only be given to dogs.

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

What to tell/ask your veterinarian before giving Firocoxib.

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 Firocoxib is prescribed.
- How often your dog may need to be examined by your veterinarian.
- The risks and benefits of using Firocoxib. Serious adverse reactions, including death, have been associated with Firocoxib administration at doses above the recommended dose in puppies less than seven months of age.

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

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

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 to your dog, including those you can get without a prescription and any dietary supplements.

Tell your veterinarian if your dog:

- Is under 7 months of age.
- Is pregnant, nursing or if you plan to breed your dog.

How to give Firocoxib to your dog.

Firocoxib should be given according to your veterinarian's instructions. Do not change the way you give Firocoxib to your dog without first speaking with your veterinarian. Your veterinarian will tell you what amount of Firocoxib is right for your dog and for how long it should be given. Firocoxib chewable tablets may be offered to the dog by hand, or you can place the tablet in your dog's mouth. Firocoxib may be given with or without food.

What are the possible side effects that may occur in my dog during Firocoxib therapy?

Firocoxib, 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 Firocoxib 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 Firocoxib:

- 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 Firocoxib tablets. If you have additional questions about possible side effects, talk with your veterinarian or call 1-833-571-1525.

Can Firocoxib be given with other medications?

Firocoxib should not be given with other NSAIDs (for example, aspirin, carprofen, etodolac, deracoxib, meloxicam, or tepoxalin) 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 Firocoxib tablets. 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 eats more than the prescribed amount of Firocoxib?

Consult your veterinarian immediately if your dog eats more than the prescribed amount of Firocoxib.

What else should I know about Firocoxib?

- This sheet provides a summary of information about Firocoxib tablets. If you have any questions or concerns about Firocoxib, osteoarthritis pain, or postoperative pain following soft-tissue and orthopedic surgery, talk with your veterinarian.
- As with all prescribed medicines, Firocoxib tablets should only be given to the dog for which they were prescribed. They should be given to your dog only for the condition for which they were prescribed, at the prescribed dose.
- It is important to periodically discuss your dog's response to Firocoxib tablets. Your veterinarian will determine if your dog is responding as expected and if your dog should continue receiving Firocoxib tablets.

Contact Information:

To report suspected adverse drug events, for technical assistance or to obtain a copy of Safety Data Sheet, contact Felix Pharmaceuticals Private Limited at 1-833-571-1525. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae

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