

Approval Date: NOV 25 2008

FREEDOM OF INFORMATION SUMMARY

**ORIGINAL ABBREVIATED NEW ANIMAL
DRUG APPLICATION**

ANADA 200-498

**NOROCARP Caplets
(carprofen)
Caplets**

**Indicated for relief of pain and inflammation associated with
osteoarthritis and for the control of postoperative pain
associated with soft tissue and orthopedic surgeries in dogs**

Sponsored by:

Norbrook Laboratories, Ltd.

FDA-2009-N-0665

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FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-498
- b. Sponsor: Norbrook Laboratories, Ltd.
Station Works
Newry BT35 6JP
Northern Ireland
- Drug Labeler Code: 055529
- U.S. Agent: Bill Zollers, Ph.D
Norbrook, Inc.
9733 Loiret Boulevard
Lenexa, KS 66219
- c. Established Name: Carprofen
- d. Proprietary Name: NOROCARP Caplets
- e. Dosage Form: Caplets
- f. How Supplied: 25 mg caplets in bottles of 30, 60 and 180 caplets
75 mg caplets in bottles of 30, 60 and 180 caplets
100 mg caplets in bottles of 30, 60 and 180 caplets
- g. How Dispensed: Rx
- h. Amount of Active Ingredients: 25 mg, 75 mg, and 100 mg
- i. Route of Administration: Oral
- j. Species/Class: Dogs
- k. Recommended Dosage: 2 mg/lb (4.4 mg/kg) of body weight. The total daily 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. Caplets are scored and dosage should be calculated in half-caplet increments.
- l. Pharmacological Category: Non-steroidal, anti-inflammatory drug (NSAID)

- m. Indications: NOROCARP Caplets 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.
- n. Pioneer Product: RIMADYL Caplets; carprofen; NADA 141-053; Pfizer, Inc.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

A. Blood-level Bioequivalence Study

One blood-level bioequivalence study was conducted to determine the comparative bioavailability of the generic caplet formulation and pioneer caplet formulation of carprofen.

Testing Facility: Norbrook Laboratories Limited,
Research Division
105, Armagh Road
Newry,
Co. Down,
Northern Ireland, BT35 6PU

Objective: The objective of this study was to determine the comparative blood-levels of Norbrook Laboratories Limited's 25 mg carprofen caplet (generic) and Pfizer Animal Health's 25 mg RIMADYL caplet (reference) in a two period crossover study in dogs.

Summary: The design of this study is a comparative bioavailability study using healthy adult dogs in a single-dose, two-period, two sequence, crossover design with randomization of experimental units to two sequences. Fourteen dogs (7 males and 7 females) were blocked by weight without regard to sex and, within block, randomly assigned to either of two treatment sequences where the treatment sequences were reference followed by generic or vice versa. A 35-day washout interval separated the two periods. Blood samples were collected at approximately 17 hours before dose administration, and at 0.25, 0.5, 0.75, 1.0, 1.33, 1.66, 2.0, 3.0, 4.0, 6.0, 8.0, 12.0, 18.0, 24.0, 48.0 and 72.0 hours following dose administration for the measurement of carprofen in plasma.

Results: The area under the curve was compared using the trapezoidal rule from time 0 out to the last sampling time associated with quantifiable drug concentrations (AUC). The natural logarithm of AUC was computed and used as the variable for analysis. The maximum concentration measured for all time periods (C_{MAX}) was determined and the natural logarithm of C_{MAX} was computed and used as the variable for analysis.

The criteria for determining bioequivalence, as described in CVM's Bioequivalence Guidance is to construct a 90% confidence interval about the difference of the two means, generic minus pioneer, based on the log scale of AUC and C_{MAX} and then take the anti-log of the confidence limits multiplied by 100. The resulting bounds should be between 80.00% and 125.00%. As seen in the table below both AUC and C_{MAX} fall within those bounds.

Variable	Norbrook Mean	Pfizer Mean	Lower Bound	Upper Bound
AUC ($\mu\text{g/mL}\cdot\text{hr}$)	403.2*	375.7*	100.38%	114.74%
C_{MAX} ($\mu\text{g/mL}$)	37.7*	37.1*	86.34%	119.85%
T_{MAX} (hr)	3.43 [†]	2.62 [†]	NA	NA

* Geometric Mean

[†] Arithmetic Mean

The variable time to maximum concentration (T_{MAX}) is permitted to be interpreted by clinical judgment. In this case, there is no reason to expect the difference in T_{MAX} will affect the efficacy of the drug, since both AUC and C_{MAX} are bioequivalent and the product is administered as a single dose. Therefore, the study objective to determine the bioequivalence of the generic and pioneer carprofen caplets was achieved.

B. Dissolution Study

Objective: *In vitro* dissolution data were submitted in support of a request for waiver of *in vivo* bioequivalence study requirements for the 75 mg and 100 mg strength caplets.

Testing Facility: Norbrook Laboratories Limited,
Research Division
105, Armagh Road
Newry,
Co. Down,
Northern Ireland, BT35 6PU

Study Design: Twelve tablets of each product strength were examined using USP 26, dissolution apparatus 2 (paddle) at 50 rpm. The dissolution medium was USP simulated intestinal fluids without enzyme, pH 7.5. This is the same method that has been used for quality control purposes for RIMADYL caplets. Samples were taken at 5, 10, 15, 20, and 30 minutes of testing and the carprofen concentrations were determined by HPLC with UV

detection. The percent drug released from each strength and for each formulation was calculated at each time point.

