

Caplets/Chewable Tablets For oral use in dogs only Sterile Injectable Solution 50 mg/mL For subcutaneous use in dogs only Non-steroidal, anti-inflammatory drug

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

DESCRIPTION: Rimadyl (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-oz-methyl-9H-carbazole-2-acetic acid. The empirical formula is C₁₅H₁₂ClNO₂ and the molecular weight 273.72. The chemical structure of carprofen is shown above. Carprofen is a white, crystalline compound, it is freely soluble in ethanol, but practically insoluble in water at 25°C.

Kilmadyl Injectable is a sterile solution containing carprofen. Each mL of Rimadyl Injectable contains 50.0 mg carprofen, 30.0 mg arginine, 88.5 mg glycocholic acid, 169.0 mg lecthin, 10.0 mg benzyl alcohol, 6.17 mg sodium hydroxide, with additional sodium hydroxide and hydrochloric acid as needed to adjust pH, and water for injection.

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

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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. The constitutive cyclooxygenase, COX-1, synthesizes prostaglandins necessary for normal gastrointestinal and renal function. The inducible cyclooxygenases, 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 activity. The specificity of a particular NSAID for COX-2 versus COX-1 may vary from species to species. In an *in vitro* study using canni ecell cultures, carprofen demonstrated selective inhibition of COX-2 versus COX-1. *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 cells system) inflammatory reactions.

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

Based upon comparison with data obtained from intravenous administration, carprofen is approximately 8 hours (range 4.5–8.8 hours) after oral administration of 1, 5, and 25 mg/kg of body weight. After a 100 mg single intravenous bolus dose, the mean elimination half-life of carprofen is approximately 8 hours (range 4.5–8.8 hours) after oral administration of 1, 5, and 25 mg/kg of body weight. After a 100 mg single intravenous bolus dose, the mean elimination half-life over a mean elimination of 1, 5, and 25 mg/kg of body weight. After a 100 mg single intravenous bol

Comparison of a single 25 mg dose in Beagle dogs after subcutaneous and oral administration demonstrated that the dorsoscapular subcutaneous administration results in a slower rate of drug input (as reflected by mean peak observed concentrations) but comparable total drug absorption within a 12 hour dosing interval (as reflected by area under the curve from hours zero to 12 postdose).

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 unine (10–20%). Some enterohepatic circulation of the drug is observed.

INDICATIONS: Rimady is 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: Rimadyl 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 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. **L** 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 diseases in patients with underlying or pre-existing disease more often than in healthy patients. **L** 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. **The use of parenteral fluids during surgery should be considered to reduce the potential risk of renal complications when using NSAIDs perioperatively.

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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 durretic 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 Rimadyl with other anti-inflammatory drugs, such as other NSAIDs or corticosteroids, should be avoided because of the potential increase of adverse reactions, including asstrointestinal ulcerations and/or perforations. Sensitivity to frug-associatelys, with appropriate monitoring. Concomitant use of Rimadyl and the neal toxicity or gastrointestinal ulceration in well-controlled safety studies of up to Insert the studies of the controlled safety studies of up to Insert the device of the studies of the properties of the studies of the studie

Due to the palatable nature of Rimadyl chewable tablets, store out of reach of dogs in a secured location. Severe adverse reactions may occur if large quantities of tablets are ingested. If you suspect your dog has consumed Rimadyl chewable tablets above the labeled dose, please call your veterinarian for immediate assistance and notify Pfizer Animal Health (1-800-366-5288).

WFORMATION FOR DOG OWNERS:

Rimadyl, 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, diarrhea, dark or tarry stools, increased wrater 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 Rimadyl 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 dops 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: owniting (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	Rimadyl (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 nathology parameters listed represent reports of increases from pre-treatment values; medical judgement 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*	Rimadyl (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

There were no serious adverse events reported during clinical field studies for the injectable formulation. 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 Studies with the Injectable

Observation*	Rimadyl (n=168)	Placebo (n=163)
Vomiting	10.1	9.2
Diarrhea/soft stool	2.4	3.7
Dermatitis	0.6	1.2
Dysrhythmia	0.6	0.6
Swelling	0	1.2
Dehiscence	1.2	0
WBC increase	13.7	6.7

