1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 50 mg Tablets for Dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Carprofen 50 mg

Excipients:

Qualitative composition of excipients and other constituents
Cellulose, Microcrystalline
Lactose Monohydrate
Croscarmellose Sodium
Povidone K30
Sodium Laurilsulfate
Magnesium Stearate

A white/off white circular tablet with a break line on one face and "50" scored on the opposing face.

3 CLINICAL INFORMATION

3.1 Target Species

Dogs.

3.2 Indications for use, for each target species

For analgesia and reduction of chronic inflammation in musculoskeletal disturbances in dogs, for example in degenerative joint disease.

3.3 Contraindications

Do not use in cats. Do not use in dogs suffering from cardiac, hepatic or renal disease, where there is a possibility of gastrointestinal ulceration or bleeding, or where there is evidence of a blood dyscrasia. Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use in dogs less than 6 weeks of age, or in aged animals, may involve additional risk. If such use cannot be avoided, such 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. 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

None.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse reactions

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

[1]As with other NSAIDs there is a risk of renal or idiosyncratic hepatic adverse events.
[2]Typical undesirable effects associated with NSAIDs that generally occur within the first week of treatment. Transient and disappear after treatment is stopped, but in very rare cases, may be serious or fatal. If adverse reactions occur, stop treatment, and seek the advice of a veterinarian.

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 nation competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The use is not recommended during pregnancy or lactation.

3.8 Interaction with other medicinal products and other forms of interactions

Do not administer 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. Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given non-steroidal anti-inflammatory drugs.

Monitor drug compatibility closely where adjunctive therapy is required.

3.9 Administration routes and dosage

For oral use.
The tablets can be divided into equal halves.
An initial dose of 2 to 4 mg carprofen/kg bodyweight/day is recommended to be given as a single daily dose or in 2 equally divided doses. To ensure a correct dosage body weight should be determined as accurately as possible.

The dose may be reduced to 2 mg carprofen/kg bodyweight/day administered as a single daily maintenance dose after 7 days, subject to clinical response: see maintenance dose table below:

Maintenance Dose Table	Number of tablets per dose
Bodyweight (kg)	50 mg
5.0	-
10.0	-
12.5	1/2
15.0	-
20.0	-
25.0	1
37.5	1 + 1/2
50	2

Duration of treatment will be dependent upon the response seen. Long-term treatment should be under regular veterinary supervision.

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

Do not exceed the stated dose. 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, indicating restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12Withdrawal periods

Not applicable.

4 PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QM01AE91

4.2 Pharmacodynamics

Carprofen, (±)-6-chloro-α-methylcarbazole-2-acetic acid, is a non-steroidal anti-inflammatory drug (NSAID). It is a derivative of phenylpropionic acid and a member of the arylpropionic acid class of NSAIDs. As a representative of the 2-arylpropionic family, it contains a chiral center at C_2 of the propionic moiety and therefore, exists in 2 sterioisomeric forms, the (+)-S and (-)-R enantiomers. Carprofen, like most other NSAIDs is an inhibitor of the enzyme cyclo-oxygenase of the arachidonic acid cascade. It has been reported that the inhibition of prostaglandin synthesis by Carprofen is slight in relation to its anti-inflammatory and analgesic potency. The precise mode of action of Carprofen is not clear.

4.3 Pharmacokinetics

Following oral administration of 4 mg carprofen/kg to dogs, peak plasma concentrations (mean Cmax = 28.51 microgram/ml) were achieved in 4 hours.
Absorption of carprofen is rapid and complete in the dog. The volume of distribution is small with the highest drug concentrations occurring in plasma. Ratios of tissue to plasma concentration are less than one which is consistent with a high level of binding of carprofen to plasma proteins.

5 PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale:
Polypropylene tubs: 3 years.
Blister packs: 2 years.

5.3 Special precautions for storage

Do not store above 25ºC.
Store in a dry place.
Protect from light.

5.4 Nature and composition of immediate packaging

Polypropylene snap secure tubs sealed with cotton wool and white polyethylene snap secure caps in tubs of 100 and 500. Alu/Alu blister strips containing 10 (50 mg) tablets per strip in cartons of 20, 100 and 500 tablets.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Norbrook Laboratories (Ireland) Limited

7 MARKETING AUTHORISATION NUMBER(S)

VPA22664/071/002

8 DATE OF FIRST AUTHORISATION

25 July 2003

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

22/01/2025

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).