Carprovet[®]

(carprofen) 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: Carprovet (carprofen) is 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-o-methyl-9H-carbazole-2-acetic acid. The empirical formula is C144/201009 and the molecular weight 273.72. The chemical structure of carprofen is:

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of inhaint anesthetics needed.¹⁵ If additional pairs in warranted after administration of the total daily dose of Carprovet, 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 corticosteroits use to NSAID use. Store out of reach of dogs in a secured location. Severe adverser reactions may occur if large quantities of tablets are ingested. If you suspect your dog has consumed Carprovet chewable tablets above the tabeled dose, please call your veterinarian for immediate assistance and notify Dectra at (166) 933-2472. INFORMATION FOR DOG OWNERS: Carprovet, like other drugs of its class; is not free from adverse reactions. Two sections and be advised of the potential for a during a negative and the intermed of the onlight class pairs of the total bab.

INFORMATION FOR DOG OWNERS: Caprovet, 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 decreased appetite, vomiting, diarted, adv or tarry stools, increased union, increased unitation, pale gums due to anema, yellowing of gums, skin or white of the eye due to jaundice, lethargy, incoordination, sizure, or behavioral changes. Serious adverse reactions and be informed of the given or white of the eye due to jaundice, lethargy, incoordination, sizure, or behavioral changes. Serious adverse reactions associated with this drug class can occur without warming and in rare situations result in death (see ADVERSE REACTIONS). Owners should be advised to discontinue Carprovet therapy and contact their veterinarian immediately if signs of intolerance are observed. The vast majority optients 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 an NSAID. ADVERSE REACTIONS: During investigational studies for the caplet formulation with twice daily administration of 1 mg/b, no clinically significant adverse reactions were reported. Some clinical signs mover 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/b. The following categories of abnormal health observations were reported in Clinical Field Studies Field Study (2 mg/b, once daily). **Percenta**

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:

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 Liomiting, darhea, constription, inappetence, melena, hennatemesis, adsorbintestinal ulereration, astrointestinal bleeding, pancreatitis. Hepatic: inappetence, womiting, jaundice, acute hepatic toxicity, hepatic enzyme elevation, abnormal liver function test(s), hyperbillirubinicar mappetence, melenations, adsorbintestinal ulereration, astrointestinal bleeding, pancreatitis. Neurologic: Ataxia, paresis, paralysis, seizures, vestibular signs, discorientation. Uninary: Hematunia, polyuria, polytipsia, urinary incontinence, urinary tract infection, azotemia, acute renal failure, tubular abnormalities including acute tubular necrosis, renal tubular acidosis, glucosuria. Behavlorat: Setation, lethargy, hyperactivity, resilessness, aggressiveness. Hematologic: rinnume-mediated hemolybic anemia, immune-mediated thrombocytopenia, blood loss anemia, epistaxis. Dermatologic: rinnume-mediated hemolybic anemia, immune-mediated thrombocytopenia, blood loss anemia, epistaxis. Dermatologic: rinnume-mediated issistance or to otbian a cory of the satety data sheet (SDS), contact Dechra at (866) 933-2472. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-IETS, or www.fda.gov/reportanimalae DOSAGE ADD ADMINISTRATIONE Alwargs provide Client Information Sheet with prescription. Carefulty usorsider the potential benefits and risk of Carprovet and other treatment options before deciding to use Carprovet. 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 thal daily dose may be administered as 2 mg/lb (4.4 mg/kg) of body weight once daily or thev

Separate placebo-controlled, masked, multicenter field studies confirmed the effectiveness of carprofen caplets for the control of postoperative pain when dosed at 2 mg/h one daily in various breeds of dogs. In these studies, dogs presented for varion/stysterectomy, cruciale 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 unansethetized 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 deverse 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 valuation. Over the 6-week treatment period, black or bloody stoois 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 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 and in 1 dog (2 incidents) treated with 3 mg/lb twice daily.

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Carprovet Chewable Tablets 25 mg, 60 tablets	NDC 17033-352-60
Carprovet Chewable Tablets 25 mg, 180 tablets	NDC 17033-352-18
Carprovet Chewable Tablets 75 mg, 30 tablets	NDC 17033-357-30
Carprovet Chewable Tablets 75 mg, 60 tablets	NDC 17033-357-60
Carprovet Chewable Tablets 75 mg, 180 tablets	NDC 17033-357-18
Carprovet Chewable Tablets 100 mg, 30 tablets	NDC 17033-351-30
Carprovet Chewable Tablets 100 mg, 60 tablets	NDC 17033-351-60
Carprovet Chewable Tablets 100 mg, 180 tablets	NDC 17033-351-18
Approved by FDA under ANADA # 200-490	