Similarity of profiles was based upon the model-free approach defined in CDER's 8/97 guidance for industry titled "Dissolution Testing of Immediate Release Dosage Forms". In brief, the similarity factor (f_2) used for confirming comparability is defined as follows:

$$f_2 = 50 * \log \left\{ \left[1 + \frac{1}{n} \sum_{t=1}^n (R_t - T_t)^2 \right]^{-0.5} * 100 \right\}$$

where n = the number of time points, R_t is the mean dissolution value of the reference product at time t , and T_t is the mean dissolution value of the test product at time t . Comparability is defined by f_2 values are equal to or greater than 50.

Results: The relative dissolution profiles for the test and reference products are provided in Figures 1 – 3.

Figure 1: Comparative mean dissolution profiles: 25 mg caplet

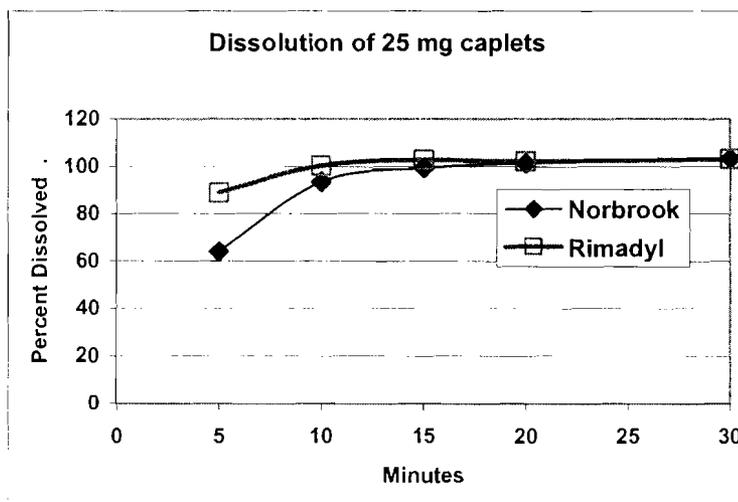


Figure 2: Comparative mean dissolution profiles: 75 mg caplet

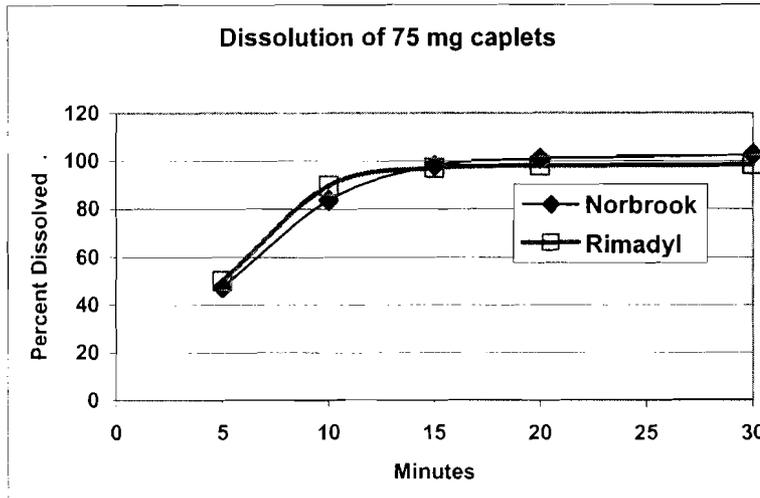
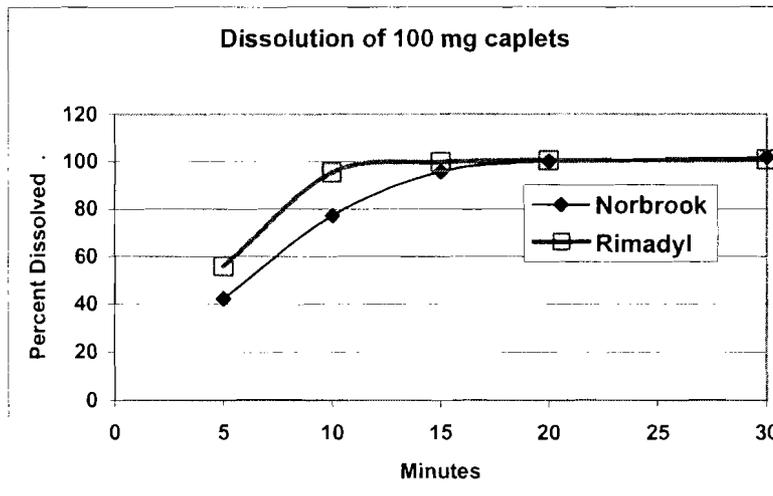


Figure 3: Comparative mean dissolution profiles: 100 mg caplet



Conclusions: As seen in these figures, although the Norbrook product had a slightly slower initial dissolution rate than Rimadyl, by 15 minutes of testing, both products and all strengths were >90% dissolved. Furthermore, since the 25 mg test and reference products are bioequivalent, we see that the slight initial differences in percent dissolved does not influence product relative bioavailability. Accordingly, we conclude that this difference in the initial *in vitro* dissolution results will not influence product relative bioavailability.

In addition, the formulations of the Norbrook product demonstrated dose proportionality. Consequently, considering these findings along with the determination of product bioequivalence, CVM concludes that Norbrook has submitted the information needed to support the granting of a biowaiver for their 75 mg and 100 mg strength caplets.

3. 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 ANADA.

Human Warnings are provided on the product label as follows:

Keep out of the reach of children.

Not for human use.

