1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprogesic 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

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

3.3 Contraindications

Do not use in cats.
Do not use in pregnant or lactating bitches.
Do not use in puppies less than 4 months of age.
Do not use in cases of hypersensitivity to the 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 gastrointestinal ulceration or bleeding, or where there is evidence of a blood dyscrasia.
Do not use in animals suffering from haemorrhagic syndrome.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use in aged dogs may involve additional risk. If such a 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:

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after handling the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

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 rare 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 national 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 safety of the veterinary medicinal product has not been established during pregnancy and lactation. Laboratory studies in rats and rabbits have shown evidence of fetotoxic effects of carprofen at doses close to the therapeutic dose. Do not use in pregnant or lactating bitches.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer NSAIDs and glucocorticoids 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.

3.9 Administration routes and dosage

Oral use.

4 mg carprofen per kg bodyweight per day.
An initial dose of 4 mg carprofen per kg bodyweight per day given as a single 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 pre-operative treatment with an injectable Carprofen product may be followed with Carprofen Tablets at 4 mg/kg/day for up to 5 days.
Return any halved tablets to the blister pack and use within 48 hours.
See dosage table below:

Bodyweight (kg)	Number of tablets to be administered twice daily
12.5	◖
25.0	●
37.5	●◖
50	●●

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, 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:
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 centre at C2 of the propionic moiety and therefore, exists in 2 sterioisomeric forms, the (+)-S and (-)-R enantiomers.

Carprofen possesses anti-inflammatory, analgesic and anti-pyretic activity.

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

Absorption is rapid with >90 % absorption after oral administration. The volume of distribution is small and carprofen is highly bound to plasma proteins. Biotransformation of carprofen occurs in the liver to form the ester glucuronide and two 1-O-acyl-β-D-glucuronide diastereoisomers. These are secreted in the biliary tract and excreted in the faeces.
The C_{max} is 28.51 μg/ml and the AUC is 237.33 μg/ml.hour.

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 25 ºC.

Protect from light.
Store in a dry place.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is supplied in either:
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)

VPA22664/079/002

8. DATE OF FIRST AUTHORISATION

08 December 2006

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

14 February 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).