

1. VETERINARY MEDICATION NAME

Rx Condroprodyl® 100 mg.

2. PHARMACEUTICAL PRESENTATION

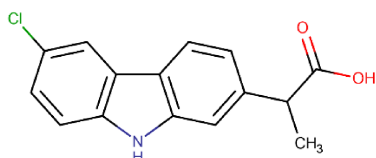
Tablets

3. FORMULA

Each tablet contains:

Carprofen	100 mg
Excipient q.s.	1 tablet

4. STRUCTURAL FORMULA



5. THERAPEUTIC INDICATIONS

Non-steroidal anti-inflammatory drug with analgesic and antipyretic activity. Effective in relieving the signs associated with osteoarthritis, orthopedic and soft tissue surgeries.

6. SPECIES

Canines.

7. ADMINISTRATION ROUTE

Oral.

8. DOSAGE

General dosage:

- 4 mg/kg (2.2 lb) of body weight as a single daily dose
- 2 mg/kg (2.2 lb) of body weight every 12 hours (Maddison, 2008).

Administer with food.

Rx Condroprodyl® 100 mg

1 tablet per 25 kg (55 lb) of body weight once daily.

The dosage may be adjusted at the discretion of the Veterinarian.

9. MECHANISM OF ACTION

Carprofen is a non-narcotic, non-spheroidal anti-inflammatory drug with analgesic and antipyretic activity equivalent to indomethacin in animals. It is a reversible cyclooxygenase (COX) inhibitor with greater selectivity for cyclooxygenase-2 (COX-2), which is involved in pain and inflammation relief. Cyclooxygenase-1 (COX-1), which is involved in the physiological maintenance of the gastrointestinal mucosa under homeostatic conditions and also in maintaining renal blood flow, is not affected by carprofen. This results in excellent tolerance and safety for treated animals compared to other NSAIDs or corticosteroids (Mullins, 2012; Plumb, 2008; USPC, 2007).

10. PHARMACOKINETICS

Carprofen has an oral bioavailability of approximately 90% when administered to dogs. Peak serum levels occur 1 to 3 hours after administration. The drug exhibits 99% plasma protein binding and has a low volume of distribution (0.12 to 0.22 L/kg, (2.2 lb)). Carprofen is extensively metabolized in the liver mainly through glucuronidation and oxidation. Approximately 70 to 80% of a dose is eliminated in the feces and 10 to 20% is eliminated in the urine. Some degree of enterohepatic circulation occurs. The elimination half-life of carprofen in dogs is approximately 13 to 18 hours (Plumb, 2008).

11. WARNINGS

All animals receiving NSAID treatment should be evaluated prior to and during the course of therapy (Borges *et al.*, 2013). It should not be used in canines that have exhibited hypersensitivity to carprofen (Papich, 2016).

Do not administer in canines with cardiac, hepatic and/or renal alterations or gastroduodenal ulcers (Plumb, 2008).

Administration in animals younger than 6 weeks of age or in older animals may involve additional risk, so strict supervision by the Veterinarian is required (Peterson *et al.*, 2011; Plumb, 2008).

12. ADVERSE REACTIONS

Adverse effects in dogs appear to be uncommon, with the most likely being mild gastrointestinal disturbances. However, serious adverse effects have been reported, including renal disease, hematological abnormalities, and severe gastrointestinal reactions. The reported incidence of hepatopathy is approximately 0.05% in treated dogs. Idiosyncratic hepatotoxicity has been reported in dogs treated with carprofen (Labradors may be over-represented). The mechanism of hepatotoxicity is not known, but it has been speculated that glucuronide metabolites may react with

plasma and hepatocellular proteins, leading to the formation of antigenically altered proteins by NSAIDs, which causes hepatic toxicity. Typically, discontinuing the drug results in recovery; however, although some cases have been fatal (Fick, 2020; Luna *et al.*, 2007; Plumb, 2008).

13. OVERDOSAGE

When carprofen is ingested at doses greater than 20 mg/kg (2.2 lb), dose-related toxicity may occur, including gastrointestinal ulceration and hepatocellular injury. At oral doses greater than 40 mg/kg (2.2 lb), diuresis is recommended to prevent renal damage. Neurological signs, including seizures, stupor, and coma, have also been reported with extreme overdoses greater than 200 mg/kg (0.09 oz/lb) of body weight (Fick, 2020).

14. DRUG INTERACTIONS

The administration of carprofen with other GI ulcerogenic drugs should be avoided (Sumano *et al.*, 2006).

Co-administration of acetylsalicylic acid (SSA) with carprofen is not recommended; when used at the same time, plasma levels of carprofen may decrease and the likelihood of gastrointestinal adverse effects (blood loss) may be increased (Plumb, 2008; Sumano *et al.*, 2006).

