





Pack Outsert size 425 x 280 mm / Folding Size: 33 x 33 mm

ANIMAL SAFETY:

Laboratory studies in unanesthetized dogs and clinical field studies have demonstrated that carprofen is well tolerated in dogs after oral administration.

In target animal safety studies, carprofen was administered orally to healthy Beagle dogs at 1, 3, and 5 mg/lb twice daily (1, 3 and 5 times the recommended total daily dose) for 42 consecutive days with no significant adverse reactions. Serum albumin for a single female dog receiving 5 mg/lb twice daily decreased to 2.1 g/dL after 2 weeks of treatment, returned to the pre-treatment value (2.6 g/dL) after 4 weeks of treatment, and was 2.3 g/dL at the final 6-week evaluation. Over the 6-week treatment period, black or bloody stools were observed in 1 dog (1 incident) treated with 1 mg/lb twice daily and in 1 dog (2 incidents) treated with 3 mg/lb twice daily. Redness of the colonic mucosa was observed in 1 male that received 3 mg/lb twice daily.

Two of 8 dogs receiving 10 mg/lb orally twice daily (10 times the recommended total daily dose) for 14 days exhibited hypoalbuminemia. The mean albumin level in the dogs receiving this dose was lower (2.38 g/dL) than each of 2 placebo control groups (2.88 and 2.93 g/dL, respectively). Three incidents of black or bloody stool were observed in 1 dog. Five of 8 dogs exhibited reddened areas of duodenal mucosa on gross pathologic examination. Histologic examination of these areas revealed no evidence of ulceration, but did show minimal congestion of the lamina propria in 2 of the 5 dogs.

In separate safety studies lasting 13 and 52 weeks, respectively, dogs were administered orally up to 11.4 mg/lb/day (5.7 times the recommended total daily dose of 2 mg/lb) of carprofen. In both studies, the drug was well tolerated clinically by all of the animals. No gross or histologic changes were seen in any of the treated animals. In both studies, dogs receiving the highest doses had average increases in serum L-alanine aminotransferase (ALT) of approximately 20 IU.

In the 52-week study, minor dermatologic changes occurred in dogs in each of the treatment groups but not in the control dogs. The changes were described as slight redness or rash and were diagnosed as non-specific dermatitis. The possibility exists that these mild lesions were treatment related, but no dose relationship was observed.

Clinical field studies were conducted with 549 dogs of different breeds at the recommended oral doses for 14 days (297 dogs were included in a study evaluating 1 mg/lb twice daily and 252 dogs were included in a separate study evaluating 2 mg/lb once daily). In both studies the drug was clinically well tolerated and the incidence of clinical adverse reactions for carprofen-treated animals was no higher than placebo-treated animals (placebo contained inactive ingredients found in carprofen). For animals receiving 1 mg/lb twice daily, the mean post-treatment serum ALT values were 11 IU greater and 9 IU less than pre-treatment values for dogs receiving carprofen and placebo, respectively. Differences were not statistically significant. For animals receiving 2 mg/lb once daily, the mean post-treatment serum ALT values were 4.5 IU greater and 0.9 IU less than pre-treatment values for dogs receiving carprofen and placebo, respectively. In the latter study, 3 carprofen-treated dogs developed a 3-fold or greater increase in (ALT) and/or (AST) during the course of therapy. One placebo-treated dog had a greater than 2-fold increase in ALT. None of these animals showed clinical signs associated with laboratory value changes. Changes in the clinical laboratory values (hematology and clinical chemistry) were not considered clinically significant. The 1 mg/lb twice daily course of therapy was repeated as needed at 2-week intervals in 244 dogs, some for as long as 5 years.

Clinical field studies were conducted in 297 dogs of different breeds undergoing orthopedic or soft tissue surgery. Dogs were administered 2 mg/lb of carprofen two hours prior to surgery then once daily, as needed for 2 days (soft tissue surgery) or 3 days (orthopedic surgery). Carprofen was well tolerated when used in conjunction with a variety of anesthetic-related drugs. The type and severity of abnormal health observation in carprofen- and placebo-treated animals were approximately equal and few in number (see Adverse Reactions). The most frequent abnormal health observation was vomiting and was observed at approximately the same frequency in carprofen- and placebo-treated animals. Changes in clinicopathologic indices of hematopoietic, renal, hepatic, and clotting function were not clinically significant. The mean post-treatment serum ALT values were 7.3 IU and 2.5 IU less than pre-treatment values for dogs receiving carprofen and placebo, respectively. The mean post-treatment AST values were 3.1 IU less for dogs receiving carprofen and 0.2 IU greater for dogs receiving placebo.

STORAGE:

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F) [see USP Controlled Room Temperature]

Use within 90 days of splitting.

HOW SUPPLIED: Carprofen Chewable Tablets are scored, and contain 25 mg, 75 mg, or 100 mg of carprofen per tablet. Each tablet size is packaged in bottles containing 30, 60, or 180 tablets.