Consult a physician in cases of accidental ingestion by humans.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that NOROCARP Caplets, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile Generic Labeling and Currently Approved Pioneer Labeling are attached as indicated below:

Generic Labeling for ANADA 200-498:

Package Insert

Dog Owner Information Sheet

Bottle label and carton for the following:

25 mg caplets in bottles of 30, 60 and 180 caplets

75 mg caplets in bottles of 30, 60 and 180 caplets

100 mg caplets in bottles of 30, 60 and 180 caplets

Pioneer Labeling for NADA 141-053:

Package Insert

Dog Owner Information Sheet

Bottle label for the following:

25 mg caplets in bottles of 30, 60 and 180 caplets

75 mg caplets in bottles of 30, 60 and 180 caplets

100 mg caplets in bottles of 30, 60 and 180 caplets

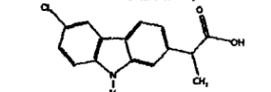
A4 - Width 210 mm x Height 297 mm

NOROCARP® CAPLETS (carprofen)

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 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 carboxylic acid, 6-ethoxy- α -methyl- β -carbazole-2-carboxylic acid. The empirical formula is C₁₇H₁₉NO₃ and the molecular weight is 273.32. 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-steroidal, non-aspirin anti-inflammatory agent with characteristic analgesic and antipyretic activity approximately equivalent 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 different 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 in response to 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 culture, 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 mononuclear synovial cells, indicating inhibition of acute (PMN) and chronic (synovial cell) inflammatory reactions.³

Several studies have demonstrated that carprofen has modulatory effects on both humoral and cellular immune responses.^{4,5} Data also indicate that carprofen inhibits the production of interleukin-1 (IL-1), interleukin-6 (IL-6), and PGE₂ by its inhibitory effects on prostaglandin biosynthesis.⁶

Based upon comparison with data obtained from intravenous administration, carprofen is rapidly and nearly completely absorbed (more than 90% bioavailable) when administered orally.⁷ Peak blood plasma concentrations are achieved in 1-2 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 4.3-8.8 hours) after single oral doses ranging from 1-25 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 90% bound to plasma protein and exhibits a very small volume of distribution.

Carprofen is eliminated in the dog primarily by biotransformation in the liver. The major pathway of the resulting metabolites is the acetylation of carprofen and the other glucuronides of 2 phenolic metabolites, 7-hydroxy-carprofen and 8-hydroxy-carprofen in the liver (70-80%) and the (10-15%). Some of the metabolites of the drug are shown below.

INDICATIONS: Carprofen 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 surgery in dogs.

CONTRAINDICATIONS: Carprofen should not be used in dogs exhibiting previous hypersensitivity to carprofen.

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.^{8,9} 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.^{10,11} 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 azotemia or decompensation of their renal disease while on NSAID therapy.¹²⁻¹⁴ 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. Since NSAIDs possess the potential to induce gastrointestinal ulcerations and/or gastrointestinal perforation, concurrent use of carprofen and other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be avoided. If additional pain medication is needed after

administration of the total daily dose of carprofen, a non-NSAID or non-corticosteroid class of analgesic should be considered. The use of another NSAID is not recommended. Sensitivity to drug-associated adverse reactions varies with the individual patient. Carprofen treatment was not associated with renal toxicity or gastrointestinal ulceration in well-controlled safety studies of up to ten times the dose in dogs.

Norocarp® Caplets 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 Norocarp® Caplets 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 include cardiac, anticonvulsant, and behavioral medications. It has been suggested that treatment with carprofen may reduce the level of inhaled anesthetics needed.¹⁵

If additional pain medication is warranted after administration of the total daily dose of Norocarp® Caplets, additional analgesic should be considered. The use of another NSAID is not recommended. Consider appropriate restraint times when switching from one NSAID to another or when switching from corticosteroid use to NSAID use.

WARNINGS: Keep out of reach of children. Not for human use. Consult a physician in case 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 baseline values should be performed 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, Adverse Safety and Post-Approval Experience).

ADVERSE REACTIONS: In a clinical study comparing Norocarp® Caplets, 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 mucous membranes, and/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 Norocarp® Caplets therapy and contact their veterinarian immediately if signs of intolerance are observed.

The 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 to monitor their dogs closely and to follow up for all dogs during administration of any NSAID.

ADVERSE REACTIONS: During investigational studies of osteoarthritis with twice daily administration of 1 mg/kg, no clinically significant adverse reactions were reported. Some clinical signs were observed during field studies (see Adverse Safety and Post-Approval Experience) and placebo-treated dogs. Incidences of the following were observed in both groups: vomiting (4%), diarrhea (4%), changes in appetite (7%), lethargy (14%), behavior (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 oral administration of 2 mg/kg. 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/kg once daily)

Observation	carprofen (n=128)	Placebo (n=122)
Inappetence	1.6	1.5
Vomiting	3.1	0.8
Diarrhea/Soft stool	3.1	4.5
Behavior change	0.8	0.8
Dermatitis	0.8	0.8
PUPD	0.8	-
SAP increase	5.4	3.3
ALT increase	5.4	4.5
AST increase	2.3	0.8
BUN increase	3.1	1.5
Bilirubinuria	12.3	12.1
Ketonuria	14.7	8.1

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 control 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/kg once daily)

Observation*	carprofen (n=148)	Placebo (n=143)
Vomiting	0.1	12.4
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
Pneumonia	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.

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.

Neurologic: Inappetence, vomiting, jaundice, acute hepatic toxicity, hepatic enzyme elevation, abnormal liver function tests, hyperbilirubinemia, bilirubinuria, hypoproteinemia, 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 infections, azotemia, acute renal failure, tubular abnormalities including acute tubular necrosis, renal tubular acidosis, glomerulonephritis.

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

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

Dermatologic: Pruritis, increased shedding, alopecia, pyodermitis moist dermatitis (hot spots), necrotizing panniculitis, alopecia, ventral oedema, pemphigus 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 1-913-599-5777.

