

AUG 21 2002

FREEDOM OF INFORMATION SUMMARY

Supplemental NADA

141-111

Rimadyl® Chewable Tablets
(carprofen)

An additional claim for chewable tablet: "for the control of postoperative pain associated with soft tissue and orthopedic surgery in dogs"

PFIZER, INC.
235 East 42nd Street
New York, NY 10017

141-111

FOIS-1

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FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

NADA Number: 141-111

Sponsor: Pfizer Inc
235 East 42nd St.
New York, NY 10017

Established Name: carprofen

Proprietary Name: Rimadyl[®] Chewable Tablets

Dosage Form: Oral tablets

How Supplied: Scored chewable tablets are packaged in bottles containing 14, 60, or 180 tablets.

How Dispensed: Rx - U.S. Federal Law restricts this drug to use by or on the order of a licensed veterinarian.

Amount of Active Ingredient: Each tablet contains 25 mg, 75 mg, or 100 mg of carprofen per tablet.

Route of Administration: Oral

Species/Class: Dogs/Canine

Recommended Dosage: The recommended dosage for oral administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight daily. The total dose may be administered as 2 mg/lb of body weight once 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-caplet increments. Tablets can be halved by placing the tablet on a hard surface and pressing down on both sides of the score. Rimadyl[®] Chewable Tablets are palatable and willingly consumed by most dogs. Tablets may be fed free choice or placed on food. Care should be taken to ensure that the dog consumes the complete dose.

Pharmaceutical Category: Non-steroidal anti-inflammatory drug

Indications: Rimadyl[®] 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 surgery in dogs.

Effect of Supplement: The supplement to NADA 141-111 provides revisions to 21CFR 520.309 *Indications for Use*. The supplement provides for an additional claim for carprofen chewable tablets for the control of postoperative pain associated with soft tissue and orthopedic surgery in dogs.

II. EFFECTIVENESS

A. Dosage Characterization:

Effectiveness of the dosage of 1 mg/lb body (2.2 mg/kg) weight twice daily for the relief of pain associated with osteoarthritis was established in the original approval of Rimadyl® Chewable Tablets for dogs (NADA 141-111), dated May 14, 1999. Effectiveness of the 2 mg/lb (4.4 mg/kg) body weight once daily dosage for the relief of pain associated with osteoarthritis was established by a supplement to NADA 141-111, dated November 26, 2001. Effectiveness of Rimadyl® Caplets (NADA 141-053) at a dosage of 2 mg/lb (4.4 mg/kg) body weight once daily for the control of pain associated with soft tissue and orthopedic surgery in dogs was demonstrated by a supplement dated, July 8, 2002. Based on the comparable bioavailability between caplet and chewable tablet (see NADA 141-111 FOI Summary, dated May 14, 1999), Rimadyl® Chewable Tablets administered at a dosage of 2 mg/lb (4.4 mg/kg) body weight once daily are safe and effective for the control of pain associated with soft tissue and orthopedic surgery in dogs.

B. Substantial Evidence:

No new substantial evidence was required for this approval.

III. TARGET ANIMAL SAFETY

Studies demonstrating the safety of Rimadyl® for use in dogs are contained in the original FOI Summary dated October 25, 1996. No new animal safety data were required for approval of this supplement.

IV. HUMAN SAFETY

This drug is intended for use in dogs, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: "Not for human use. Keep this and all drugs out of the reach of children. Consult a physician in case of accidental ingestion by humans."

V. AGENCY CONCLUSIONS

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing

regulations. The data demonstrates that Rimadyl[®] Chewable Tablets for dogs, when administered under labeled conditions of use, are safe and effective for the intended use.

The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise is needed to diagnose and provide guidance in the control of postoperative pain. Furthermore, the veterinarian monitors patients for possible adverse effects of the drug.

Under Section 512(c)(2)(F)(iii) of the FFDCFA, this approval for non-food producing animals does not qualify for marketing exclusivity because the supplemental application does not contain substantial evidence of the effectiveness of the drug involved, or any studies of animal safety, required for the approval of the application and conducted or sponsored by the applicant.

| <u>U.S. Patent Number</u> | <u>Date of Expiration</u> |
|---------------------------|---------------------------|
| US 4,264,500 | February 28, 2003 |
| US 6,013,808 | April 15, 2019 |

VI. ATTACHMENTS

Facsimile Labeling is attached as indicated below:

Package Insert

Patient Package Insert

Bottle

RIMADYL®

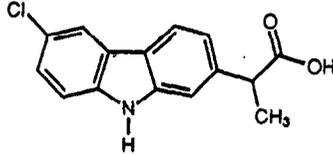
(carprofen)

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: 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- α -methyl-9H-carbazole-2-carboxylic acid. The empirical formula is $C_{15}H_{11}ClNO_2$ 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. 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.² 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.³⁻⁵ 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 4.5-9.2 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. Rimadyl 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 other 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: Rimadyl 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.

