

Contact Information: To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Pegasus Laboratories, Inc. at 1-800-874-9764 or www.ppharmaceutical.com.

Information For Dog Owners: Firocoxib Chewable Tablets for Dogs, like other drugs of its class, is not free from adverse reactions. Owners should be advised of the potential for adverse reactions and be informed of the clinical signs associated with drug intolerance. Adverse reactions may include vomiting, diarrhea, decreased appetite, dark or tarry stools, increased water consumption, increased urination, pale gums due to anemia, yellowing of gums, skin or whites of the eye due to jaundice, lethargy, incoordination, seizure, or behavioral changes.

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Information for Dog Owners about Firocoxib Chewable Tablets for Dogs

Firocoxib Chewable Tablets for Dogs

Firocoxib Chewable Tablets for Dogs 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 Chewable Tablets for Dogs. You should read this information before you start giving your dog Firocoxib Chewable Tablets for Dogs and review it each time your prescription is refilled. This sheet is provided only as a summary and does not take the place of instruction from your veterinarian. Talk to your veterinarian if you do not understand any of this information or if you want to know more about Firocoxib Chewable Tablets for Dogs.

What is Firocoxib Chewable Tablets for Dogs? Firocoxib Chewable Tablets for Dogs 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 Chewable Tablets for Dogs is indicated for the control of post-operative pain and inflammation following soft-tissue and orthopedic surgeries (e.g. spays, cruciate ligament repair). Your veterinarian may administer Firocoxib Chewable Tablets for Dogs 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 Chewable Tablets for Dogs for osteoarthritis? Firocoxib Chewable Tablets for Dogs 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;
- Firocoxib Chewable Tablets for Dogs are 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 Chewable Tablets for Dogs for the control of pain and inflammation following soft-tissue and orthopedic surgery?

- Firocoxib Chewable Tablets for Dogs 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 for Dogs 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 Chewable Tablets for Dogs? Your dog should not be given Firocoxib Chewable Tablets for Dogs if he/she:

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

Firocoxib Chewable Tablets for Dogs should only be given to dogs. People should not take Firocoxib Chewable Tablets for Dogs. Keep Firocoxib Chewable Tablets for Dogs and all medications out of the reach of children. Call your physician immediately if you accidentally take Firocoxib Chewable Tablets for Dogs.

What to tell/ask your veterinarian before giving Firocoxib Chewable Tablets for Dogs:

- 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 Chewable Tablets for Dogs is prescribed;
- How often your dog may need to be examined by your veterinarian;
- The risks and benefits of using Firocoxib Chewable Tablets for Dogs. Serious adverse reactions, including death, have been associated with Firocoxib Chewable Tablets for Dogs 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 Chewable Tablets for Dogs or other NSAIDs, such as aspirin;
- Any digestive upset (vomiting and/or diarrhea);
- Any kidney disease;
- Any liver disease;
- 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;
- Are pregnant, nursing or if you plan to breed your dog.

How to give Firocoxib Chewable Tablets for Dogs to your dog. Firocoxib Chewable Tablets for Dogs should be given according to your veterinarian's instructions. Do not change the amount of Firocoxib Chewable Tablets for Dogs to your dog without first speaking with your veterinarian. Your veterinarian will tell you what amount of Firocoxib Chewable Tablets for Dogs is right for your dog and for how long it should be given.

Firocoxib Chewable Tablets for Dogs may be offered to the dog by hand or you can place the tablet in your dog's mouth. Firocoxib Chewable Tablets for Dogs may be given with or without food.

