Summary of Product Characteristics

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:
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablets:
A white/off white circular tablet with a break line on one face and "50" scored on the opposing face.
The tablets can be divided into equal halves.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

In the dog: 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.

4.3 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 case of 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 gastrointestinal ulceration or bleeding, or where there is evidence of a blood dyscrasia.

Do not use in animals suffering from hemorrhagic syndrome.

4.4 Special warnings for each target species

Refer to statements under 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, 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.
Refer to section 4.8.

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. If adverse reactions occur, use of the veterinary medicinal product should be stopped and the advice of a veterinarian should be sought. As with other NSAIDs there is a risk of rare 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. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use in pregnant or lactating bitches.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts 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 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.
Do not exceed the stated dose.
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	●●

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

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.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Non-steroidal anti-inflammatory drug
ATC Vet Code: QM01AE91

5.1 Pharmacodynamic properties

Carprofen, (±)-6-chloro-a-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 possesses anti-inflammatory, anaglesic 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.

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose, Microcrystalline
Lactose Monohydrate
Croscarmellose Sodium
Povidone K30
Sodium Laurilsulfate
Magnesium Stearate

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Carprogesic 50 mg Tablets are 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.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/079/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 December 2006
Date of last renewal: 07 December 2011

10 DATE OF REVISION OF THE TEXT

February 2019