Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 50 mg Flavoured Tablets for Dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active Substance:

Carprofen	50 mg

Excipients:

For the full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Tablet.
Light brown, round, flat, bevel edged tablet.
The tablets can be divided into equal parts.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

For analgesia and reduction of chronic inflammation, for example in degenerative joint disease in the dog.

The tablets also can be used in the management of post operative pain.

4.3 Contraindications

Do not exceed the stated dose.

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 blood dyscrasia or hypersensitivity to the product.

Do not use in puppies less than 4 months.

Do not use in cases of hypersensitivity to active substance or to any of the excipients.

Refer to section 4.7 and 4.8

4.4 Special warnings for each target species

See sections 4.3 and 4.5.

4.5 Special precautions for use

i.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 rise 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.

The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

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

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

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 generally occur 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.

As with other NSAIDs there is a risk of rare renal or idosyncratic 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. For breeding animals, do not use during reproduction period.

4.8 Interaction with other medicinal products and other forms of interactions

Carprofen is highly bound to plasma proteins and compete with other highly bound drugs, which can increase their respective toxic effects. Do not use this veterinary medicinal product concurrently with or within 24 hours of other NSAIDs or concurrently with glucocorticoids.
Concurrent administration of potentially nephrotoxic drugs should be avoided. Refer also to section 4.5.

Do not administer concurrently with anticoagulants.

4.9 Amounts to be administered and administration route

For oral administration. The tablets are palatable and willingly consumed by most dogs when offered.
2 to 4 mg carprofen per kg bodyweight per day.
An initial dose of 4 mg carprofen per kg bodyweight per day given as a single daily dose or in two equally divided doses may, subject to clinical response, be reduced after 7 days to 2 mg carprofen/kg bodyweight/day given as a single dose.
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 preoperative treatment may be followed with Carprofen tablets at 4mg/kg/day for up to 5 days.
Do not exceed the stated dose.

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

No signs of toxicity were observed when dogs were administered the product at levels up to 6 mg/kg twice daily for 8 days (3 times the maximum recommended dose rate of 4 mg/kg/day) and 6 mg/kg once daily for a further 7 days (1.5 times the maximum recommended dose rate of 4 mg/kg/day).

There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAIDs, should be applied.

Severe adverse reactions may occur if large quantities are ingested. If you suspect that your dog has consumed tablets above the labelled dose, contact your veterinarian.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids, proprionic acid derivatives, carprofen.
ATC Vet Code: QM01AE91

5.1 Pharmacodynamic properties

Carprofen is a member of the 2-arylpropionic acid group of non steroidal anti-inflammatory drugs (NSAIDs) and possesses anti-inflammatory, analgesic and antipyretic activity.

Carprofen like most other NSAIDs is an inhibitor of the enzyme cyclo-oxygenase of the arachidonic acid cascade. However the inhibition of prostaglandin synthesis by carprofen is slight in relation to its anti-inflammatory and analgesic potency. At therapeutic doses in the dog inhibition of the products of cyclo-oxygenase (prostaglandins and thromboxanes) or lipoxygenase (leukotrienes) has been absent or slight. The precise mode of action of carprofen is not clear.

5.2 Pharmacokinetic particulars

After a single oral administration of 4 mg of carprofen per kg of bodyweight in dogs, the time to obtain a maximum plasmatic concentration of 31 µg/ml is 2.5 hours. The oral bioavailability is more than 90 % of the total dose. Carprofen is more than 98 % bound to plasma proteins and its volume of distribution is low. Carprofen is excreted in the bile with 70 % of an intra-venous dose of carprofen being eliminated in the faeces, mainly as the glucuronide conjugate. Carprofen undergoes an enantioselective enterohepatic cycle in dogs, with only the S(+) enantiomer being significantly recycled. The plasmatic clearance of the S(+) carprofen is about twice that of the R(-) carprofen. The biliary clearance of S(+) carprofen seems to be subject to stereoselectively too as it is about three times higher than that of R(-) carprofen.

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Sodium laurilsulfate
Spray dried pig liver powder EHT
Sucrose
Yeast extract (dried)
Ground wheatgerm
Starch pregelatinised
Povidone K30
Microcrystalline cellulose
Guar gum
Magnesium stearate

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf-life after first opening the immediate packaging: 24 hours.
Any divided tablet portions remaining after 24 hours should be discarded.

6.4 Special precautions for storage

Store in a dry place.
Protect from light.
Do not store above 25 ºC.
Divided tablets should be stored in the blister pack.

6.5 Nature and composition of immediate packaging

Aluminium-Aluminium packs of 5 tablets per strip in cartons containing 20, 100, 200, or 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 materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/091/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 March 2011
Date of last renewal: 20 March 2016

10 DATE OF REVISION OF THE TEXT

January 2019