DOSE AND ADMINISTRATION: Always provide Client Information Sheet with prescription. Carefully consider the potential benefits and risks of Carprofen and other treatment options before deciding to use Carprofen. Use the lowest effective dose for the shortest duration consistent with individual response.

The recommended dosage for oral administration to dogs is 2 mg/kg (4 mg/lb) of body weight once daily. The total daily dose may be administered as 2 mg/kg of body weight once daily or divided and administered as 1 mg/kg (2 mg/lb) twice daily. For the control of postoperative pain associated with soft tissue and orthopedic surgeries, dogs should be administered 2 mg/kg (4 mg/lb) of body weight once daily for 3-5 days (soft tissue) or 4-7 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 observations in carprofen- and placebo-treated animals were approximately equal and few abnormal health observations were vomiting and was observed at approximately the same frequency in carprofen- and placebo-treated animals. Changes in clinical pathology indices of hematologic, 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 controlled room temperature 15°-30°C (59°-86°F).

HOW SUPPLIED: Norocarp® Caplets are scored, and contain 25 mg, 75 mg, or 100 mg of carprofen per caplet. Each caplet size is packaged in bottles containing 30, 60, or 180 caplets.

REFERENCES: 1. Baruth H, et al. In: Anti-inflammatory and Analgesic Drugs, Vol. II, Inflammation and Pain, Boca Raton, FL, CRC Press, pp. 33-47, 1986.

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3. Grossman CJ, Wiseman J, Lucas FS, et al. Inhibition of constitutive and inducible cyclooxygenase activity in human platelets and mononuclear cells by NSAIDs and COX-2 inhibitor. *Inflammation Research* 4:253-257, 1995.

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For a copy of the Material Safety Data Sheet (MSDS) or to report adverse reactions call Norbrook, Inc. at 1-913-599-5777.

ANADA xxx-xxx, Approved by FDA

Distributed by: Norbrook, Inc. Lenexa, KS 66219

Observe Label Directions

Norocarp is a registered trademark of Norbrook Laboratories Limited.

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 progressed as non-specific dermatitis. The patchy lesions that were these mild lesions were treatment related, but no dose relationship was observed.

In separate safety studies lasting 13 and 62 weeks, respectively, dogs were administered orally up to 11.4 mg/kg/day (5.7 times the recommended total daily dose of 2 mg/kg) 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 alanine aminotransferase (ALT) of approximately 20 IU.

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different breeds at the recommended oral doses for 14 days (257 dogs were included in a study evaluating 1 mg/kg twice daily and 252 dogs were included in a separate study evaluating 2 mg/kg 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 Norocarp caplets). For animals receiving 1 mg/kg twice daily, the mean post-treatment serum ALT values were 11 IU greater and 0 IU less than pre-treatment values for dogs receiving carprofen and placebo, respectively. Differences were not statistically significant. For animals receiving 2 mg/kg once daily, the mean post-treatment serum ALT values were 4.5 IU greater and 0.3 IU less than pre-treatment values for dogs receiving carprofen and placebo, respectively. In the latter study, a carprofen-treated dog developed a 2-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 the laboratory value changes. Changes in clinical laboratory values (hematology and clinical chemistry) were not considered clinically significant. The 1 mg/kg twice daily course of therapy was repeated as needed at 2-week intervals in 244 dogs, some for as long as 6 years.

Clinical field studies were conducted in 257 dogs of different breeds undergoing orthopedic or soft tissue surgery. Dogs were administered 2 mg/kg of carprofen caplets two hours prior to surgery then once daily, as needed for 3 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 observations in carprofen- and placebo-treated animals were approximately equal and few abnormal health observations were vomiting and was observed at approximately the same frequency in carprofen- and placebo-treated animals. Changes in clinical pathology indices of hematologic, 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 controlled room temperature 15°-30°C (59°-86°F).

HOW SUPPLIED: Norocarp® Caplets are scored, and contain 25 mg, 75 mg, or 100 mg of carprofen per caplet. Each caplet size is packaged in bottles containing 30, 60, or 180 caplets.

REFERENCES: 1. Baruth H, et al. In: Anti-inflammatory and Analgesic Drugs, Vol. II, Inflammation and Pain, Boca Raton, FL, CRC Press, pp. 33-47, 1986.

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For a copy of the Material Safety Data Sheet (MSDS) or to report adverse reactions call Norbrook, Inc. at 1-913-599-5777.

ANADA xxx-xxx, Approved by FDA

Distributed by: Norbrook, Inc. Lenexa, KS 66219

Observe Label Directions

Norocarp is a registered trademark of Norbrook Laboratories Limited.

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 progressed as non-specific dermatitis. The patchy lesions that were these mild lesions were treatment related, but no dose relationship was observed.

In separate safety studies lasting 1

Each scored tablet contains 25 mg of carprofen, a non-steroidal anti-inflammatory drug (NSAID) with analgesic, antipyretic, and anti-inflammatory activity. Carprofen is indicated for the relief of osteoarthritis and for the control of pain and orthopedic surgeries in dogs.

Warnings: Always remove client information from the packaging. Do not use in dogs with known hypersensitivity to NSAIDs or other drugs in this class. Do not use in dogs with severe renal or hepatic dysfunction. Do not use in dogs with known or suspected gastrointestinal ulceration or bleeding. Do not use in dogs with known or suspected cardiovascular disease. Do not use in dogs with known or suspected renal or hepatic disease. Do not use in dogs with known or suspected dehydration. Do not use in dogs with known or suspected hypotension. Do not use in dogs with known or suspected hypovolemia. Do not use in dogs with known or suspected hypoxemia. Do not use in dogs with known or suspected hypothermia. Do not use in dogs with known or suspected hypocalcemia. Do not use in dogs with known or suspected hypomagnesemia. Do not use in dogs with known or suspected hypokalemia. Do not use in dogs with known or suspected hypophosphatemia. Do not use in dogs with known or suspected hypocalcemia. Do not use in dogs with known or suspected hypomagnesemia. Do not use in dogs with known or suspected hypokalemia. Do not use in dogs with known or suspected hypophosphatemia.

