

CARPROFEN - carprofen soft chewable tablet
FELIX PHARMACEUTICALS PRIVATE LIMITED

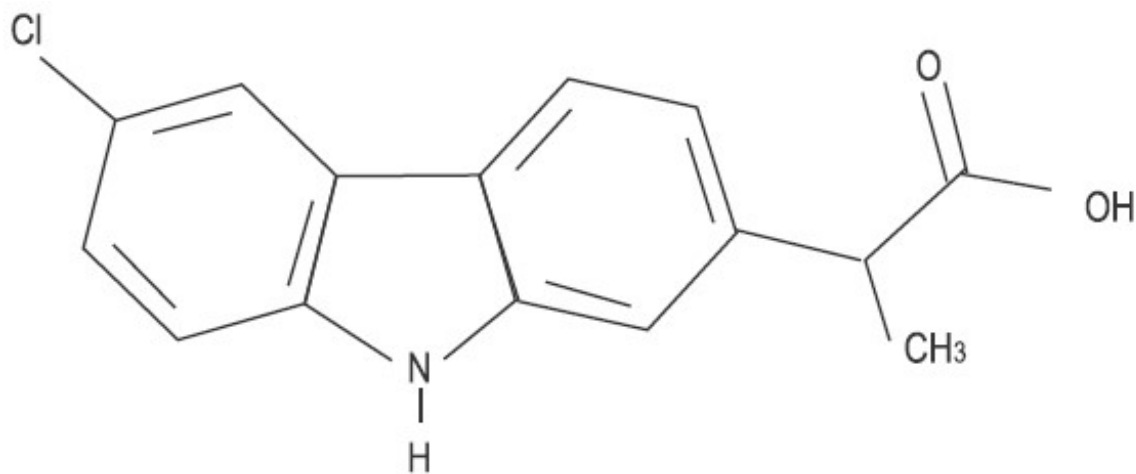
CARPROFEN
Soft Chewable Tablets
Non-steroidal anti-inflammatory drug
For oral use in dogs only

CAUTION

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

Carprofen Soft Chewable Tablets are a non-steroidal anti-inflammatory drug (NSAID) of the propionic acid class that includes ibuprofen, naproxen, and ketoprofen. Carprofen is the nonproprietary designation for a substituted carbazole, 6-chloro- α -methyl-9H-carbazole-2-acetic acid. The empirical formula is $C_{15}H_{12}ClNO_2$ and the molecular weight 273.72. The chemical structure of carprofen is:



Carprofen is a white, crystalline compound. It is freely soluble in ethanol, but practically insoluble in water at 25°C.

CLINICAL PHARMACOLOGY

Carprofen is a non-narcotic, non-steroidal anti-inflammatory agent with characteristic analgesic and antipyretic activity approximately equipotent to indomethacin in animal models.¹

The mechanism of action of carprofen, like that of other NSAIDs, is believed to be associated with the inhibition of cyclooxygenase activity. Two unique cyclooxygenases

have been described in mammals.² The constitutive cyclooxygenase, COX-1, synthesizes prostaglandins necessary for normal gastrointestinal and renal function. The inducible cyclooxygenase, COX-2, generates prostaglandins involved in inflammation. Inhibition of COX-1 is thought to be associated with gastrointestinal and renal toxicity while inhibition of COX-2 provides anti-inflammatory activity. The specificity of a particular NSAID for COX-2 versus COX-1 may vary from species to species.³ In an *in vitro* study using canine cell cultures, carprofen demonstrated selective inhibition of COX-2 versus COX-1.⁴ Clinical relevance of these data has not been shown. Carprofen has also been shown to inhibit the release of several prostaglandins in two inflammatory cell systems: rat polymorphonuclear leukocytes (PMN) and human rheumatoid synovial cells, indicating inhibition of acute (PMN system) and chronic (synovial cell system) inflammatory reactions.¹

Several studies have demonstrated that carprofen has modulatory effects on both humoral and cellular immune responses.⁵⁻⁹ Data also indicate that carprofen inhibits the production of osteoclast-activating factor (OAF), PGE₁, and PGE₂ by its inhibitory effect in prostaglandin biosynthesis.¹

Based upon comparison with data obtained from intravenous administration, carprofen is rapidly and nearly completely absorbed (more than 90% bioavailable) when administered orally.¹⁰ Peak blood plasma concentrations are achieved in 1-3 hours after oral administration of 1, 5, and 25 mg/kg to dogs. The mean terminal half-life of carprofen is approximately 8 hours (range 4.5-9.8 hours) after single oral doses varying from 1-35 mg/kg of body weight. After a 100 mg single intravenous bolus dose, the mean elimination half-life was approximately 11.7 hours in the dog. Carprofen is more than 99% bound to plasma protein and exhibits a very small volume of distribution.

