Dog Owner Information about Flexprofen™ for Osteoarthritis and Post-Surgical Pain

Generic name: carprofen ("car-pro-fen")

What is Flexprofen™?
Flexprofen™ is a nonsteroidal anti-inflammatory drug (NSAID) that is used to reduce pain and inflammation (swelling) due to osteoarthritis and post-surgical pain in dogs. Flexprofen™ is a nonprescription drug for dogs. It is available as a chewable tablet and is given to dogs by mouth.

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 (involuntary to stand, climb stairs, jump or run, or difficulty in performing these activities)
- Stiffness or decreased movement at joints
- Cracking or snapping (e.g., for surgeries such as those on the hip, rear or elbow, or any surgical site)
- Changes in behavior (restlessness, sleep, or scratching)

What kind of results can I expect when my dog is on Flexprofen™?
While Flexprofen™ is not a cure for osteoarthritis, it can relieve the pain and inflammation of OA and improve your dog’s mobility.

- Flexprofen™ relieves pain in your dog.
- Flexprofen™ reduces the inflammation in your dog’s joints.

What should not take Flexprofen™?
Your dog should not take Flexprofen™ if:

- Your dog is allergic to any NSAID or the active ingredient of Flexprofen™.
- Your dog has an allergic reaction to any of the following (for example, aspirin, ibuprofen, ketoprofen, meloxicam, phenylbutazone or aspirin) such as hives, facial swelling, or inability to eat.

Flexprofen™ chewable tablets should be given to dogs only. Cats should not be given Flexprofen™. Call your veterinarian immediately if your cat receives Flexprofen™. People should not take Flexprofen™. Keep Flexprofen™ and all medicines out of the reach of children. Call your pharmacist immediately if you accidentally take Flexprofen™.

How to give Flexprofen™ to your dog?
Flexprofen™ should be given according to your veterinarian’s instructions. Your veterinarian will tell you what amount of Flexprofen™ to give for your dog and how long it should be given. Flexprofen™ should be given by mouth and may be given with or without food.

What to Know your veterinarian before giving Flexprofen™,
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
- The need for regular monitoring of your dog’s health
- How often your dog needs to be reexamined by your veterinarian
- The risks and benefits of using Flexprofen™

Tell your veterinarian if your dog has ever had the following medical problems:

- Hypersensitivity reactions from Flexprofen™ or other NSAIDs, such as aspirin
- Allergic skin disease
- A bleeding disorder (for example, von Willebrand’s disease)

Tell your veterinarian about:

- 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 has:

- Pregnant, nursing or if you plan to breed your dog.

What are the possible side effects that may occur in my dog during Flexprofen™ therapy?
Flexprofen™, like other drugs, may cause some side effects. Although rare, side effects have been reported in dogs taking NSAIDs, including Flexprofen™. Side effects can occur with or without warning and in rare situations may result in death.

- The most common NSAID-related side effects generally involve the stomach (such as bleeding ulcers), and rare or allergy problems. Look for the following side effects that can indicate your dog may be having a problem with Flexprofen™ or may have another medical problem:
  - Decrease or increase in appetite
  - Vomiting
  - Change in bowel movements (such as diarrhea, black, tarry or bloody stools)
  - Change in behavior (such as decreased or increased activity level, restlessness, seizure or aggression)
  - Yellowing of gums, skin, or whites of the eyes (jaundice)
  - Change in drinking habits (increased amount consumed)
  - Changes in urination habits (frequency, color, smell)
  - Changes in skin (redness, scale, 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 Flexprofen™ therapy. If you have any additional questions about possible side effects, talk to your veterinarian.

Can Flexprofen™ be given with other medicines?
Flexprofen™ should not be given with other NSAIDs (for example, aspirin, ibuprofen, ketoprofen, meloxicam, phenylbutazone or aspirin) such as ibuprofen, metaclopromide or eltroxin.

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

What do I do if my dog eats more than the prescribed amount of Flexprofen™?
Contact your veterinarian immediately. If your dog eats more than the prescribed amount of Flexprofen™, how to store Flexprofen™

Keep Flexprofen™ in a secure storage area out of the reach of your dog and other pets. If your dog ingests more than your veterinarian prescribed, or if your pets take Carprofen, contact your veterinarian right away.

