SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprodyl Quadri 50 mg Tablets for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains:

Carprofen…...50mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Clover-shaped scored beige tablet
The tablet can be divided into four equal parts.

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 pregnant and lactating bitches.
Do not use in dogs aged less than 4 months in the absence of specific data.
Do not use in cats.
Do not use in dogs, suffering from cardiac, hepatic or renal disease, when there is a possibility of gastrointestinal ulceration or bleeding or where there is evidence of blood dyscrasia.
Do not use in case of hypersensitivity to the active substance, to other NSAIDs or to any of the excipients.

4.4 Special warnings for each target species

See 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 a reduced dosage and careful clinical management.
Avoid use in any dehydrated, hypovolaemic or hypotensive dog, as there is a potential risk of increased renal toxicity.
Concurrent administration of potential nephrotoxic drugs should be avoided.
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.
As with other NSAIDs, photodermatitis during treatment with carprofen has been observed in laboratory animals and in humans. These skin reactions have never been observed in dogs.
Do not administer other NSAIDs concurrently or within 24 hours of each other.
Due to the good palatability of the tablet, they should be stored in a safe place out of the reach of animals. Intake of dose exceeding the recommended number of tablets may lead to severe adverse effects. If this is the case, seek veterinary assistance immediately.

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

Special precautions for the protection of the environment
Not applicable

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Dog

Rare (1 to 10 animals / 10,000 animals treated):	Renal disorder [1] Hepatic disorder[1,3]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting[2], Soft stool/Diarrhoea[2], Blood in faeces [2] Appetite loss[2], Lethargy[2]

[1]As with other NSAIDs

[2]Typical undesirable effects associated with NSAIDs, these adverse reactions generally occur 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.

[3]Idiosyncratic effects

If adverse reactions occur, use of the product should be stopped and the advice of a veterinarian should be sought.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system.
See the package leaflet for respective contact details.

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. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use in pregnant or lactating bitches.
For breeding animals, do not use during reproduction period.

4.8 Interaction with other medicinal products and other forms of interaction

Carprofen is highly bound to plasma proteins and compete with other highly bound drugs, which can increase their respective toxic effects.
Do not use this veterinary medicinal drug concurrently with other NSAIDs or with glucocorticoids.
Concurrent administration of potentially nephrotoxic drugs (e.g. aminogylcoside antibiotics) should be avoided.
Refers also to section 4.5

4.9 Amount(s) to be administered and administration route

For oral administration.
4 mg carprofen per kg bodyweight per day.
An initial dose of 4 mg carprofen per kg bodyweight per day given as a single daily dose. The analgesic effect from each dose persists for at least 12 hours.
The daily dose may be reduced, subject to clinical response.
Duration of treatment will be dependant upon the response seen. Long term treatment should be under regular veterinary supervision.
To extend analgesic and anti-inflammatory cover post-operatively parenteral pre- operative treatment with an injectable carprofen may be followed with carprofen tablets at 4 mg/kg/day for 5 days.
Do not exceed the stated dose.

The breakability method is the following: Put the tablet on a plain surface, with its scored side facing the surface (convex face up).
With the tip of forefinger, exert a slight vertical pressure on the middle of the tablet to break it in its width into halves. In order to obtain quarters, then exert a slight pressure on the middle of one half with forefinger to break it in its length.

The tablet is divisible and can be used as follows:

Number of tablets per day	Dog weight (kg)
¼	> 3 - < 6
½	≥ 6 - < 9
¾	≥ 9 - < 12.5
1	≥ 12.5 - < 15.5
1 ¼	≥ 15.5 - < 18.5
1 ½	≥ 18.5 - < 21.5
1 ¾	≥ 21.5 - < 25
2	≥ 25 - < 28
2 ¼	≥ 28 - < 31
2 ½	≥ 31 - < 34
2 ¾	≥ 34 - < 37
3	≥ 37 - < 40
3 ¼	≥ 40 - < 43
3 ½	≥ 43 - < 45

The tablets are flavoured, and are accepted by dogs, but they may be administered directly in the mouth of the dog or added to food if necessary.

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

Bibliographic data report that carprofen is well tolerated in dogs at twice the recommended dosage for 42 days.
Doses up to 3 times the recommended dose are reported to be without adverse effects.
There is no specific antidote to carprofen but general supportive therapy as applied to clinical overdose with NSAIDs should be applied.

4.11 Withdrawal period(s)

No applicable.

5. PHARMACOLOGICALPROPERTIES

ATC vet 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, is not well known. However, it was shown that the inhibition of the cyclo-oxygenase enzyme by carprofen is relatively weak at the recommended dosage. Moreover, it was shown that carprofen doesn’t inhibit the generation of thromboxane (TX) B2 in dog clotting blood and neither prostaglandin (PG) E2 nor 12-hydroxyeicosatetraenoic acid (HETE) in inflammatory exudate are inhibited. This suggests the mechanism of action of carprofen is not the inhibition of the eicosanoids.

Some authors suggested an activity of carprofen on one or numerous inflammatoy mediators not yet identified but no clinical evidence could be shown.
Carprofen exists in two enantiomeric forms, R(-)-carprofen and S(+)-carprofen and the racemic form is the one marketed. Laboratory animal studies suggest that the S(+) enantiomer possesses greater anti-inflammatory potency.
Ulcerogenic potential of carprofen has been shown in the rodents but not in the dogs.

5.2 Pharmacokinetic particulars

After a single oral administration of 4 mg of carprofen per kg of bodyweight in dog, the time to obtain a maximum plasmatic concentration of 23µg/ml is about 2 hours. The oral bioavailability is more than 90% of the total dose. Carprofen is more than 98% bound to plasma proteins and its volume of distribution is low.
Carprofen is excreted in the bile with 70 % of an intra-venous dose of carprofen being eliminated in the faeces, mainly as the glucuronide conjugate. Carprofen undergoes an enantioselective enterohepatic cycle in dog, with only the S(+) enantiomer being significantly recycled. The plasmatic clearance of the S(+) carprofen is about twice that of the R(-) carprofen. The biliary clearance of S(+) carprofen seems to be subject to stereoselectivity too as it is about three times higher than that of R(-) carprofen.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pig liver flavour
Yeast,
Croscarmellose sodium,
Copovidone,
Magnesium stearate,
Anhydrous colloidal silica,
Microcrystalline cellulose,
Lactose monohydrate.

6.2 Major incompatibilities

None.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 72 hours

6.4 Special precautions for storage

Do not store above 30°C.
Protect from light.
Divided tablets should be stored in the blister pack. Any divided tablet portions remaining after 72 hours should be discarded.

6.5 Nature and composition of immediate packaging

Blister complex: PVDC-PVC/Aluminium heat sealed blisters with 10 tablets / blister.
Cardboard box with 2 blisters of 10 tablets
Cardboard box with 10 blisters of 10 tablets Cardboard box with 20 blisters of 10 tablets
Cardboard box with 30 blisters of 10 tablets Cardboard box with 40 blisters of 10 tablets
Cardboard box with 50 blisters of 10 tablets

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater. 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 14966/5023

9. DATE OF FIRST AUTHORISATION

31 January 2008

10. DATE OF REVISION OF THE TEXT

September 2025

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Gavin Hall
Approved: 26 September 2025