SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CARPRODYL F 20 mg, tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active ingredient:
Carprofen .....20 mg
Excipients
Yellow iron oxide (E172) .....0.0375 mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet.
Circular, beige, scored tablets.
The tablets can be divided into equal halves.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

Reduction of inflammation and pain caused by musculo-skeletal disorders and degenerative joint disease.
As a follow up to parenteral analgesia in the management of post-operative pain.

4.3 Contraindications

Do not use in cats.
Do not use in pregnant or lactating bitches.
Do not use in cases of known hypersensitivity to the active substance or to any of the excipients of the product.
Do not use in dogs suffering from cardiac, hepatic or renal disease, where there is a possibility of gastro-intestinal ulceration or bleeding, or where there is evidence of a blood dyscrasia.
Do not use in pups less than 4 months of age.

4.4 Special warnings for each target species

Refer to Sections 4.3 and 4.5.

4.5 Special precautions for use

Special precautions for use in animals
Use in aged dogs may involve additional risk. If such a use cannot be avoided, dogs may require careful clinical management.
Avoid use in any dehydrated, hypoproteinemic, hypovolaemic or hypotensive dog, as there is a potential risk of increased renal toxicity.
NSAIDs can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infection, appropriate concurrent antimicrobial therapy should be instigated.

Response to long term treatment should be monitored at regular intervals by a veterinary surgeon.
As the tablets are flavoured, they should be stored in a safe place out of the reach of animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In the event of accidental ingestion of the tablets, seek medical advice and show the doctor the package leaflet.
Wash hands after handling the product.

4.6 Adverse reactions (frequency and seriousness)

Typical undesirable effects associated with NSAIDs, such as vomiting, soft faeces/diarrhea, faecal occult blood, loss of appetite and lethargy have been reported. These adverse reactions occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.
Rare cases of gastrointestinal bleeding are reported.
If adverse reactions occur, use of the product should be stopped and the advice of a veterinarian should be sought.
As with other NSAIDs there is a rare risk of renal or idiosyncratic hepatic adverse events.

4.7 Use during pregnancy, lactation or lay

Studies in laboratory species (rat and rabbit) have shown evidence of foetotoxic effects of carprofen at doses close to the therapeutic dose.
In dogs, the safety of the veterinary medicinal product has not been investigated during pregnancy and lactation. Do not use in pregnant or lactating bitches.

4.8 Interaction with other medicinal products and other forms of interaction

Carprofen must not be administered with glucocorticoids.
Do not administer other NSAIDs concurrently or within 24 hours of each other. Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs, which can lead to toxic effects.

Concurrent administration of potential nephrotoxic drugs should be avoided.

4.9 Amounts to be administered and administration route

For oral administration.

4 mg carprofen per kg bodyweight per day
To limit the inflammation and relieve the pain caused by musculo-skeletal disorders and degenerative joint disease:
An initial dose of 4 mg carprofen per kg bodyweight per day given as a single daily dose or in two equally divided doses. The daily dose may be reduced, subject to clinical response.
Duration of treatment will be dependent upon the response seen. Long term treatment should be under regular veterinary supervision.
To extend analgesic and anti-inflammatory cover post-operatively, parenteral preoperative treatment with carprofen injection may be followed with carprofen tablets at 4mg/kg/day for 5 days.
Do not exceed the stated dose.

The tablets are flavoured and consequently taken by most of dogs voluntarily.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No signs of toxicity appeared when dogs were treated with carprofen at levels up to 6 mg/kg twice daily for 7 days (3 times the recommended dose rate of 4 mg/kg) and 6 mg/kg once daily for a further 7 days (1.5 times the recommended dose rate of 4 mg/kg).
There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAIDs, should be applied.
Severe adverse reactions may occur if large quantities are ingested. If you suspect that your dog has consumed tablets above the labelled dose, contact your veterinarian.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Non-steroidal anti-inflammatory drug.
ATCvet code: QM01AE91.

5.1 Pharmacodynamic properties

Carprofen, is a non-steroidal anti-inflammatory drug (NSAID) of the 2-aryl propionic acid class and possesses anti-inflammatory, analgesic and antipyretic activities.
The mechanism of action of carprofen, like 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. In an *in vitro* study, using canine cell cultures, carprofen demonstrated selective inhibition of COX-2 versus COX-1. Clinical relevance of these data has not be shown.
Carprofen has also been shown to inhibit the release of several prostaglandins in two inflammatory cell systems: rat polymorphonuclear leukocytes (PMN) and human rheumatoid synovial cells, indicating inhibition of acute (PMN system) and chronic (synovial cell system) inflammatory reactions.
Several studies have demonstrated that carprofen has modulatory effects on both humoral and cellular immune responses. Carprofen, also inhibits the production of osteoclast-activating factor (OAF), PGE_1 and PGE_2 by its inhibitory effect on prostaglandin biosynthesis.

5.2 Pharmacokinetic particulars

After oral administration, carprofen is well absorbed in the dogs. Following the administration of the product tablets in dogs, a mean Cmax (maximum concentration in serum) of 6.1 mg/L and 3.6 mg/L was achieved at approximately 1 hour for Carprofen R(-) and Carprofen S(+), respectively. For both enantiomers, the mean half-life was approximately 9 hours. The analgesic effect from each dose persists for at least 12 hours.
Carprofen has a small volume of distribution and a low systemic clearance. It is highly bound to plasma protein.
Carprofen is metabolised in the liver by conjugation and oxidation. The excretion of the glucuronide conjugate is mainly faecal after biliary excretion.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pork aroma
Tablet grade inactivated yeast (inactivated yeast, magnesium stearate and tricalcium phosphate)
Low-substituted hydroxypropyl cellulose
Yellow iron oxide (E172)
Silica colloidal anhydrous
Tablet grade lactose monohydrate (lactose monohydrate, povidone, crospovidone)
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Halved tablets should be used within 7 days.

6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions
Store tablets and half-tablets in the original blister in order to protect from light.

6.5 Nature and composition of immediate packaging

Material of the primary container
Complex (polyamide/Aluminium/PVC)/Aluminium blisters

Pack sizes
Box containing 20 tablets: 2 blisters of 10 tablets
Box containing 100 tablets: 10 blisters of 10 tablets
Box containing 200 tablets: 20 blisters of 10 tablets
Box containing 500 tablets: 50 blisters of 10 tablets

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

8. MARKETING AUTHORISATION NUMBER

Vm 14966/3046

9. DATE OF THE FIRST AUTHORISATION

04 June 2008

10. DATE OF REVISION OF THE TEXT

October 2025

Gavin Hall
Approved: 16 October 2025