REFERENCES

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 ERENCES:
 Bandth H, *et al*: In Anti-Inflammatory and Anti-Rheumatic Drugs, Vol. II, Newer Anti-Inflammatory Drugs, Rainsford KD, ed. CRC Press, Booa Hadron, p. 33, 1986.
 Vane JA, Botting FM. Mechanism of action of anti-inflammatory drugs. Scand J Rheumatol 25: 102, pp. 9-21.
 Grossman CJ, Wiseman J, Lucas FS, *et al*: Inhibition of constitutive and inducible cyclooxygenase activity in human pletelets and mononuclear cells by NASUs and COX-2 inhibitors. Inflammation Research 44:253-257, 1995.
 Ricketts AP, Lundy KM, Seibel SE. Evaluation of selective inhibition of canine cyclooxygenase 1 and 2 by carprofen and other nonsteroidal anti-inflammatory drugs. An J Vef Res 59:11, pp. 1441-1448, November 1998.
 Ceuppens JL, *et al*: Honosenous prostaglandin E2 enhances polyclonal immunoglobulin production by ionically inhibiting T suppressor cell activity. *Cell Immunol* 70:41, 1982.
 Schleimer RP, *et al*: The effects of topotslagandin synthesis inhibition on the immune response. *Immunopharmacology* 3:205, 1981.
 Leung KH, *et al*: The effects of topotslagandin synthesis inhibition on the immune response. *Immunopharmacology* 3:205, 1981.
 Leung KH, *et al*: The effects of topotslagandin synthesis inhibition on the immune response. *Immunopharmacology* 3:205, 1981.
 Leung KH, *et al*: Holycenson prostaglandin Synthesis inhibition on the immune response. *Immunopharmacology* 3:205, 1981.
 Leung KH, *et al*: Biopharmaceutical evaluation of carproferi following single Intravenous, oral, and rectal doses in dogs. Biopharm Drug Digos 11 (7):556, 1990.
 Kore AM: Toxicology of nonsteroidal anti-inflammatory drugs. Veterinary Clinics of North America, Small Aminal Practice 20, March 1990.
 Binns SH: Pathoreoida anti-inflammatory drugs. Veterinary Clinics of North America, Small Aminal Practice 20, March 1990.
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For a copy of the Safety Data Sheet (SDS) call (866) 933-2472. To report adverse reactions call Dechra at (866) 933-2472. Manufactured for Dechra Veterinary Products, 7015 College Boulevard, Suite 525, Overland Park, KS 66211 USA Rev. September 2019

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Carprovet[®]

(carprofen) Chewable Tablets For Osteoarthritis and Post-Surgical Pain Generic name: carprofen ("car-pro-fen")

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

What is Carprovet?

Carprovet is a non-steroidal anti-inflammatory drug (NSAID) that is used to reduce pain and inflammation (soreness) due to osteoarthritis and pain following surgery in dogs. Carprovet is 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 Carprovet 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 Carprovet?

While Carprovet is 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 Carprovet is discontinued or not given as directed, your dog's pain and inflammation may come back.

Who should not take Carprovet?

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

- Has had an allergic reaction to carprofen, the active ingredient of Carprovet.
- 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.

Carprovet should be given to dogs only.

Cats should not be given Carprovet. Call your veterinarian immediately if your cat receives Carprovet.

People should not take Carprovet. Keep Carprovet and all medicines out of reach of children. Call your physician immediately if you accidentally take Carprovet.

How to give Carprovet to your dog.

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

What to tell/ask your veterinarian before giving Carprovet.

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 Carprovet is prescribed.
- How often your dog may need to be examined by your veterinarian.
 The right and basefits of using Corpervat.
- The risks and benefits of using Carprovet.

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

- Experienced side effects from Carprovet or other NSAIDs, such as aspirin
- Digestive upset (vomiting and/or diarrhea)
- Liver diseaseKidney 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 Carprovet therapy?

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

Can Carprovet be given with other medicines?

Carprovet 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 Carprovet. 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 Carprovet?

Contact your veterinarian immediately if your dog eats more than the prescribed amount of Carprovet.

How to store Carprovet.

Keep Carprovet 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 Carprovet chewable tablets, contact your veterinarian right away.

What else should I know about Carprovet?

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

As with all prescribed medicines, Carprovet 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 Carprovet at regular check ups. Your veterinarian will best determine if your dog is responding as expected and if your dog should continue receiving Carprovet.

To report a suspected adverse reaction call Dechra at (866) 933-2472.

Manufactured for: Dechra Veterinary Products

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