

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Carproyl F 50 mg, tablets for dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains:

Active ingredient:

Carprofen 50 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet.

Circular, beige, scored tablets

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 case of known hypersensitivity to active substance or to any of the excipients.

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, hypovolaemic or hypotensive dog, as there is a potential risk of increased renal toxicity. Concurrent administration of potentially 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.

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.

Response to long term treatment should be monitored at regular intervals by a veterinary surgeon.

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.

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 dependant 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.

Due to the flavourings in the tablets, store in a secure location. 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 or IMMUNOLOGICAL 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 been 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), PGE₁ and PGE₂ by its inhibitory effect on prostaglandin biosynthesis.

5.2 Pharmacokinetic properties

After oral administration, carprofen is well absorbed in the dogs. Following the administration of the product tablets in dogs, a mean C_{max} (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

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 4 blisters of 5 tablets
Box containing 20 blisters of 5 tablets
Box containing 40 blisters of 5 tablets
Box containing 100 blisters of 5 tablets

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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 Santé Animale
Z.I. la Ballastière
33500 Libourne
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10815/003/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21st June 2013

10 DATE OF REVISION OF THE TEXT