NOROCARP CAPLETS

(carprofen)

25 mg

EDUCATION, INC., U.S.A., INC.
188 C. 18. 115

Store at controlled room temperature 15° - 30°C (59° - 86°F).
Manufactured by:
NOROCARP LABORATORIES LIMITED
Newry, Northern Ireland
Distributed by:
LINTAS PHARMACEUTICALS
Limerick, K.S. 56219

Lot No.:
Exp. Date:



Each scored caplet contains 75 mg of naproxen. The active ingredient, naproxen, relieves pain and inflammation associated with osteoarthritis and rheumatoid arthritis, and other chronic musculoskeletal conditions. It does not relieve fever and does not affect the course of the underlying disease. It is not recommended for use in children. Naproxen should be administered as 2 tablets or body weight tablets, twice daily, with meals, for the control of postoperative pain, administration of anesthesia, and relief of pain. Naproxen is a non-steroidal anti-inflammatory drug (NSAID) and, like all NSAIDs, may increase the risk of bleeding, especially in the elderly. Naproxen is a prescription drug. Use only as directed. For complete Warnings and Precautions, see the full prescribing information. See the full prescribing information for complete Warnings and Precautions.

NOROCARP CAPLETS
(naproxen)
75 mg
70 Caplets
FOR ORAL USE IN ERGAS 300 V



Store at controlled room temperature 15 - 30 °C (59 - 86 °F).
Manufactured by:
Norbrook Laboratories Limited,
Newry, Northern Ireland.
Marketed by:
Norbrook Ltd,
Limerick, E.S. 88119

Lot No.
Exp. Date

Each scored caplet contains 75 mg of carprofen, a non-steroidal anti-inflammatory drug (NSAID) with analgesic, antipyretic, and anti-inflammatory properties. It is indicated for the relief of pain and inflammation associated with osteoarthritis and for the control of pain and inflammation associated with soft tissue injuries and osteoarthritis in dogs and cats. It is also indicated for the relief of pain and inflammation associated with soft tissue injuries and osteoarthritis in dogs and cats. It is contraindicated in dogs and cats with a known hypersensitivity to carprofen or any of the excipients. It is also contraindicated in dogs and cats with a history of gastrointestinal ulceration or bleeding, renal insufficiency, or hepatic insufficiency. It should be used with caution in dogs and cats with a history of cardiovascular disease, hypertension, or hypotension. It should be used with caution in dogs and cats with a history of bleeding disorders. It should be used with caution in dogs and cats with a history of renal or hepatic insufficiency. It should be used with caution in dogs and cats with a history of gastrointestinal ulceration or bleeding. It should be used with caution in dogs and cats with a history of cardiovascular disease, hypertension, or hypotension. It should be used with caution in dogs and cats with a history of bleeding disorders. It should be used with caution in dogs and cats with a history of renal or hepatic insufficiency. It should be used with caution in dogs and cats with a history of gastrointestinal ulceration or bleeding.

NOROCARP CAPLETS

(carprofen)

75 mg

60 Caplets

FOR ORAL USE IN DOGS & CATS

Store at controlled room temperature (15°-30° C).
Manufactured by:
Norbrook Laboratories Limited
Newry, Northern Ireland
Manufactured for:
Norbrook, Inc.
Lexington, KY 40503

Lot No.
Exp. Date



Each scored caplet contains 75 mg of carprofen.

Indications: Carprofen 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.

Dosage: Always provide Client Information Sheet with prescription. 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 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. Caplets are scored and dosage should be calculated in half-caplet increments.

NORCARP CAPLETS (carprofen)

75 mg

180 Caplets

FOR ORAL USE IN DOGS ONLY

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

Manufactured By:
Norbrook Laboratories Limited
Newry, Northern Ireland

Distributed By:
Norbrook, Inc.
Lenexa, KS 66215

Lot No.:
Exp. Date:



Each scored caplet contains 100 mg of carprofen.

Indications: Carprofen is indicated for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with orthopedic and orthopedic surgery in dogs.

Dosage: Always provide Client instructions. The recommended dosage for oral administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight daily. The total daily dose should not exceed 2.2 mg/lb of body weight once daily or 11 mg/kg (2.2 mg/lb) twice daily. For the control of postoperative pain, administer the caplet approximately 2 hours before the procedure.

Caplets are scored and dosage should be indicated in half caplet increments.

NOROCARP CAPLETS

(carprofen)

100 mg

60 Caplets

FOR ORAL USE IN DOGS ONLY

Warnings: Keep out of reach of children. Not for human use. Consult a physician in case of accidental ingestion by humans. **For use in dogs only.** Do not use in cats. See package insert for complete Warnings and Precautions.

Store at controlled room temperature

15° - 30° C (59° - 86° F).

Manufactured By:

Norbrook Laboratories Limited

Newry, Northern Ireland

Distributed By:

Norbrook Inc.

Lincoln, NC 28519

Lot No.:

Exp. Date:



Each scored caplet contains 100 mg of carprofen.

Indications: Carprofen 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.

Dosage: Always provide Client Information Sheet with prescription. 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 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. Caplets are scored and dosage should be calculated in half-caplet increments.