NDC Number	Tablet Size	Tablets/Bottle
86101-008-31	25 mg	30
86101-008-61	25 mg	60
86101-008-74	25 mg	180
86101-009-31	75 mg	30
86101-009-61	75 mg	60
86101-009-74	75 mg	180
86101-010-31	100 mg	30
86101-010-61	100 mg	60
86101-010-74	100 mg	180

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To report suspected adverse drug events, for technical assistance or to obtain a copy of the 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 <http://www.fda.gov/reportanimalae>.

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Dog Owner Information about

CARPROFEN  
Chewable Tablets  
for Osteoarthritis and Post-Surgical Pain

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

What are Carprofen Chewable Tablets?

Carprofen Chewable Tablets are a nonsteroidal anti-inflammatory drug (NSAID) that is used to reduce pain and inflammation (soreness) due to osteoarthritis and pain following surgery in dogs. Carprofen Chewable Tablets are a prescription 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 (reluctance to stand, climb stairs, jump or run, or difficulty in performing these activities)
- Stiffness or decreased movement of joints

To control surgical pain (e.g. for surgeries such as spays, ear procedures or orthopedic repairs) your veterinarian may administer Carprofen Chewable Tablets before the procedure and recommend that your dog be treated for several days after going home.

What kind of results can I expect when my dog is on Carprofen Chewable Tablets?

While Carprofen Chewable Tablets are not a cure for osteoarthritis, it can relieve the pain and inflammation of OA and improve your dog's mobility.

- Response varies from dog to dog but can be quite dramatic.
- In most dogs, improvement can be seen in a matter of days.
- If Carprofen Chewable Tablets are discontinued or not given as directed, your dog's pain and inflammation may come back.

Who should not take Carprofen Chewable Tablets?

Your dog should not be given Carprofen Chewable Tablets if he/she:

- Has had an allergic reaction to carprofen, the active ingredient of Carprofen Chewable Tablets.
- Has had an allergic reaction to aspirin or other NSAIDs (for example deracoxib, etodolac, firocoxib, meloxicam, phenylbutazone or tepoxalin) such as hives, facial swelling, or red or itchy skin.

**Carprofen Chewable Tablets should be given to dogs only.** Cats should not be given Carprofen Chewable Tablets. Call your veterinarian immediately if your cat receives Carprofen Chewable Tablets. People should not take Carprofen Chewable Tablets. Keep Carprofen Chewable Tablets and all medicines out of reach of children. Call your physician immediately if you accidentally take Carprofen Chewable Tablets.

How to give Carprofen Chewable Tablets to your dog.

Carprofen Chewable Tablets should be given according to your veterinarian's instructions. Your veterinarian will tell you what amount of Carprofen Chewable Tablets are right for your dog and for how long it should be given. Most dogs will take Carprofen Chewable Tablets right out of your hand or the tablet can be placed in the mouth. Carprofen Chewable Tablets may be given with or without food.

What to tell/ask your veterinarian before giving Carprofen Chewable Tablets.

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 Carprofen Chewable Tablets are prescribed.
- How often your dog may need to be examined by your veterinarian.
- The risks and benefits of using Carprofen Chewable Tablets.

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

- Experienced side effects from Carprofen Chewable Tablets or other NSAIDs, such as aspirin
- Digestive upset (vomiting and/or diarrhea)
- Liver disease
- Kidney disease
- 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 is:

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

What are the possible side effects that may occur in my dog during Carprofen Chewable Tablets therapy?

Carprofen Chewable Tablets, like other drugs, may cause some side effects. Serious but rare side effects have been reported in dogs taking NSAIDs, including Carprofen Chewable Tablets. Serious side effects can occur with or without warning and in rare situations result in death.

The most common NSAID-related side effects generally involve the stomach (such as bleeding ulcers), and liver or kidney problems. Look for the following side effects that can indicate your dog may be having a problem with Carprofen Chewable Tablets or may have another medical problem:

- 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, amount consumed)
- 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 Carprofen Chewable Tablets therapy. If you have additional questions about possible side effects, talk to your veterinarian.

Can Carprofen Chewable Tablets be given with other medicines?

Carprofen Chewable Tablets should not be given with other NSAIDs (for example, aspirin, deracoxib, etodolac, firocoxib, meloxicam, tepoxalin) or steroids (for example, cortisone, dexamethasone, prednisone, 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 Carprofen Chewable Tablets. 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 do I do in case my dog eats more than the prescribed amount of Carprofen Chewable Tablets?

Contact your veterinarian immediately if your dog eats more than the prescribed amount of Carprofen Chewable Tablets.

How to store Carprofen Chewable Tablets.

Carprofen Chewable Tablets are designed to taste good to animals.

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

What else should I know about Carprofen Chewable Tablets?

This sheet provides a summary of information about Carprofen Chewable Tablets. If you have any questions or concerns about Carprofen Chewable Tablets or osteoarthritis pain, or postoperative pain, talk to your veterinarian.

As with all prescribed medicines, Carprofen Chewable Tablets should only be given to the dog for which it was 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 Carprofen Chewable Tablets at regular check ups. Your veterinarian will best determine if your dog is responding as expected and if your dog should continue receiving Carprofen Chewable Tablets.

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