Carprofen is eliminated in the dog primarily by biotransformation in the liver followed by rapid excretion of the resulting metabolites (the ester glucuronide of carprofen and the ether glucuronides of 2 phenolic metabolites, 7-hydroxy carprofen and 8-hydroxy carprofen) in the feces (70-80%) and urine (10-20%). Some enterohepatic circulation of the drug is observed.

INDICATIONS

Carprofen Soft Chewable Tablets are indicated for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

CONTRAINDICATIONS

Carprofen Soft Chewable Tablets should not be used in dogs exhibiting previous hypersensitivity to carprofen.

WARNINGS

Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans. **For use in dogs only.** Do not use in cats.

All dogs should undergo a thorough history and physical examination before initiation of NSAID therapy. Appropriate laboratory tests to establish hematological and serum

biochemical baseline data prior to, and periodically during, administration of any NSAID should be considered. **Owners should be advised to observe for signs of potential drug toxicity (see Information for Dog Owners, Adverse Reactions, Animal Safety and Post-Approval Experience).**

PRECAUTIONS

As a class, cyclooxygenase inhibitory NSAIDs may be associated with gastrointestinal, renal and hepatic toxicity. Effects may result from decreased prostaglandin production and inhibition of the enzyme cyclooxygenase which is responsible for the formation of prostaglandins from arachidonic acid.¹¹⁻¹⁴ When NSAIDs inhibit prostaglandins that cause inflammation they may also inhibit those prostaglandins which maintain normal homeostatic function. These anti-prostaglandin effects may result in clinically significant disease in patients with underlying or pre-existing disease more often than in healthy patients.^{12,14} NSAID therapy could unmask occult disease which has previously been undiagnosed due to the absence of apparent clinical signs. Patients with underlying renal disease for example, may experience exacerbation or decompensation of their renal disease while on NSAID therapy.¹¹⁻¹⁴ The use of parenteral fluids during surgery should be considered to reduce the potential risk of renal complications when using NSAIDs perioperatively.

Carprofen is an NSAID, and as with others in that class, adverse reactions may occur with its use. The most frequently reported effects have been gastrointestinal signs. Events involving suspected renal, hematologic, neurologic, dermatologic, and hepatic effects have also been reported. Patients at greatest risk for renal toxicity are those that are dehydrated, on concomitant diuretic therapy, or those with renal, cardiovascular, and/or hepatic dysfunction. Concurrent administration of potentially nephrotoxic drugs should be approached cautiously, with appropriate monitoring. Concomitant use of Carprofen Soft Chewable Tablets with other anti-inflammatory drugs, such as other NSAIDs or corticosteroids, should be avoided because of the potential increase of adverse reactions, including gastrointestinal ulcerations and/or perforations. Sensitivity to drug-associated adverse reactions varies with the individual patient. Dogs that have experienced adverse reactions from one NSAID may experience adverse reactions from another NSAID. Carprofen treatment was not associated with renal toxicity or gastrointestinal ulceration in well-controlled safety studies of up to ten times the dose in healthy dogs.

Carprofen is not recommended for use in dogs with bleeding disorders (e.g., Von Willebrand's disease), as safety has not been established in dogs with these disorders. The safe use of carprofen in animals less than 6 weeks of age, pregnant dogs, dogs used for breeding purposes, or in lactating bitches has not been established. Studies to determine the activity of carprofen when administered concomitantly with other protein-bound or similarly metabolized drugs have not been conducted. Drug compatibility should be monitored closely in patients requiring additional therapy. Such drugs commonly used include cardiac, anticonvulsant and behavioral medications. It has been suggested that treatment with carprofen may reduce the level of inhalant anesthetics needed.¹⁵

If additional pain medication is warranted after administration of the total daily dose of Carprofen Soft Chewable Tablets, alternative analgesia should be considered. The use of another NSAID is not recommended. Consider appropriate washout times when

switching from one NSAID to another or when switching from corticosteroids use to NSAID use.

Due to the flavoring contained in Carprofen Soft Chewable Tablets, keep tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose. Severe adverse reactions may occur if large quantities of tablets are ingested. If you suspect your dog has consumed Carprofen Soft Chewable Tablets above the labeled dose, please call your veterinarian for immediate assistance and notify Felix Pharmaceuticals Private Limited at 1-833-571-1525.