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

Post-Approval Experience:

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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 by body system.
Gastrointestinal: Vomiting, diarrhea, constipation, inappetence, melena, hematemesis, gastrointestinal ulceration, gastrointestinal bleeding, pancreatitis. Hepatic: happetence, vomiting, jaundice, acute hepatic toxicity, hepatic enzyme elevation, abnormal liver function testfs), hyperbilirubinemia, bilirubinuria, hypoalbuminemia. Approximately one-fourth of hepatic reports were in Labrador Retrievers.
Neurologic: Ataxia, paresis, paralysis, seziurae, vestbiluar signa, disorientation.
Urinary: Hematuria, polyuria, polydipsia, urinary incontinence, urinary tract infection, azotemia, acute renal failure, tubular abnormalities including acute tubular nearoissis, renal tubular acidosis, glucosuria.
Behavioral: Sedation, lethargy, hyperactivity, restlessness, aggressiveness.
Hematologic: Inmune-mediated hemolytic anemia, immune-mediated thrombocytopenia, blood loss anemia, epistaxis.
Dermatologic: Puritus, increased sheddina, alopecia, pyrotraumatic moist dermatitis (hot spots), necrotizing panniculitis/vasculitis, ventral ecchymosis. In rare situations, injection site reactions including necrosis, abscess and seroma formation, and granulomas have been reported with the injectable formulation.

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injectable formulation.
Immunologic or hypersensitivity: Facial swelling, hives, erythema.
In rare situations, death has been associated with some of the adverse reactions listed above.
To report a suspected adverse reaction call 1-800-366-5288.

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DOSAGE AND ADMINISTRATION: Always provide Client Information Sheet with prescription. Carefully consider the potential benefits and risk of Rimadyl and other treatment options before deciding to use Rimadyl. 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 (1.2 mg/kg) through cally. For the control of postoperative pain, administer approximately 2 hours before the procedure. Rimadyl 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 no both sides of the score. Rimadyl tablets are palatable and willingly consumed by most dogs when offered by the owner. Therefore, they may be fed by hand or placed on food. Care should be taken to ensure that the dog consumes the complete dose.

The recommended dosage for subcutaneous administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight daily. The total daily dose may be administered as either 2 mg/lb of body weight once daily or divided and administered as 1 mg/lb (2.2 mg/kg) twice daily. For control of postoperative pain, administer approximately 2 hours before the procedure.

PALATABILITY: A controlled palatability study was conducted which demonstrated that Rimadyl chewable tablets were readily accepted and consumed on first offering by a majority of dogs.

EFFECTIVENESS: Confirmation of the effectiveness of Rimadyl 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 7 placebo-controlled, masked studies examining the anti-inflammatory and analgesic effectiveness of Rimadyl caplets in various breeds of dogs.

Separate placebo-controlled, masked, multicenter field studies confirmed the anti-inflammatory and analgesic effectiveness of Rimadyl 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 Rimadyl at labeled doses.

Based upon the blood level comparison between subcutaneous and oral administration, Rimadyl effectiveness for osteoarthritis after dorsoscapular subcutaneous and oral administration should be similar, although there may be a slight delay in the onset of relief after the control of the contr

Separate placebo-controlled, masked, multicenter field studies confirmed the effectiveness of Rimadyl 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 Rimadyl preoperatively and for a maximum of 3 days (soft issue) or 4 days (orthopedic) postoperatively. In general, dogs administered Rimadyl showed statistically significant reduction in pain socres compared to controls.

ANIMAL SAFETY STUDIES: Laboratory studies in unanesthetized dogs and clinical field studies have demonstrated that Rimadyl is wel tolerated in dogs after oral administration.

In target animal safety studies, Rimadyl 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 1.2 g/d. after 2 veeks of treatment, returned to the pre-treatment value (2.6 g/d.14 veeks of treatment, and was 2.3 g/d.l 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 two u o ough reteving in night or any twice vary to unless the recommendent dual vary observin in varys extinuted inpolarionimental. The intermediate displacement of the dogs receiving this dose was lower (2.38 g/d) than each of 2 placebo compto groups (2.88 and 2.39 g/d), 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 exam of these areas revenue of these areas revenue of the seminal propria in 2 of the semination of the lamina propria in 2 of the

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.