NOROCARP CAPLETS (carprofen)

100 mg

FOR ORAL USE IN DOGS ONLY

180 Caplets

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.**

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

Manufactured By:
Norbrook Laboratories Limited
Newry, Northern Ireland

Distributed By:
Norbrook, Inc.
Lenexa, KS 66219

Lot No:

Exp. Date:

 **Norbrook**

Lot No. Exp. Date

30 Caplets

25 mg

NOROCARP CAPLETS
(carprofen)

NOROCARP CAPLETS
(carprofen)

Each scored caplet contains 25 mg of carprofen.

Indications: Carprofen is indicated for the relief of pain and inflammation associated with soft tissue and orthopedic injuries in dogs.

Dosage: Administer 25 mg/kg (1 mg/lb) of carprofen orally once daily for 3-5 days. The recommended dosage for oral administration to dogs is 2 mg/kg (1.4 mg/lb) of body weight daily. The total daily dose may be administered as 2 mg/kg of body weight once daily or divided into 2 mg/kg (1.4 mg/lb) of body weight twice daily. Administer approximately 2 hours before the procedure. Caplets are scored and dosage should be calculated in half-caplet increments.

25 mg

30 Caplets

FOR ORAL USE IN DOGS ONLY

Norbrook

NOROCARP CAPLETS
(carprofen)

Warnings: Keep out of reach of children. Not for human use. Consult a physician in case of accidental Fall in to water only. Do not use in cats. Please refer to insert for complete Warnings and Precautions.

Store at controlled room temperature 15° - 20° C (59° - 68° F).
Manufactured By:
Norbrook Laboratories Limited
Newry, Northern Ireland

25 mg

30 Caplets

FOR ORAL USE IN DOGS ONLY

Norbrook



Lot No. Exp. Date

60 Caplets

25 mg

NOROCARP CAPLETS
(carprofen)

NOROCARP CAPLETS
(carprofen)

Each scored caplet contains 25 mg of carprofen.

Indications: Carprofen is indicated for the relief of pain and inflammation associated with postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

Dosage: Administer 2 mg/kg (0.9 mg/lb) of body weight orally every 12 hours. The recommended dosage for oral administration is 2 mg/kg (0.9 mg/lb) of body weight daily. The total daily dose may be administered as 2 mg/kg of body weight once daily or divided and administered as 1 mg/kg (0.45 mg/lb) twice daily. Carprofen should be administered 2 hours before the procedure. Caplets are scored and dosage should be adjusted in half-caplet increments.

FOR ORAL USE IN DOGS ONLY



NOROCARP CAPLETS
(carprofen)

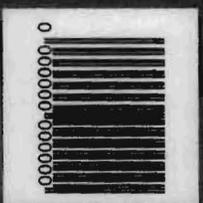
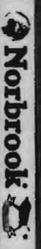
Warnings: Keep out of reach of children. Not for human use. Consult a physician in case of accidental ingestion by human. Do not use in cats, birds, or dogs with Doberman Pinschers and Presqueles.

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

Manufactured By:
Norbrook Laboratories Limited
Newry, Northern Ireland

Distributed By:
Norbrook Laboratories Limited
Lanark, SC 19219

FOR ORAL USE IN DOGS ONLY



25 mg
60 Caplets

25 mg
60 Caplets



180 Caplets

25 mg

NOROCARP CAPLETS
(carprofen)

NOROCARP CAPLETS
(carprofen)

Each steroid caplet contains 25 mg of carprofen.

Indications: Carprofen 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.

Dosage: Always provide Client Information Sheet with prescription. The recommended dosage for oral administration to dogs is 2 mg/kg (4.4 mg/lb) of body weight daily. The total daily dose should be divided into 2 equal parts and administered as 1 mg/kg (2.2 mg/lb) twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure. Caplets are scored and may be broken in half. Caplets are not to be crushed.

FOR ORAL USE IN DOGS ONLY



NOROCARP CAPLETS
(carprofen)

Warnings: Keep out of reach of children. This is a prescription drug. For use in dogs only. Do not use in cats.

Manufactured By:
Astellor, Laboratorios Genmed
Hesry, Northern Ireland

Distributed By:
Norbrook, Inc.
Kenosha, WI 53142

FOR ORAL USE IN DOGS ONLY



25 mg

180 Caplets



30 Caplets

75 mg

NOROCARP CAPLETS
(carprofen)

NOROCARP CAPLETS
(carprofen)

Each oral caplet contains 75 mg of carprofen.
Indications: Carprofen 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.

Dosage: Always refer to the Full Information Sheet with prescription. The recommended dosage for oral administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight daily. The oral daily dose may be administered as 2 mg/lb of body weight (4.4 mg/kg) of body weight once daily or as 1 mg/lb (2.2 mg/kg) of body weight twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure. Caplets are scored and dosage should be calculated in half-caplet increments.

75 mg

30 Caplets

FOR ORAL USE IN DOGS ONLY



NOROCARP CAPLETS
(carprofen)

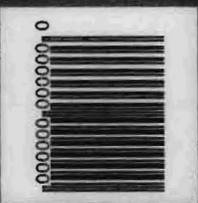
Warnings: Keep out of reach of children. Do not use if your dog has a known hypersensitivity to any of the ingredients or if your dog has had an allergic reaction to any of the ingredients. For use in dogs only. Do not use in cats.
Please refer to insert for complete Warnings and Precautions.