INFORMATION FOR DOG OWNERS

Carprofen Soft Chewable Tablets, like other drugs of their class, are 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 decreased appetite, vomiting, diarrhea, dark or tarry stools, increased water consumption, increased urination, pale gums due to anemia, yellowing of gums, skin or white of the eye due to jaundice, lethargy, incoordination, seizure, or behavioral changes. **Serious adverse reactions associated with this drug class can occur without warning and in rare situations result in death (see Adverse Reactions). Owners should be advised to discontinue Carprofen Soft Chewable Tablets therapy and contact their veterinarian immediately if signs of intolerance are observed.** The vast majority of patients with drug related adverse reactions have recovered when the signs are recognized, the drug is withdrawn, and veterinary care, if appropriate, is initiated. Owners should be advised of the importance of periodic follow up for all dogs during administration of any NSAID.

ADVERSE REACTIONS

During investigational studies for the caplet formulation with twice daily administration of 1 mg/lb, no clinically significant adverse reactions were reported. Some clinical signs were observed during field studies (n=297) which were similar for carprofen caplet- and placebo-treated dogs. Incidences of the following were observed in both groups: vomiting (4%), diarrhea (4%), changes in appetite (3%), lethargy (1.4%), behavioral changes (1%), and constipation (0.3%). The product vehicle served as control.

There were no serious adverse events reported during clinical field studies with once daily administration of 2 mg/lb. The following categories of abnormal health observations were reported. The product vehicle served as control.

Percentage of Dogs with Abnormal Health Observations Reported in Clinical Field Study (2 mg/lb once daily)		
Observation	Carprofen (n=129)	Placebo (n=132)
Inappetence	1.6	1.5
Vomiting	3.1	3.8

Diarrhea/Soft stool	3.1	4.5
Behavior change	0.8	0.8
Dermatitis	0.8	0.8
PU/PD	0.8	--
SAP increase	7.8	8.3
ALT increase	5.4	4.5
AST increase	2.3	0.8
BUN increase	3.1	1.5
Bilirubinuria	16.3	12.1
Ketonuria	14.7	9.1

Clinical pathology parameters listed represent reports of increases from pre-treatment values; medical judgment is necessary to determine clinical relevance.

During investigational studies of surgical pain for the caplet formulation, no clinically significant adverse reactions were reported. The product vehicle served as control.

Percentage of Dogs with Abnormal Health Observations Reported in Surgical Pain Field Studies with Caplets (2 mg/lb once daily)		
Observation*	Carprofen (n=148)	Placebo (n=149)
Vomiting	10.1	13.4
Diarrhea/soft stool	6.1	6.0
Ocular disease	2.7	0
Inappetence	1.4	0
Dermatitis/Skin lesion	2.0	1.3
Dysrhythmia	0.7	0
Apnea	1.4	0
Oral/Periodontal disease	1.4	0
Pyrexia	0.7	1.3
Urinary tract disease	1.4	1.3
Wound drainage	1.4	0

*A single dog may have experienced more than one occurrence of an event.

During investigational studies for the chewable tablet formulation, gastrointestinal signs were observed in some dogs. These signs included vomiting and soft stools.

Post-Approval Experience:

Although not all adverse reactions are reported, the following adverse reactions are based on voluntary post-approval adverse drug experience reporting. The categories of adverse reactions are listed in decreasing order of frequency by body system.

Gastrointestinal: Vomiting, diarrhea, constipation, inappetence, melena, hematemesis, gastrointestinal ulceration, gastrointestinal bleeding, pancreatitis.

Hepatic: Inappetence, vomiting, jaundice, acute hepatic toxicity, hepatic enzyme elevation, abnormal liver function test(s), hyperbilirubinemia, bilirubinuria, hypoalbuminemia. Approximately one-fourth of hepatic reports were in Labrador Retrievers.

Neurologic: Ataxia, paresis, paralysis, seizures, vestibular signs, disorientation.

Urinary: Hematuria, polyuria, polydipsia, urinary incontinence, urinary tract infection, azotemia, acute renal failure, tubular abnormalities including acute tubular necrosis, renal tubular acidosis, glucosuria.

Behavioral: Sedation, lethargy, hyperactivity, restlessness, aggressiveness.

Hematologic: Immune-mediated hemolytic anemia, immune-mediated thrombocytopenia, blood loss anemia, epistaxis.