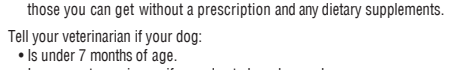
(Information for Dog Owners cont. on next page)

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Firocoxib Chewable Tablets for Dogs

For oral use in dogs only. **Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Description: Firocoxib Chewable Tablets for Dogs belong to the covix class of non-narcotic, non-steroidal anti-inflammatory drugs. Firocoxib is a white crystalline compound described chemically as 3-(cyclopropylmethyl)-4-(4-(methylsulfonyl)phenyl)-5-dimethylpyridine. The empirical formula is C₁₈H₂₁N₃S and the molecular weight is 336.4. The structural formula is shown below:



Pharmacokinetics: The absolute bioavailability of Firocoxib Chewable Tablets for Dogs is approximately 38% when administered as a 5 mg/kg oral dose to fasted adult dogs. Firocoxib is absorbed from the blood via hepatic metabolism and fecal excretion (CL_{systemic} = -0.4 L/hr/kg). Despite a high level of plasma protein binding (96%), firocoxib exhibits a large volume of distribution (V_d = 284 L/kg, n = 4; -4.6 L/kg) and a terminal elimination half-life of 7.8 hours (CV = 30%). The oral drug absorption process is highly variable among subjects. Co-administration of firocoxib with food delays drug absorption (T_{max} from 1 to 5 hours) and decreases peak concentrations (C_{max} from 1.3 to 0.9 mcg/mL). However, food does not affect the overall oral bioavailability at the recommended dose.

Indications: Firocoxib Chewable Tablets for Dogs are indicated for the control of pain and inflammation associated with osteoarthritis and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery in dogs.

Dosage and Administration: Always provide the Client Information Sheet with prescription. Carefully consider the potential benefits and risks of Firocoxib Chewable Tablets for Dogs and other treatment options before deciding to use Firocoxib Chewable Tablets for Dogs. Use the lowest effective dose for the shortest duration consistent with your individual response. The recommended dosage of Firocoxib Chewable Tablets for Dogs for oral administration in dogs is 2.27 mg/lb (5.0 mg/kg) body weight once daily as needed for up to 14 days or 2 days as needed for postoperative pain and inflammation associated with soft-tissue and orthopedic surgery. The dogs can be treated with Firocoxib Chewable Tablets for Dogs as needed for up to two hours prior to surgery. The tablets are scored and dosage should be calculated in half tablet increments. Firocoxib Chewable Tablets for Dogs can be administered with or without food.

Contraindications: Dogs with known hypersensitivity to firocoxib should not receive Firocoxib Chewable Tablets for Dogs.

Warnings: Not for use in humans. Keep this and all medications out of the reach of children. Consult a physician in case of accidental ingestion by humans.

Keep Firocoxib Chewable Tablets for Dogs in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

For oral use in dogs only. Use of this product at doses above the recommended 2.27 mg/lb (5.0 mg/kg) in puppies less than seven months of age has been associated with serious adverse reactions, including death (see Animal Safety). Due to tablet sizes and scoring, dogs weighing less than 12.5 lb (5.7 kg) cannot be accurately dosed.

All dogs should undergo a thorough history and physical examination before the initiation of NSAID therapy. Appropriate laboratory testing to establish hematological and serum biochemistry data is recommended prior to and periodically during administration of any NSAID.

Owners should be advised to observe for signs of potential drug toxicity (see Adverse Reactions and Animal Safety) and be given a Client Information Sheet about Firocoxib Chewable Tablets for Dogs.

Contact Information: To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Pegasus Laboratories, Inc. at 1-800-874-9764 or www.ppharmaceutical.com.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

Precautions: This product cannot be accurately dosed in dogs less than 12.5 pounds in body weight.

Consider appropriate washout times when switching from one NSAID to another or when switching from corticosteroid use to NSAID use.

