For the use only of a Registered Veterinary Practitioner, Hospital or Laboratory or a Farm

CARODYL®

(Carprofen Tablets and Injection)

Composition:

Each chewable tablet of **CARODYL® 25mg** contains:	
Carprofen	25 mg
Excipients	q.s.
Each chewable tablet of **CARODYL® 75mg** contains:	
Carprofen	75 mg
Excipients	q.s.
Each chewable tablet of **CARODYL® 100mg** contains:	
Carprofen	100 mg
Excipients	q.s.
Each ml of **CARODYL® Injection** contains	
Carprofen U.S.P	50 mg
Water for Injection IP	Q.S.

Description: CARODYL® (Carprofen) is a non-steroidal anti-inflammatory drug (NSAID) of the propionic acid class that includes ibuprofen, naproxen and ketoprofen. Carprofen is the non-proprietary designation for a substituted carbazole.

Chemistry: 6-chloro-α-methyl-9H-carbazole-2-acetic acid

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.

Pharmacodynamics: 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. In an in vitro study using canine cell cultures, carprofen demonstrated selective inhibition of COX-2 versus COX-1. Data also indicate that carprofen inhibits the production of osteoclast activating factor (OAF), PGE1, and PGE2 by its inhibitory effects on prostaglandin biosynthesis.

Pharmacokinetics: Based on comparative data obtained from intravenous administration, carprofen is rapidly and nearly completely absorbed (more than 90% bioavailable) when administered orally. 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 4.5–9.8 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. Carprofen 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 ether glucuronides of 2 phenolic metabolites, 7-hydroxy carprofen and 8-hydroxy carprofen) in the feces (70–80%) and urine (10–20%). Some entero-hepatic circulation of the drug is observed.

Indications: CARODYL® 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 and Administration: The recommended dosage for subcutaneous administration to dogs is 4 mg/kg of body weight daily (1 ml / 12.5 kg). The total daily dose may be administered as either 4 mg/kg of body weight once daily or divided and administered as 2 mg/kg twice daily. For control of postoperative pain, administer approximately 2 hours before the procedure.

Carefully consider the potential benefits and risks of CARODYL® and other treatment options before deciding to use CARODYL®. Use the lowest effective dose for the shortest duration consistent with individual response.

CARODYL® 25

Weight	Tablet Size	Dose	# of Easy Chews
2 - 5 kg	25 mg	12.5 mg	◑ ½ tab
5.1 - 7 kg	25 mg	25 mg	● 1 tab
7.1 - 10 kg	25 mg	37.5 mg	●◑ 1½ tabs
10.1 - 14 kg	25 mg	50 mg	●● 2 tabs
14.1 - 18 kg	25 mg	75 mg	●●● 3 tabs

CARODYL® 75

Weight	Tablet Size	Dose	# of Easy Chews
7.1 - 10 kg	75 mg	37.5 mg	◑ ½ tab
14.1 - 18 kg	75 mg	75 mg	● 1 tab

CARODYL® 100

Weight	Tablet Size	Dose	# of Easy Chews
10.1 - 14 kg	100 mg	50 mg	◑ ½ tab
18.1 - 27 kg	100 mg	100 mg	● 1 tab
27.1 - 41 kg	100 mg	150 mg	●◑ 1½ tabs
41.1 - 55 kg	100 mg	200 mg	●● 2 tabs

Contraindications: CARODYL® should not be used in dogs exhibiting previous hypersensitivity to carprofen.

Warnings: Keep out of reach of children. Not for human use. Consult a physician in cases of accidental human exposure. For use in dogs only.

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.

Precautions: The most frequently reported effects have been gastrointestinal signs. Events involving suspected renal, hematologic, neurologic, dermatologic, and hepatic effects have also been reported. CARODYL® 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. Due to the palatable nature of Carodyl® 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 Carodyl® chewable tablets above the labeled dose, please call your veterinarian for immediate assistance.

As with any parenterally injected product, good hygienic procedures should be used when administering CARODYL® Injection. It is suggested to use different sites for additional injections.

The safe use of CARODYL® in animals less than 6 weeks of age, pregnant dogs, dogs used for breeding purposes, or in lactating bitches has not been established.

Safety has not been established for Intravenous or Intramuscular administration. Studies to determine the activity of CARODYL® when administered concomitantly with other protein-bound or similarly metabolized drugs have not been conducted. Drug compatibility should be monitored closely in dogs 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. If additional pain medication is warranted after administration of the total daily dose of CARODYL®, alternative analgesia should be considered. The use of another NSAID is not recommended. Consider appropriate washout times when switching from one NSAID to another or when switching from corticosteroid use to NSAID use.

Adverse reactions: Based on reported studies, no clinically significant adverse reactions were reported. Some reported clinical Incidences include: vomiting, diarrhea, changes in appetite, lethargy, behavioral changes, and constipation. The product vehicle served as control. There were no serious adverse events reported with once daily oral administration of 4 mg/kg.

Information for dog owners: CARODYL®, 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, and pale gums due to anemia, yellowing of gums, skin or white of the eye due to jaundice, lethargy, incoordination, seizure, or behavioral changes. The vast majority of dogs 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.

Animal Safety: Reported studies in unanesthetized dogs and clinical field trials have demonstrated that CARODYL® is well tolerated in dogs as chewable tablets after oral administration and as injection after subcutaneous administration.

Presentation: Vial of 2 ml with Combipack of Syringe & Needle.

Storage: Do not store above 25°C. Protect from light. Once broached, the product may be stored at temperatures up to 25°C for 28 days.

Keep out of reach of children.

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SAVAVET
Shaping the Future

SAVA HEALTHCARE LIMITED
Plot No. 507-B to 512 GIDC Estate,
Wadhwan City – 363035, Surendranagar,
Gujarat, India
www.savavet.com