1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carpcoat 80 mg film-coated tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Carprofen 80 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Tablet Core	
Cellulose, microcrystalline	
Saccharin sodium	
Vanillin	
Lactose monohydrate	
Sodium starch glycolate (type A)	
Magnesium stearate	
Tablet Coating	
Polyvinyl alcohol	
Talc	
Titanium dioxide	
Glycerol monocaprylocaprate	
Sodium laurilsulfate	
Iron oxide black (E172)	1.036 mg
Iron oxide red (E172)	1.829 mg
Iron oxide yellow (E172)	0.942 mg

Brown film-coated tablet with a modified ball shape (diameter 10 mm).

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

Reduction of inflammation and pain in acute and chronic diseases of the musculoskeletal system (e.g. osteoarthritis).
For the reduction of postoperative pain following soft tissue surgery after previous parenteral analgesia.

3.3 Contraindications

Do not use in cases of hypersensitivity to carprofen or to any of the excipients.
Do not use in dogs suffering from severe cardiac, hepatic or renal disease, or where there is a possibility of gastrointestinal ulceration or bleeding.

Do not use in dehydrated, hypovolemic and hypotensive animals.
Do not use in cats.
Do not use on pregnant or lactating bitches.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Use in dogs younger than 6 weeks or in aged dogs may involve additional risk. If such a use cannot be avoided, use only according to the benefit-risk assessment by the responsible veterinarian and treated dogs may require careful clinical management.
NSAIDs (non-steroidal anti-inflammatory drugs) can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infection, appropriate concurrent antimicrobial therapy should be instigated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Carprofen is a non-steroidal anti-inflammatory drug. Accidental ingestion of the veterinary medicinal product may cause gastrointestinal effects, such as nausea and gastric pain and hypersensitivity reactions. Care should be taken to avoid accidental ingestion by children. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Allergic reaction Elevated liver enzymes, hepatopathy, hepatic disorder Diarrhoea[1], melaena[1], soft stool[1], vomiting[1] Elevated renal parameters[1], increased urine volume[1], Oliguria[1] Appetite loss[1], lethargy[1], polydipsia[1]

[1]Typical side effects associated with NSAIDs; temporary, usually occur during the first week of treatment and disappear after treatment is stopped, but in very rare cases they can be very serious or even fatal. If side effects occur, treatment should be stopped immediately and the dog should be taken to a veterinarian without delay.

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.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:
Laboratory studies in laboratory animals (rat, rabbit) have shown evidence of foetotoxic effects of carprofen at doses close to the therapeutic dose.

Do not use in dogs during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Carprofen must not be administered together with glucocorticoids and other NSAIDs.
If pre-treatment with steroidal or NSAIDs, a treatment-free period should be strictly observed, otherwise possible side effects may worsen. Carprofen is highly bound to plasma proteins and competes with other highly bound drugs, which can lead to toxic effects. It should therefore not be administered simultaneously with other substances that also have a high plasma protein binding.
Concurrent administration of anticoagulants should be avoided because of the increased tendency to bleeding.
Concurrent administration of potentially nephrotoxic drugs should be avoided.

3.9 Administration routes and dosage

Oral use
Administer the dose of 4 mg carprofen per kg body weight once daily.
The specified dosage should not be increased.

The duration of treatment depends on the clinical course of the disease and should be determined by the responsible veterinarian. Long-term treatment should only be carried out under veterinary supervision. To ensure a correct dosage, body weight should be determined as accurately as possible.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No signs of toxicity were observed when dogs were administered carprofen at levels up to 9 mg/kg once daily for 14 days.
There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAIDs, should be applied.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM 01 AE 91.

4.2 Pharmacodynamics

Carprofen is a non-steroidal anti-inflammatory drug from the group of 2-arylpropionic acids. It has anti-inflammatory, analgesic and antipyretic activity.
Carprofen, like most NSAIDs, is a specific inhibitor of cyclooxygenase in the arachidonic acid cascade. This interrupts prostaglandin synthesis. The prostaglandins play an important role in the formation of inflammatory reactions and as one of the protective mechanisms for the mucous membrane of the gastrointestinal tract against ulceration. Cyclooxygenase (COX) has two isoenzymes, COX-1 and COX-2. The COX-1 enzyme is constantly in the blood and has autoregulatory functions (e.g. mucosa protection in the gastrointestinal tract and kidney protection).

In contrast, COX-2 is not constantly in the blood. It is believed that this enzyme induces the inflammatory process. It is concluded that the degree of inhibition of COX-1 determines the rate of gastrointestinal ulceration and the ratio of the isoenzymes to one another determines the rate of side effects or effectiveness. In dogs carprofen has a favourable COX-2:COX-1 ratio.

The exact other mechanisms of action of carprofen have not yet been fully elucidated.

4.3 Pharmacokinetics

In dogs the absorption of carprofen is rapid. After a single oral administration of 4 mg of carprofen per kg of bodyweight in dogs, the mean time to obtain a maximum plasma concentration of 26 µg/ml is one hour (0.25-2 hours). The body volume of distribution is low because the binding to plasma protein is 99%. The harmonic mean half-life (t½) is 6.4 hours.
Carprofen is mainly excreted in the bile with 70 % of an intra-venous dose of carprofen being eliminated in the faeces, mainly as the glucuronide conjugate, and 8-15 % via urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.

5.3. Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

PVC/PE/PVDC-aluminium blisters, containing 10 tablets each.
Pack sizes:
Cardboard box of 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120 or 250 tablets.

Not all pack sizes may be marketed.

5.5 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 or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10980/047/004

8. DATE OF FIRST AUTHORISATION

9 DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

01/10/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).