As a class, cyclooxygenase inhibitory NSAIDs may be associated with renal, gastrointestinal and hepatic toxicity. Sensitivity to drug-associated adverse events varies with the individual patient. Dogs that have experienced adverse reactions from one NSAID may experience adverse reactions from another NSAID. Patients at greatest risk for adverse events are those that are dehydrated, on concomitant diuretic therapy, or those with existing renal, cardiovascular, and/or hepatic dysfunction. Concomitant administration of potentially nephrotoxic drugs should be carefully approached and monitored. NSAIDs may inhibit the prostaglandins that maintain normal homeostatic function. Such anti-prostaglandin effects may result in clinically significant disease in patients with underlying or pre-existing disease that has not been previously diagnosed. Since NSAIDs possess the potential to produce gastrointestinal ulceration and/or gastrointestinal perforation, concomitant use of Firocoxib Chewable Tablets for Dogs with other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be avoided. The concomitant use of protein bound drugs with Firocoxib Chewable Tablets for Dogs has not been studied in dogs. Commonly used protein-bound drugs include cardiac, anticonvulsant, and behavioral medications. The influence of concomitant drugs that may inhibit the metabolism of Firocoxib Chewable Tablets for Dogs has not been evaluated. Drug compatibility should be monitored in patients requiring adjunctive therapy.

If additional pain medication is needed after the daily dose of Firocoxib Chewable Tablets for Dogs, a non-NSAID class of analgesic may be necessary.

Appropriate monitoring procedures should be employed during all surgical procedures. Anesthetic drugs may affect renal perfusion, approach concomitant use of anesthetics and NSAIDs with caution. The use of parenteral fluids during surgery should be considered to decrease potential renal complications when using NSAIDs preoperatively.

The safe use of Firocoxib Chewable Tablets for Dogs in pregnant, lactating or breeding dogs has not been evaluated.

Adverse Reactions: **Osteoarthritis:** In controlled field studies, 128 dogs (ages 11 months to 15 years) were evaluated for safety when given Firocoxib chewable tablets at a dose of 2.27 mg/lb (5.0 mg/kg) orally once daily for 30 days. The following adverse reactions were observed. Dogs may have experienced more than one of the observed adverse reactions during the study.

Adverse Reactions Seen in U.S. Field Studies

Adverse Reactions	Firocoxib Group n=128	Active Control n=121
Vomiting	5	8
Diarrhea	1	10
Decreased Appetite or Anorexia	3	3
Lethargy	1	3
Pain	2	1
Somnolence	1	1
Hyperactivity	1	0

Firocoxib chewable tablets were safely used during field studies concomitantly with other therapies, including vaccines, antihelmintics, and antibiotics.

Soft-tissue Surgery: In controlled field studies evaluating soft-tissue postoperative pain and inflammation, 258 dogs (ages 10.5 weeks to 16 years) were evaluated for safety when given firocoxib chewable tablets at a dose of 2.27 mg/lb (5.0 mg/kg) orally applied approximately 2 hours prior to surgery and once daily thereafter for up to two days. The following adverse reactions were observed. Dogs may have experienced more than one of the observed reactions during the study.

Adverse Reactions Seen in the Soft-Tissue Surgery Postoperative Pain Field Studies

Adverse Reactions	Firocoxib Group n=127	Control Group n=131
Vomiting	5	6
Diarrhea	1	1
Bruising at Surgery Site	1	1
Respiratory Arrest	1	0
SD Crepitus in Rear Leg and Flank	1	0
Swollen Paw	1	0

*Sham-dosed (pilled)

Orthopedic Surgery: In a controlled field study evaluating orthopedic postoperative pain and inflammation, 258 dogs (ages 10.5 weeks to 16 years) were evaluated for safety when given firocoxib chewable tablets at a dose of 2.27 mg/lb (5.0 mg/kg) orally applied approximately 2 hours prior to surgery and once daily thereafter for up to two days. The following adverse reactions were observed. Dogs may have experienced more than one of the observed reactions during the study.

Adverse Reactions Seen in the Orthopedic Surgery Postoperative Pain Field Study

Adverse Reactions	Firocoxib Group n=118	Control Group n=108
Vomiting	1	0
Diarrhea	2**	1
Bruising at Surgery Site	2	3
Inappetence/Decreased Appetite	1	2
Pyrexia	0	1
Incision Swelling, Redness	9	5
Oozing Incision	2	0

A case may be represented in more than one category. *Sham-dosed (pilled).

**One dog had hemorrhagic gastroenteritis.

Post-Operative Experience (Rev