# Summary of Product Characteristics

## 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:***
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

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

### 4.3 Contraindications

Use of this product in cats is contra-indicated.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 or hypersensitivity to the product.

### 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 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.

**4.6 Adverse reactions (frequency and seriousness)**

Typical undesirable effects associated with NSAIDs, such as vomiting, soft faeces/diarrhoea, 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 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**

This product is not indicated for use in pregnant or lactating bitches.

**4.8 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.

**4.9 Amounts to be administered and administration route**

For oral administration.

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.

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 and 1/2 |
| 50 | 2 |

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

**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-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.

### 5.2 Pharmacokinetic particulars

Following oral administration of 4mg 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.

## 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

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)**

VPA22664/071/002

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 25 July 2003
Date of last renewal: 28 April 2009

**10 DATE OF REVISION OF THE TEXT**

January 2019