Dermatologic: Pruritus, increased shedding, alopecia, pyotraumatic moist dermatitis (hot spots), necrotizing panniculitis/vasculitis, ventral ecchymosis.

Immunologic or hypersensitivity: Facial swelling, hives, erythema.

In rare situations, death has been associated with some of the adverse reactions listed above.

CONTACT INFORMATION

Contact Felix Pharmaceuticals Private Limited at 1-833-571-1525. To report suspected adverse drug experiences, contact Felix Pharmaceuticals Private Limited at 1-833-571-1525. For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>

To obtain a Safety Data Sheet(s), contact Felix Pharmaceuticals Private Limited at 1-833-571-1525.

DOSAGE AND ADMINISTRATION

Always provide Client Information Sheet with prescription. Carefully consider the potential benefits and risk of Carprofen Soft Chewable Tablets and other treatment options before deciding to use Carprofen Soft Chewable Tablets. Use the lowest effective dose for the shortest duration consistent with individual response. The recommended dosage for oral administration to dogs is 2 mg/lb of body weight daily. The total daily dose may be administered as 2 mg/lb of body weight once daily or divided and administered as 1 mg/lb twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure. Carprofen Soft Chewable Tablets are scored and dosage should be calculated in half-tablet increments. Tablets can be halved

by placing the tablet on a hard surface and pressing down on both sides of the score. Carprofen Soft Chewable Tablets may be fed by hand or placed in food. Care should be taken to ensure that the dog consumes the complete dose.

EFFECTIVENESS

Confirmation of the effectiveness of carprofen for the relief of pain and inflammation associated with osteoarthritis, and for the control of postoperative pain associated with soft tissue and orthopedic surgeries, was demonstrated in 5 placebo-controlled, masked studies examining the anti-inflammatory and analgesic effectiveness of carprofen caplets in various breeds of dogs.

Separate placebo-controlled, masked, multicenter field studies confirmed the anti-inflammatory and analgesic effectiveness of carprofen caplets when dosed at 2 mg/lb once daily or when divided and administered at 1 mg/lb twice daily. In these 2 field studies, dogs diagnosed with osteoarthritis showed statistically significant overall improvement based on lameness evaluations by the veterinarian and owner observations when administered carprofen at labeled doses.

Separate placebo-controlled, masked, multicenter field studies confirmed the effectiveness of carprofen caplets for the control of postoperative pain when dosed at 2 mg/lb once daily in various breeds of dogs. In these studies, dogs presented for ovariohysterectomy, cruciate repair and aural surgeries were administered carprofen preoperatively and for a maximum of 3 days (soft tissue) or 4 days (orthopedic) postoperatively. In general, dogs administered carprofen showed statistically significant reduction in pain scores compared to controls.

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 pretreatment 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 tablets). 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]

HOW SUPPLIED

Carprofen Soft Chewable Tablets contain 25 mg, 75 mg, or 100 mg of carprofen per tablet.

Carprofen Soft Chewable Tablets are available as:

25 mg tablets: yellowish brown to dark yellowish brown, mottled, rounded, and square-shaped tablets that have a scoreline on one side and are plain on the other side.

75 mg tablets: reddish brown to dark reddish brown, mottled, and octagonal tablets that have a scoreline on one side and are plain on the other side.

100 mg tablets: brown to dark brown, mottled, rounded, and square-shaped tablets that are debossed with the letter "C" on one side and have a scoreline on the other side.

Each tablet size is packaged in bottles containing 30 tablets.

NDC Number	Tablet Size	Tablets/Bottle
86101-041-30	25 mg	30
86101-042-30	75 mg	30
86101-043-30	100 mg	30

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Dog Owner Information about

CARPROFEN Soft Chewable Tablets for Osteoarthritis and Post-Surgical Pain

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

What are Carprofen Soft Chewable Tablets?

Carprofen Soft 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 Soft Chewable Tablets are a prescription drug for dogs. They are available as a soft chewable tablet and are 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 Soft 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 Soft Chewable Tablets?

While Carprofen Soft Chewable Tablets are not a cure for osteoarthritis, they 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 Soft Chewable Tablets are discontinued or not given as directed, your dog's pain and inflammation may come back.

Who should not take Carprofen Soft Chewable Tablets?

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

- Has had an allergic reaction to carprofen, the active ingredient of Carprofen Soft 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 Soft Chewable Tablets should be given to dogs only. Cats should not be given Carprofen Soft Chewable Tablets. Call your veterinarian immediately if your cat receives Carprofen Soft Chewable Tablets. People should not take Carprofen Soft Chewable Tablets. Keep Carprofen Soft Chewable Tablets and all medicines out of reach of children. Call your physician immediately if you accidentally take Carprofen Soft Chewable Tablets.