Co-administration of corticosteroids with NSAIDs may significantly increase the risks of gastrointestinal adverse effects (Plumb, 2008).

Carprofen may increase serum digoxin levels; use with caution in patients with severe heart failure (Plumb, 2008).

Carprofen can reduce the saluretic and diuretic effects of furosemide (Plumb, 2008; Sumano *et al.*, 2006).

Drugs with high protein binding (e.g., phenytoin, valproic acid, oral anticoagulants, other anti-inflammatory agents, salicylates, sulfonamides, sulfonylurea antidiabetic agents): because carprofen is highly protein-bound (99%), it could potentially displace other highly protein-bound drugs (Plumb, 2008).

Severe toxicity has been reported when NSAIDs are used in conjunction with methotrexate (Plumb, 2008).

Probenecid increases the serum concentration and half-life of carprofen (Plumb, 2008; Sumano *et al.*, 2006).

Given that carprofen's hepatotoxicity may be mediated by its hepatic metabolites, concomitant use of hepatic enzyme inducers (such as phenobarbital, rifampin, etc.) should be avoided (Plumb, 2008).

15. INTERACTIONS WITH LABORATORY TESTS

In dogs, carprofen can decrease total T₄ and THS levels, but apparently does not affect free T₄ concentrations (Plumb, 2008).

Although it has not been concluded that selective COX-2 NSAIDs predispose to clinical bleeding, they have been shown to affect some laboratory tests of platelet function in dogs (Mullins *et al.*, 2012).

16. USE DURING PREGNANCY AND/OR LACTATION

No studies have been conducted to establish the safety of carprofen in pregnant or lactating canines (USPC, 2007).

17. PRECAUTIONS

Store in a cool, dry place away from direct sunlight and/or heat.

Keep out of reach of children and pets. Product for exclusive use in Veterinary Medicine.

18. EXPIRATION PERIOD

Shelf life of the veterinary medicinal product as packaged for sale: 24 months.

19. HOLDER OF THE REGISTRY

HOLLAND DE MEXICO SA DE CV
Calle 21 Este No 12, Col. Civac
Jiutepec, Morelos, CP 62578

20. REGISTRATION NUMBER

Q-4196-158

21. SALE, DISPENSATION, AND/OR USE PROHIBITION

Prescription required.

Consult your veterinarian.

22. PRESENTATION

Box with 20 tablets.

23. REFERENCES

- 23.1 Borges, *et al.* Nonsteroidal anti-inflammatory therapy. Changes on renal function of healthy dogs. *Acta Cirúrgica Brasileira* - Vol. 28 (12) 2013: 842-847.
- 23.2 Fick *et al.* Efficacy of a single session in-series hemoperfusion and hemodialysis in the management of carprofen overdose in two dogs. *J Vet Emerg Crit Care*. 2020; 30(2): 226-31.
- 23.3 Luna *et al.* Evaluation of adverse effects of long-term oral administration of carprofen, etodolac, flunixin meglumine, ketoprofen, and meloxicam in dogs. *Am J Vet Res*, 2007; 68 (3): 258-64
- 23.4 Maddison, J. *Small Animal Clinical Pharmacology*. Elsevier, China, 2008.
- 23.5 Mullins *et al.* Effects of carprofen, meloxicam and deracoxib on platelet function in dogs. *Vet Anaesth Analg*. 2012; 39 (2): 206-17.
- 23.6 Papich M. *Saunders Handbook of Veterinary Drugs: Small and Large Animal*. Elsevier, USA, 2016
- 23.7 Peterson *et al.* *Small Animal Pediatrics - The First 12 Months of Life*. 1st ed., Elsevier Saunders, 2011.
- 23.8 Plumb DC. *Veterinary Drug Handbook Sixth Edition*. 6th ed. Ames, iowa: Blackwell Publishing; 2008.136-138.
- 23.9 USPC. Carprofen (veterinary-systemic). Rockville, USA, Pharmacopeial Convention, Inc, 2007.

CERTIFICATE OF ACCURACY

I, the undersigned, Diana Alicia de Regules Silva, Certified Translator No. P037-2020 SPANISH-ENGLISH-SPANISH, duly sworn and authorized by the Mexican Supreme Court of Justice, as per the Federal Judiciary Council's publication in the Federal Official Gazette on December 11, 2024 (accessible at https://www.dof.gob.mx/2024/CJF/listado_peritos_PJF_2025.pdf page 204):

1. I hereby certify that I have translated a **3**-page document in Spanish, titled "**FICHA TÉCNICA**" into a **3**-page English document, titled "**TECHNICAL DATA SHEET**" both of which are attached herewith.



Diana A. de Regules Silva
Certified expert translator
+52 55.5431.4434
dianaderegules@me.com