DOSEAGE AND ADMINISTRATION: Always provide Client Information Sheet with prescription. 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. Rimadyl 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. Rimadyl chewable 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.

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 5 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.

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, uterine repair and several other procedures were administered Rimadyl preoperatively and for a maximum of 3 days (soft tissue) or 4 days (orthopedic) postoperatively. In general, dogs administered Rimadyl showed statistically significant reduction in pain scores compared to controls.

ANIMAL SAFETY STUDIES: Laboratory studies in unanesthetized dogs and clinical field studies have demonstrated that Rimadyl is well 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

such as corticosteroids and NSAIDs, should be avoided or very closely monitored. Sensitivity to drug-associated adverse reactions varies with the individual patient. For example, Rimadyl treatment was not associated with renal (toxicity or gastrointestinal ulceration) in well-controlled safety studies of up to ten times the dose in dogs.

Rimadyl 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 Rimadyl in pregnant dogs, dogs used for breeding purposes, or in lactating bitches has not been established. Studies to determine the activity of Rimadyl 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.¹¹

If additional pain medication is warranted after administration of the total daily dose of Rimadyl, alternative analgesia should be considered. The use of another NSAID is not recommended.

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).

INFORMATION 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 water consumption, increased urination, pale gums due to anemia, yellowing of gums, skin or white of the eye due to jaundice, lethargy, incoordination, seizures, 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 dogs during administration of any NSAID.

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 and Adverse Reactions).

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 | 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 |
| PUP/D | 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 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=148) |
| 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 tests, hyperbilirubinemia, bilirubinuria, hypoalbuminemia. Approximately one-fourth of hepatic

- Experienced side effects from Rimadyl 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)
- If 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.



Report a suspected adverse reaction call Pfizer Animal Health

Each scored tablet contains 25 mg of carprofen.

Indications: Rimadyl is indicated for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with orthopedic and orthodontic surgery.

Caution: Always provide Client instructions about proper dosing. The maximum dose is 2 mg/kg of body weight daily. The total daily

dose may be administered as 2 mg/kg of body weight daily or divided into two equal doses. The maximum dose is 2 mg/kg of body weight daily. The total daily dose may be administered as 2 mg/kg of body weight daily or divided into two equal doses. The maximum dose is 2 mg/kg of body weight daily. The total daily dose may be administered as 2 mg/kg of body weight daily or divided into two equal doses.



Manufactured by:
Pfizer Inc.
New York, NY 10017

RIMADYL®
(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.

25 mg
14 tablets - For trial use only. Not for sale.
NADA #141-111, Approved by FDA

When Low Dose out of stock of the drug, the maximum dose is 2 mg/kg of body weight daily. The total daily dose may be administered as 2 mg/kg of body weight daily or divided into two equal doses. The maximum dose is 2 mg/kg of body weight daily. The total daily dose may be administered as 2 mg/kg of body weight daily or divided into two equal doses.

Warnings and Precautions: Due to the potential for adverse effects, Rimadyl should be used with caution in dogs with renal or hepatic impairment. Rimadyl should be used with caution in dogs with renal or hepatic impairment. Rimadyl should be used with caution in dogs with renal or hepatic impairment.



Made in USA
025 B5-540-XZ

FPO: UPC
87219 04506

Each scored tablet contains 25 mg of carprofen. **Caution:** Rimadyl is indicated for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with joint trauma and orthopedic surgery in dogs. **Warnings:** Avoid use in dogs with known hypersensitivity to the active ingredient. **Precautions:** Avoid use in dogs with known hypersensitivity to the active ingredient. **Contraindications:** Avoid use in dogs with known hypersensitivity to the active ingredient. **Adverse Reactions:** See information on the label. **How to Use:** See information on the label. **Storage:** Store at controlled room temperature 15°-30°C (59°-86°F). **Keep out of reach of children.** **Keep out of reach of dogs and in a secured area.** **Severe adverse reactions may be expected if large quantities of tablets are ingested.** **If you suspect your dog has consumed Rimadyl chewable tablets, contact your veterinarian immediately for assistance and call 1-800-368-5788 for immediate assistance.** **Store at controlled room temperature 15°-30°C (59°-86°F).**

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

25 mg

180 tablets

NADA #141-111, Approved by FDA

RIMADYL®

(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.

