

NOVOX[®]

(CARPROFEN)

CHEWABLE TABLETS

ANADA 200-595

LIVER-FLAVORED

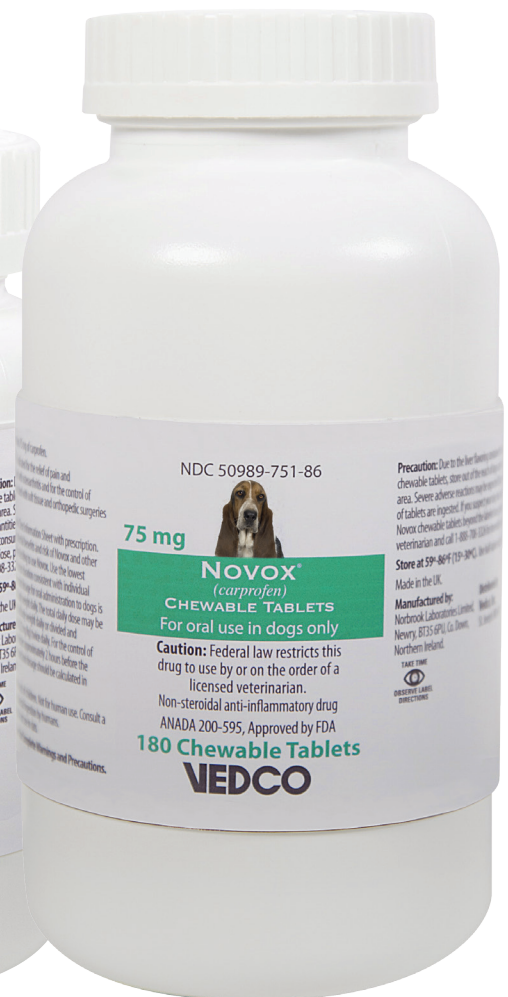


Indicated for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

IMPORTANT SAFETY INFORMATION: As a class, NSAIDs may be associated with gastrointestinal, kidney and liver side effects. These are usually mild, but may be serious. Dog owners should discontinue therapy and contact their veterinarian immediately if side effects occur. Evaluation for pre-existing conditions and regular monitoring are recommended for dogs on any medication, including Novox. Use with other NSAIDs or corticosteroids should be avoided. See full product labeling for full product information.

NOVOX[®] (CARPROFEN) CHEWABLE TABLETS

25 MG, 75 MG AND 100 MG STRENGTHS
SCORED CHEWABLE TABLETS AVAILABLE
IN BOTTLES OF 30, 60 AND 180



DOSAGE AND ADMINISTRATION

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

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

Novox 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. These liver flavored Novox chewable tablets may be offered to the dog by hand or placed on food. If the dog does not willingly consume the tablets, they may be hand-administered (pilled) as with other oral tablet medications. Care should be taken to ensure that the dog consumes the complete dose.

HOW SUPPLIED

Novox chewable tablets are scored, and contain 25 mg, 75 mg or 100 mg of carprofen per tablet. Each tablet size is packaged in bottles containing 30, 60 or 180 tablets.

NOVOX[®]
CHEWABLE TABLETS
(CARPROFEN)
LIVER-FLAVORED



SCORED
25 MG, 75 MG AND 100 MG

EFFECTIVENESS

Confirmation of the effectiveness of carprofen for the relief of pain and inflammation associated with osteoarthritis, and for the control of postoperative pain associated with soft tissue and orthopedic surgeries, was demonstrated in 5 placebo-controlled, masked studies examining the anti-inflammatory and analgesic effectiveness of carprofen caplets in various breeds of dogs. Separate placebo-controlled, masked, multicenter field studies confirmed the anti-inflammatory and analgesic effectiveness of carprofen caplets when dosed at 2 mg/lb once daily or when divided and administered at 1 mg/lb twice daily. In these 2 field studies, dogs diagnosed with osteoarthritis showed statistically significant overall improvement based on lameness evaluations by the veterinarian and owner observations when administered carprofen at labeled doses.

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

In general, dogs administered carprofen showed statistically significant reduction in pain scores compared to controls.

ANIMAL SAFETY

Laboratory studies in unanesthetized dogs and clinical field studies have demonstrated that carprofen is well tolerated in dogs after oral administration. In target animal safety studies, carprofen was administered orally to healthy Beagle dogs at 1, 3, and 5 mg/lb twice daily (1, 3, and 5 times the recommended total daily dose) for 42 consecutive days with no significant adverse reactions.

Please refer to the Novox[®] Chewable Tablets package insert for more specific information.

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SINCE
PENN
Veterinary Supply, Inc.
Phone: 800.233.0210
www.pennvet.com

VEDCO
St. Joseph, MO 64507
www.vedco.com

NOVOX[®] CAPLETS (carprofen)



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

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 carbazole, 6-chloro-*o*-methyl-9H-carbazole-2-acetic acid. The empirical formula is C₁₅H₁₂ClNO₂ and the molecular weight 273.72. Carprofen is a white, crystalline compound. It is freely soluble in ethanol, but practically insoluble in water at 25°C.

DOSAGE AND ADMINISTRATION

Always provide Client Information Sheet with prescription. Carefully consider the potential benefits and risk 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/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.

EFFECTIVENESS

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

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

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

showed statistically significant improvement in pain scores compared to controls.

INFORMATION FOR DOG OWNERS

Novox[®] 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 white of the eye due to jaundice, lethargy, incoordination, seizure, or behavioral changes.

Serious adverse reactions associated with this drug class can occur without warning and in rare situations result in death (see Adverse Reactions). Owners should be advised to discontinue Novox[®] Caplets therapy and contact their veterinarian immediately if signs of intolerance are observed.

The vast majority of patients with drug related adverse reactions have recovered when the signs are recognized, the drug is withdrawn and veterinary care, if appropriate, is initiated. Owners should be advised of the importance of periodic follow up for all dogs during administration of any NSAID.

ADVERSE REACTIONS

During investigational studies of osteoarthritis 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%).

STORAGE

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

HOW SUPPLIED

Novox[®] 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.

VEDCO

Please
Contact
Us At:

PENN
Veterinary Supply, Inc.

53 Industrial Circle
Lancaster, PA 17601

Phone: 1-800-233-0210
Online: www.pennvet.com