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

75 mg

30 Caplets

FOR ORAL USE IN DOGS ONLY



Manufactured By:
Norbrook Laboratories Limited
Newry, Northern Ireland

Distributed By:
Norbrook Ltd
Limerick, KS 58219



180 Caplets

75 mg

NOROCARP CAPLETS
(carprofen)

NOROCARP CAPLETS
(carprofen)

75 mg

180 Caplets

FOR ORAL USE IN DOGS ONLY



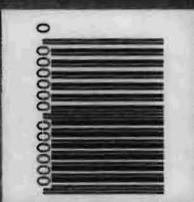
NOROCARP CAPLETS
(carprofen)

NOROCARP CAPLETS
(carprofen)

75 mg

180 Caplets

FOR ORAL USE IN DOGS ONLY



Warnings: Keep out of reach of children, not for human use. Consult a physician in cases of accidental ingestion by animals.

Do not use in dogs only, do not use in cats.

Please refer to insert for complete Warnings and Precautions.

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

Manufactured By:
Norbrook Laboratories Limited
Newry, Northern Ireland

Distributed By:
Norbrook, Inc.
Lincoln, KS 66218

Each 180-day supply contains 75 mg of carprofen.

Indications: Carprofen is indicated for the relief of pain and inflammation associated with osteoarthritis and associated with soft tissue injury or hepatic surgery in dogs.

Dosage: Always provide clear instructions about pain prescription. Administer 2 mg/kg (0.9 mg/lb) of carprofen orally to dogs 3-7 months of age, 4 mg/kg (1.8 mg/lb) to dogs 8-14 months of age, and 2 mg/kg (0.9 mg/lb) to dogs 15 months of age or older. Administer once daily or divided and administered as 1 mg/kg (0.45 mg/lb) twice daily. The total daily dose may be administered as 2 mg/kg (0.9 mg/lb) once daily or divided and administered as 1 mg/kg (0.45 mg/lb) twice daily. For the control of postoperative pain, administer 2 mg/kg (0.9 mg/lb) 2 hours before the procedure. Caplets are scored and this score should be indicated in half-caplet increments.

Lot No. Exp. Date

100 mg

30 Caplets

NOROCARP CAPLETS
(carprofen)

NOROCARP CAPLETS
(carprofen)

100 mg

30 Caplets

FOR ORAL USE IN DOGS ONLY

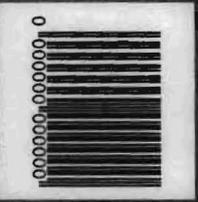


NOROCARP CAPLETS
(carprofen)

100 mg

30 Caplets

FOR ORAL USE IN DOGS ONLY



Each scored caplet contains 100 mg of carprofen.

Indications: Carprofen 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.

Dosage: Always provide clear instructions. See the prescription. The recommended dosage for oral administration to dogs is 2 mg/kg (4 mg/lb) of body weight daily. The total daily dose may be administered as 2 mg/kg of body weight once daily or divided and administered as 1 mg/kg (2 mg/lb) twice daily. Administer approximately 2 hours before the procedure. Caplets are scored and dosage should be calculated in half-caplet increments.

Warnings: Keep out of reach of children. Use only with a prescription in the care of a licensed veterinarian. For use in dogs only. Do not use in cats.

Please refer to insert for complete Warnings and Precautions.

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

Manufactured By:
Norbrook Laboratories Limited
Newry, Northern Ireland

Distributed By:
Norbrook Laboratories Limited
Lynchburg, VA 23829

60 Caplets

100 mg

Lot No.
Exp. Date

NOROCARP CAPLETS
(carprofen)

NOROCARP CAPLETS
(carprofen)

100 mg

60 Caplets

FOR ORAL USE IN DOGS ONLY

Norbrook

Each scored caplet contains 100 mg of carprofen.

Indications: Carprofen 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.

Dosage: Always provide Class I analgesia. Start with 2 mg/kg, q12h. The recommended dosage for oral administration to dogs is 2 mg/kg (0.4 mg/lb) of body weight daily. The total daily dose may be administered as 2 mg/kg of body weight once daily, q12h divided into approximately 1 mg/kg (0.2 mg/lb) of body weight administered in two equal doses. For oral administration, administer approximately 2 hours before the procedure. Caplets are scored and dosage should be calculated in half-caplet increments.

NOROCARP CAPLETS
(carprofen)

100 mg

60 Caplets

FOR ORAL USE IN DOGS ONLY

Norbrook



Warnings: Keep out of reach of children, not for human use. Consult physician in cases of accidental overdose. Do not use in cats. For use in dogs only. Do not use in cats. Please refer to insert for complete Warnings and Precautions.

Store at controlled room temperature 15° - 25° C (59° - 77° F).
Manufactured By:
Norbrook Laboratories Limited
Newry, Northern Ireland
Distributed By:
Aetna Animal Health
Lenexa, KS 65115



Lot No:
Exp. Date:

180 Caplets

100 mg

NOROCARP CAPLETS (carprofen)

NOROCARP CAPLETS (carprofen)

100 mg

180 Caplets

FOR ORAL USE IN DOGS ONLY



Each set of one each contains a 100 mg oral caplet.

Indications: Carprofen is indicated for the relief of pain and inflammation associated with osteoarthritis and for the control of pain and inflammation associated with soft tissue and orthopedic surgery in dogs.

Dosage: Always use the Client Information Sheet for a precise description of dosage. The dosage for all dogs is 2 mg/lb (4.5 mg/kg) once daily, divided into two equal doses. For example, a 20 lb dog should receive 100 mg of Norocarp Caplets (100 mg/180 caplets) twice daily for the control of postoperative pain. The oral caplets can only be given with or without food. Caplets are scored and dosage should be calculated on a half caplet if 25 animals.

NOROCARP CAPLETS (carprofen)

100 mg

180 Caplets

FOR ORAL USE IN DOGS ONLY



Warnings: Keep out of reach of children. For human use. Consult your physician if pregnant or nursing.