How to give Carprofen Soft Chewable Tablets to your dog.

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

What to tell/ask your veterinarian before giving Carprofen Soft 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 Soft Chewable Tablets are prescribed.
- How often your dog may need to be examined by your veterinarian.
- The risks and benefits of using Carprofen Soft Chewable Tablets.

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

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

Carprofen Soft Chewable Tablets, like other drugs, may cause some side effects. Serious but rare side effects have been reported in dogs taking NSAIDs, including Carprofen Soft 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 Soft 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 Soft Chewable Tablets therapy. If you have additional questions about possible side effects, talk to your veterinarian.

Can Carprofen Soft Chewable Tablets be given with other medicines?

Carprofen Soft 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 Soft 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 Soft Chewable Tablets?

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

How to store Carprofen Soft Chewable Tablets.

Carprofen Soft Chewable Tablets are designed to taste good to animals.

Keep Carprofen Soft Chewable Tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose. If your dog ingests more than your veterinarian prescribed, or if your other pets take Carprofen Soft Chewable Tablets, contact your veterinarian right away.

What else should I know about Carprofen Soft Chewable Tablets?

This sheet provides a summary of information about Carprofen Soft Chewable Tablets. If you have any questions or concerns about Carprofen Soft Chewable Tablets or osteoarthritis pain, or postoperative pain, talk to your veterinarian. As with all prescribed medicines, Carprofen Soft Chewable 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. It is important to periodically discuss your dog's response to Carprofen Soft 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 Soft Chewable Tablets.

Contact Felix Pharmaceuticals Private Limited at 1-833-571-1525. To report suspected adverse drug experiences, contact Felix Pharmaceuticals Private Limited at 1-833-571-1525. For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>

To obtain a Safety Data Sheet(s), contact Felix Pharmaceuticals Private Limited at 1-833-571-1525.

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Rev. September 2024

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC: 86101-041-30

30 Tablets

CARPROFEN

Soft Chewable Tablets

25 mg

For oral use in dogs only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Non-steroidal anti-inflammatory drug

Each scored tablets contains 25 mg of carprofen.

Approved by FDA under ANADA # 200-795

Indications: Carprofen Soft Chewable Tablets are indicated for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

Dosage: Always provide Client Information Sheet with prescription. Carefully consider the potential benefits and risk of Carprofen Soft Chewable Tablets and other treatment options before deciding to use Carprofen Soft Chewable Tablets. Use the lowest effective dose for the shortest duration consistent with individual response. The recommended dosage for oral administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight daily. The total daily dose may be administered as 2 mg/lb of body weight daily or divided and administered as 1 mg/lb (2.2 mg/kg) twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure. Tablets are scored and dosage should be calculated in half-tablet increments.

Warnings: Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans. **For use in dogs only.** Do not use in cats. **Please Refer to Insert for Complete Warnings and Precautions.**

Precaution: Due to the flavoring contained in Carprofen Soft Chewable Tablets, keep tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose. Severe adverse reactions may be expected if large quantities of tablets are ingested. If you suspect your dog has consumed Carprofen Soft Chewable Tablets beyond the labeled dose, please call your veterinarian and call 1-833-571-1525 for immediate assistance.

NDC: 86101-041-30 30 Tablets

CARPROFEN
Soft Chewable Tablets

25 mg

For oral use in dogs only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Non-steroidal anti-inflammatory drug

Each scored tablet contains 25 mg of carprofen.

Felix

Approved by FDA under ANADA # 200-795

N 3 86101041303

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

Distributed by: Felixvet Inc.,
1300 NW Briarcliff Parkway,
Suite 100, Kansas City,
Missouri 64116

Made in India
Neutral Code No. MP/DRUGS/25/90/2020

TAKE TIME OBSERVE LABEL DIRECTIONS

Rev. September 2024

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC: 86101-042-30

30 Tablets

CARPROFEN

Soft Chewable Tablets

75 mg

For oral use in dogs only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Non-steroidal anti-inflammatory drug

Each scored tablets contains 75 mg of carprofen.