What else should I know about Flexprofen™?
This sheet provides a summary of information about Flexprofen™. If you have any questions or concerns about Flexprofen™, or osteoarthritis, or post-surgical pain, talk to your veterinarian.

As a part of your treatment, Flexprofen™ 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.

It is important to periodically discuss your dog’s response to Flexprofen™ at regular visits. Your veterinarian will best determine if your dog is responding as expected and if your dog should continue receiving Flexprofen™.

To report a suspected adverse reaction call 1-800-935-1886.

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Flexprofen™ Chewable Tablets (Carprofen)

For oral use in dogs only

DEFINITION: Carprofen is a non-steroidal anti-inflammatory drug (NSAID) that is indicated in dogs for the relief of pain associated with osteoarthritis, and for the control of postoperative pain associated with soft tissue and orthopedic surgeries.

INFORMATION FOR THE PATIENT: Owners should be advised to observe their pet closely for any signs of adverse reactions. If any of the following signs develop, discontinue Flexprofen™ and contact their veterinarian immediately:

- Lethargy
- Incoordination
- Seizure
- Behavioral changes

If any of the above signs develop, discontinue Flexprofen™ and contact your veterinarian immediately.

WARNING: Do not use in cats.

Do not administer to pregnant, lactating, nursing, or developmentally immature dogs. Flexprofen should not be used in dogs exhibiting previous hypersensitivity to carprofen.

DOSAGE AND ADMINISTRATION: See PAWCHNOZÒ SA Usage and Handling Guide for complete directions for use.

EFFECTIVENESS: In target animal safety studies, carprofen was administered orally to healthy Beagle dogs at 1, 3, and 5 mg/kg bid by oral gavage for 28 days. Carprofen was well tolerated in all dosage levels and there were no deaths or treatment-related clinical signs. In clinical studies, carprofen was well tolerated in dogs that had previously failed to respond to other NSAIDs.

The mechanism of action of carprofen, like that of other NSAIDs, is believed to be associated with the inhibition of cyclooxygenase and lipoxygenase pathways of arachidonic acid metabolism. Carprofen inhibits the cyclooxygenase enzymes, cyclooxygenase-1 (COX-1) and cyclooxygenase-2 (COX-2), which are involved in the production of prostaglandins from arachidonic acid.

At therapeutic concentrations, carprofen rapidly inhibits platelet function due to its cyclooxygenase inhibitory activity, which results in the prevention of platelet aggregation and the clotting of blood.

During investigational studies for a chewable tablet formulation, gastrointestinal signs were observed in some dogs at the 10 mg/kg dose level. Gastrointestinal signs included vomiting,軟 stools, and diarrhea.

The non-steroidal anti-inflammatory drug class can cause gastrointestinal and renal adverse reactions, including gastrointestinal irritation, ulceration, and hemorrhage as well as nephritis, interstitial nephritis, and renal failure. These adverse reactions may be more likely in patients with pre-existing disease, elderly patients, and patients receiving concomitant aspirin or non-steroidal anti-inflammatory drugs.

Additionally, the use of carprofen in dogs may result in a decrease in bleeding time due to inhibition of platelet aggregation. In dogs, carprofen causes an increase in the prothrombin time, which is indicative of an inhibition of factor VII and factor X. This can result in a decreased clotting time, potentially leading to increased bleeding.

Due to the potential risk for serious adverse reactions, Flexprofen™ should be administered at the lowest effective dosage for the shortest duration possible.

Clinical studies were conducted in 297 dogs of different breeds undergoing orthopedic or soft tissue surgery. Dogs were administered 2 mg/kg of carprofen two hours prior to surgery then once daily, as needed for 2 days post-surgery.

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In order to achieve a good therapeutic response, carprofen should be used in conjunction with other pain management strategies, such as physical therapy and behavioral modification.

THERAPEUTIC USES: Flexprofen™ is indicated for the relief of pain associated with osteoarthritis, and for the control of postoperative pain associated with soft tissue and orthopedic surgeries. It is not indicated for the treatment of pain associated with other conditions such as inflammatory bowel disease or systemic lupus erythematosus.

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