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Clinical field studies were conducted with \$49 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 Rimadyl-treated animals (spacebo contained inactive ingredients from la Rimadyl). For animals receiving 1 mg/lb wice daily, the mean post-treatment serum ALT values were 11 IU greater and 9 IU less than pre-treatment values for dogs receiving Rimadyl and placebo, respectively. Differences were not statistically significant. For animals receiving 2 mg/lb once daily, the mean post-treatment serum ALT values were 10 IU greater and 0.9 IU less than pre-treatment serum ALT values were 10 IU greater and 0.9 IU less than pre-treatment serum ALT values were 10 IU greater and 0.9 IU less than pre-treatment serum (a ALT values were 10 IU greater and 0.9 IU less than pre-treatment serum (a ALT values were 10 IU greater and 0.9 IU less than pre-treatment serum (a ALT values were 10 IU greater and 0.9 IU less than pre-treatment serum (a ALT values were 10 IU greater and 0.9 IU less than pre-treatment serum (a ALT values were 10 IU greater and 0.9 IU less than pre-treatment serum (a ALT values were 10 IU greater and 0.9 IU less than pre-treatment values for dogs receiving Rimadyl and placebo. respectively. In the latter study, 3 Rimadyl-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 l dogs, some for as long as 5 years.

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Clinical field studies were conducted in 297 dogs of different breeds undergoing orthopedic or soft-tissue surgery. Dogs were administered 2 mg/lb of Rimadyl 2 hours prior to surgery then once daily, as needed for 2 days (soft tissue surgery) or 3 days (orthopedic surgery). Rimadyl was well tolerated when used in conjunction with a variety of anesthetic-related drugs. The type and severity of abnormal health observation in Rimadyl-and placebo-treated animals were approximately equal and few in number (see Adverse Reactions). The most freuent abnormal health observation was vomiting and was observed at approximately the same frequency in Rimadyl- and placebo-treated animals. Changes in clinicopathologic indices of hematopoetic, 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 Rimadyl and placebo, respectively. The mean post-treatment AST values were 3.1 IU less for dogs receiving Rimadyl and 0.2 IU greater for dogs receiving placebo.

dogs receiving Rimadyl and 0.2 IU greater for dogs receiving placebo.

Clinical field studies on the use of Rimadyl Injectable were conducted on 331 dogs undergoing orthopedic or soft tissue surgery. Dogs were administered 2 mg/lb of Rimadyl subcutaneously? hours prior to surgery and once daily thereafter, as needed, for 2 days (soft tissue surgery) or 3 days (orthopedic surgery). Rimadyl was well tolerated when used in conjunction with a variety of anesthetic-related drugs. The type and severity of ahornal health observations in Rimadyl- 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 Rimadyl- and placebo-treated animals. Changes in clinicopathologic indices of hematopoetic, renal, hepatic, and clotting function were not clinically significant. The mean post-treatment serum ALT values were 8.4 IU and 7.0 IU less than pre-treatment values for dogs receiving Rimadyl and placebo, respectively. The mean post-treatment AST values were 1.5 IU and 0.7 IU greater for dogs receiving Rimadyl and placebo, respectively. The mean post-treatment AST values were serviced and pre-present the properties of t

STORAGE: Store tablets at controlled room temperature 15°-30°C (59°-86°F). Store injectable under refrigeration 2°-8°C (36°-46°F). Once broached, product may be stored at temperatures up to 25°C (77°F) for 28 days.

HOW SUPPLIED: Rimadyl caplets and chewable tablets are scored, and contain 25 mg, 75 mg, or 100 mg of carprofen per caplet or tablet. Each caplet size is packaged in bottles containing 30, 60, or 180 caplets, or blister paks containing 4 caplets. Each chewable tablets size is packaged in bottles containing 7, 30, 60, or 180 tablets. Rimadyl Injectable is supplied in 20-mL, amber, glass, sterile, multi-dose vials.

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For a copy of the Material Safety Data Sheet (MSDS) call 1-800-733-5500. To report adverse reactions call Pfizer Animal Health at 1-800-366-5288. NADA #141-053, NADA #141-111, NADA #141-199 Approved by FDA.

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