25 mg

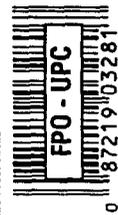
180 tablets

NADA #141-111, Approved by FDA



Precautions: Due to the palatable nature of Rimadyl chewable tablets, store out of reach of dogs and in a secured area. Severe adverse reactions may be expected if large quantities of tablets are ingested. If you suspect your dog has consumed Rimadyl chewable tablets, contact your veterinarian immediately for assistance and call 1-800-368-5788 for immediate assistance. **Store at controlled room temperature 15°-30°C (59°-86°F).**

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.**



Made in USA
025 85-8602-35

Warnings: Due to the palatable nature of Rimadyl chewable tablets, store out of reach of dogs and in a secured area. Severe adverse reactions may be expected if large quantities of tablets are ingested. If you suspect your dog has consumed Rimadyl chewable tablets beyond the labeled dose, please call your veterinarian and call 1-800-366-5788 for immediate assistance. Store at controlled room temperature 15°-30°C (59°-85°F).

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

75 mg

60 tablets

NADA #141-111, Approved by FDA

Animal Health

87219 03283

0

1

FPO:UPC

05 85-800-30

MADE IN USA

THE PUPPY

WARRANTY

MADE IN USA

05 85-800-30

Warnings: Due to the palatable nature of Rimadyl chewable tablets, store out of reach of dogs and in a secured area. Severe adverse reactions may be expected if large quantities of tablets are ingested. If you suspect your dog has consumed Rimadyl chewable tablets beyond the labeled dose, please call your veterinarian and call 1-800-366-5788 for immediate assistance. Store at controlled room temperature 15°-30°C (59°-85°F).

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

75 mg

60 tablets

NADA #141-111, Approved by FDA

Animal Health

87219 03283

0

1

FPO:UPC

05 85-800-30

MADE IN USA

THE PUPPY

WARRANTY

MADE IN USA

05 85-800-30

RIMADYL®
(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.

75 mg

60 tablets

NADA #141-111, Approved by FDA

Animal Health

87219 03283

0

1

FPO:UPC

05 85-800-30

MADE IN USA

THE PUPPY

WARRANTY

MADE IN USA

05 85-800-30

MADE IN USA



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



Made in USA
05 85-800-30

Animal Health
Kalamazoo, MI, USA
11001 AN 'AN' USA



Each chewable tablet contains 75 mg of carprofen. The recommended dosage for dogs is 2 mg/kg (0.9 mg/lb) of body weight. Always provide Client information Sheet with prescription. The recommended dosage is listed on the Client Information Sheet with prescription. Always provide Client information Sheet with prescription. The recommended dosage is listed on the Client Information Sheet with prescription.

Always provide Client information Sheet with prescription. The recommended dosage is listed on the Client Information Sheet with prescription. Always provide Client information Sheet with prescription. The recommended dosage is listed on the Client Information Sheet with prescription.

RIMADYL®

(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.

75 mg

180 tablets

NADA #141-111, Approved by FDA



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 palatable nature of Rimadyl chewable tablets, store out of reach of dogs

and in a secured area. Severe adverse reactions may be expected if large quantities of tablets are ingested. If you suspect your dog has consumed Rimadyl chewable tablets beyond the labeled dose, please call your veterinarian and call 1-800-366-5288 for immediate assistance.

Store at controlled room temperature 15°-30°C (59°-86°F).



Made in USA
025 85-8504-X5

Each chewable tablet contains 100 mg of carprofen. Formed in indentation for the relief of pain and inflammation associated with osteoarthritis and for the relief of pain and inflammation associated with soft tissue and orthopedic procedures in dogs. The recommended dosage for oral administration is 2 mg/kg (0.9 mg/lb) every 12 hours for 3 to 5 days.

Keep out of reach of children and other animals. Store at controlled room temperature (20°-25°C, 68°-77°F). Do not use if the seal is broken or if the tablets are discolored. Contains 14 tablets in a blister pack. NADA #141-111, Approved by FDA.  Animal Health, Kenilworth, NJ 07033. © 1997

RIMADYL®

(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.

100 mg

14 tablets - For trial use only. Not for sale.

NADA #141-111, Approved by FDA

Warning: Keep out of reach of children. Not for human use. Consult a veterinarian for use in dogs. Do not use in cats. Please refer to insert for complete Warnings and Precautions. 

Store at controlled room temperature (20°-25°C, 68°-77°F).  Made in USA. 025 85-5453-02