Approved by FDA under ANADA # 200-795

Indications: Carprofen Soft Chewable Tablets are indicated for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

Dosage: Always provide Client Information Sheet with prescription. Carefully consider the potential benefits and risk of Carprofen Soft Chewable Tablets and other treatment options before deciding to use Carprofen Soft Chewable Tablets. Use the lowest effective dose for the shortest duration consistent with individual response. The recommended dosage for oral administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight daily. The total daily dose may be administered as 2 mg/lb of body weight daily or divided and administered as 1 mg/lb (2.2 mg/kg) twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure. Tablets are scored and dosage should be calculated in half-tablet increments.

Warnings: Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans. **For use in dogs only.** Do not use in cats. **Please Refer to Insert for Complete Warnings and Precautions.**

Precaution: Due to the flavoring contained in Carprofen Soft Chewable Tablets, keep tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose. Severe adverse reactions may be expected if large quantities of tablets are ingested. If you suspect your dog has consumed Carprofen Soft Chewable Tablets beyond the labeled dose, please call your veterinarian and call 1-833-571-1525 for immediate assistance.

NDC: 86101-042-30 30 Tablets

CARPROFEN
Soft Chewable Tablets

75 mg

For oral use in dogs only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Non-steroidal anti-inflammatory drug

Each scored tablet contains 75 mg of carprofen.

Felix

Approved by FDA under ANADA # 200-795

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

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Missouri 64116

Made in India
Neutral Code No. MP/DRUGS/25/90/2020

Rev. September 2024

XXXXXXXXXX

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC: 86101-043-30

30 Tablets

CARPROFEN

Soft Chewable Tablets

100 mg

For oral use in dogs only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Non-steroidal anti-inflammatory drug

Each scored tablets contains 100 mg of carprofen.

Approved by FDA under ANADA # 200-795

Indications: Carprofen Soft Chewable Tablets are indicated for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

Dosage: Always provide Client Information Sheet with prescription. Carefully consider the potential benefits and risk of Carprofen Soft Chewable Tablets and other treatment options before deciding to use Carprofen Soft Chewable Tablets. Use the lowest effective dose for the shortest duration consistent with individual response. The recommended dosage for oral administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight daily. The total daily dose may be administered as 2 mg/lb of body weight daily or divided and administered as 1 mg/lb (2.2 mg/kg) twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure. Tablets are scored and dosage should be calculated in half-tablet increments.

Warnings: Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans. **For use in dogs only.** Do not use in cats. **Please Refer to Insert for Complete Warnings and Precautions.**

Precaution: Due to the flavoring contained in Carprofen Soft Chewable Tablets, keep tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose. Severe adverse reactions may be expected if large quantities of tablets are ingested. If you suspect your dog has consumed Carprofen Soft Chewable Tablets beyond the labeled dose, please call your veterinarian and call 1-833-571-1525 for immediate assistance.

NDC: 86101-043-30 30 Tablets

CARPROFEN
Soft Chewable Tablets

100 mg

For oral use in dogs only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Non-steroidal anti-inflammatory drug

Each scored tablet contains 100 mg of carprofen.



Approved by FDA under ANADA # 200-795



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

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Neutral Code No. MP/DRUGS/25/90/2020



Rev. September 2024
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CARPROFEN

carprofen soft chewable tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:86101-041
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARPROFEN (UNII: FFL0D546HO) (CARPROFEN - UNII: FFL0D546HO)	CARPROFEN	25 mg

Product Characteristics

Color	BROWN (yellowish brown to dark yellowish brown)	Score	2 pieces
Shape	SQUARE (Rounded Square)	Size	17mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86101-041-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200795	12/06/2024	

CARPROFEN

carprofen soft chewable tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:86101-042
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARPROFEN (UNII: FFL0D546HO) (CARPROFEN - UNII:FFL0D546HO)	CARPROFEN	75 mg

Product Characteristics

Color	BROWN (reddish brown to dark reddish brown)	Score	2 pieces
Shape	OCTAGON (8 sided)	Size	17mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86101-042-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200795	12/06/2024	

CARPROFEN

carprofen soft chewable tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:86101-043
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARPROFEN (UNII: FFL0D546HO) (CARPROFEN - UNII:FFL0D546HO)	CARPROFEN	100 mg

Product Characteristics

Color	BROWN (brown to dark brown)	Score	2 pieces
Shape	SQUARE (Rounded Square)	Size	17mm
Flavor		Imprint Code	C
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86101-043-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200795	12/06/2024	

Labeler - FELIX PHARMACEUTICALS PRIVATE LIMITED (985612369)

Registrant - FELIX PHARMACEUTICALS PRIVATE LIMITED (985612369)

Revised: 12/2024

FELIX PHARMACEUTICALS PRIVATE LIMITED