For use in dogs only: Do not use in cats. Please refer to insert for complete Warnings and Precautions.

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

Manufactured By:
Norbrock, Inc., Kansas, MO 64504
Norbrock, Inc., Kansas, MO 64504

Distributed By:
Norbrock, Inc.
Lenexa, KS 66221





Dog Owner Information about RIMADYL® Caplets (carprofen) Rimadyl® (pronounced "Rim-a-dill") for Osteoarthritis and Post-Surgical Pain Generic name: carprofen ("car-prō-fen")

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

What is Rimadyl?
Rimadyl is a nonsteroidal anti-inflammatory drug (NSAID) that is used to reduce pain and inflammation (soreness) due to osteoarthritis and pain following surgery in dogs. Rimadyl is a prescription drug for dogs. It is available as a caplet and 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 Rimadyl 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 Rimadyl?
While Rimadyl 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 Rimadyl is discontinued or not given as directed, your dog's pain and inflammation may come back.

Who should not take Rimadyl?
Your dog should not be given Rimadyl if he/she:

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

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

How to give Rimadyl to your dog.
Rimadyl should be given according to your veterinarian's instructions. Your veterinarian will tell you what amount of Rimadyl is right for your dog and for how long it should be given. Rimadyl should be given by mouth and may be given with or without food.

What to tell/ask your veterinarian before giving Rimadyl.

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

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

- 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)

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 Rimadyl therapy?

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

Can Rimadyl be given with other medicines?
Rimadyl should not be given with other NSAIDs (for example, aspirin, etodolac) or steroids (for example, cortisone, prednisone, dexamethasone, 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 Rimadyl. 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 Rimadyl?
Contact your veterinarian immediately if your dog eats more than the prescribed amount of Rimadyl.

What else should I know about Rimadyl?
This sheet provides a summary of information about Rimadyl. If you have any questions or concerns about Rimadyl, or osteoarthritis, or postoperative pain, talk to your veterinarian.

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

To report a suspected adverse reaction call Pfizer Animal Health at 1-800-366-5288.

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Exton, PA 19341, USA
Div. of Pfizer Inc.
NY, NY 10107

www.rimadyl.com

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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.

Precautions: Refer to Insert for Complete Warnings and Precautions.

Store: at controlled room temperature 20°-25°C (68°-77°F).
Keep in dark.

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RIMADYL®

(carprofen)

25 mg

30 caplets

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
 (NADA #141-053
 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.

Precautions: Refer to Insert for Complete Warnings and Precautions.

Store: at controlled room temperature 20°-25°C (68°-77°F).
Keep in dark.

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Each scored caplet contains 25 mg of carprofen. Indication: 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. Always provide Client Information Sheet with Rimadyl. Caution: Avoid use in dogs with renal insufficiency and risk of fibrinolytic activity. Other treatment options include NSAIDs and analgesics. Use the lowest effective dose for the shortest duration consistent with individual response. The recommended dosage for oral administration is 2 mg/kg (4.4 mg/kg) of body weight daily. The total daily dose may be administered as 2 mg/kg of body weight daily or divided and administered as 1 mg/kg (2.2 mg/kg) twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure. Caplets are scored and dosage should be calculated in half-caplet increments.

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RIMADYL[®]
(carprofen)

25 mg

180 caplets

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
(NADA #141-053)
Approved by FDA



Warnings: Keep out of reach of children. Not for human use. Consult a physician in case of accidental ingestion by humans.

For use in dogs only. Do not use in cats.

Please Refer to Insert for Complete Warnings and Precautions.

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

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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.

RIMADYL®

(carprofen)

75 mg

30 caplets

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

(NADA #141-053)

Approved by FDA



Each scored caplet contains 75 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 soft tissue and orthopedic surgeries in dogs. Dosage: 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 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. Caplets are scored and dosage should be calculated in half-caplet increments. P00073-L-000 8591000

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RIMADYL®

(carprofen)

75 mg

60 caplets

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

(NADA #141-053
Approved by FDA)



Each scored caplet contains 75 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 soft tissue and orthopedic surgeries in dogs.
Dosage: 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 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. Caplets are scored and dosage should be calculated in half-caplet increments.

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Do not use in cats.

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.

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Please Refer to Insert for Complete Warnings and Precautions

only. Do not use in cats.

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

RIMADYL[®]
(carprofen)

75 mg

180 caplets

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

(NADA #141-053
Approved by FDA)



Each scored caplet contains 75 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 soft tissue and orthopedic surgeries in dogs.

Dosage: 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 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. Caplets are scored and dosage should be calculated in half-caplet increments.

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

Precautions

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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.

RIMADYL[®]
(carprofen)

100 mg

30 caplets

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

(NADA #141-053)

Approved by FDA



Each scored caplet contains 100 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 soft tissue and orthopedic surgeries in dogs.

Dosage: 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 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. Caplets are scored and dosage should be calculated in half-caplet increments.

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Please Refer to Complete Warnings and Precautions

Do not use in cats.
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.

RIMADYL[®]
(carprofen)

100 mg

60 caplets

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

(NADA #141-053
Approved by FDA)



Each scored caplet contains 100 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 soft tissue and orthopedic surgeries in dogs.
Dosage: 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 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. Caplets are scored and dosage should be calculated in half-caplet increments.

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RIMADYL[®]
(carprofen)

100 mg

180 caplets

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

(NADA #141-053
Approved by FDA)



Each scored caplet contains 100 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 soft tissue and orthopedic surgeries in dogs.
Dosage: 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 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. Caplets are scored and dosage should be calculated in half-caplet increments.

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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.
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