Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Carporal 40 mg tablets for dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Carprofen 40 mg

Excipient(s):
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.
Light brown with brown spots, round and convex flavoured tablet with a cross-shaped break line on one side.
Tablets can be divided into 2 or 4 equal parts.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the 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.

4.3 Contraindications

Do not use in cats.
Do not use in pregnant or lactating bitches.
Do not use in dogs less than 4 months of age.
Do not use in known 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.

4.4 Special warnings for each target species

Refer to 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, dogs may require 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.
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

See 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 package leaflet or the label to the physician. 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 very rarely. 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.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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.

See section 4.3.

4.8 Interaction with other medicinal products and other forms of interactions

Do not administer other NSAIDs and glucocorticoids concurrently or within 24 hours of administration of the product.
Carprofen is highly bound to plasma proteins and may 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

Oral use.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid overdosing.

Dosage
2-4 mg carprofen per kg bodyweight per day.
For reduction of inflammation and pain caused by musculoskeletal disorders and degenerative joint disease: 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 to 2 mg carprofen/kg bodyweight/day given as a single dose. Duration of treatment depends on the response observed in the patient. For treatment beyond 14 days the dog should be regularly examined by a veterinarian.
Do not exceed the recommended dosage.
To extend analgesic and anti-inflammatory cover post-operatively, parenteral preoperative treatment with an injectable carprofen product may be followed by carprofen tablets at 4 mg/kg bw/day for up to 5 days.

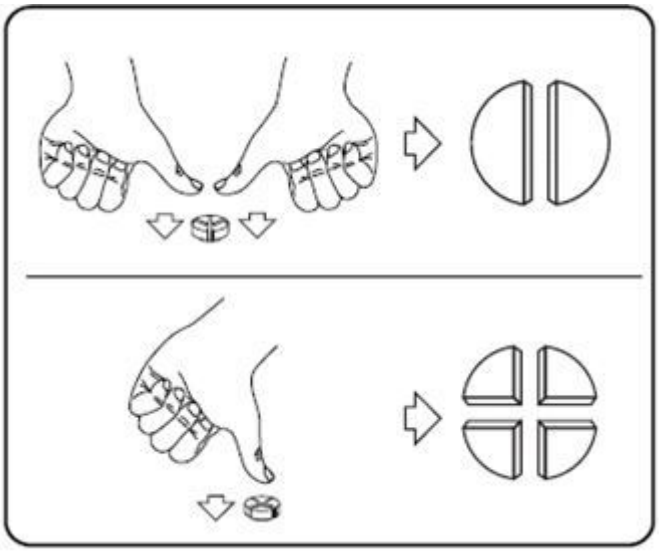
The following table is intended as a guide to dispensing the product at the dose rate of 4 mg per kg bodyweight per day.

Number of tablets for a dose rate of 4 mg/kg bw

Body weight (kg)	Carporal 40 mg Once daily	Carporal 40 mg Twice daily	Carporal 160 mg Once daily	Carporal 160 mg Twice daily
>2.5kg - 5 kg	¼			
>5 kg - 7.5 kg	½	¼ + ¼		
>7.5 kg - 10 kg	¾	½ + ¼		
>10 kg - 12.5 kg	1	½ + ½		
>12.5 kg - 15 kg	1 + ¼	¾ + ½		
>15 kg - 17.5 kg	1 + ½	¾ + ¾		
>17.5 kg - 20 kg	1 + ¾	1 + ¾		
>20 kg - 25 kg	1 + 1	1 + 1	½	¼ + ¼
>25 kg - 30 kg	1 + 1 + ½	1 + ¼ + 1 + ¼		
>30 kg -35 kg	1 + 1 + 1	1 + ½ + 1 + ½	¾	½ + ¼
>35 kg - 40 kg	1 + 1 + 1 + ½	1 + ¾ + 1 + ¾		
>40 kg - 50 kg	1 + 1 + 1 + 1	1 + 1 + 1 + 1	1	½ + ½
>50 kg - 60 kg			1 + ¼	¾ + ½
>60 kg - 70 kg			1 + ½	¾ + ¾
>70 kg - 80 kg			1 + ¾	1 + ¾

¼ = ¼ Tablet ½ = ½ Tablet ¾ = ¾ Tablet 1 = 1 Tablet

Tablets can be divided into 2 or 4 equal parts to ensure accurate dosing. Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



Halves: press down with your thumbs on both sides of the tablet.
Quarters: press down with your thumb in the middle of the tablet.

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

No signs of toxicity appeared when dogs were treated with carprofen at levels up to 6 mg/kg bw twice daily for 7 days (3 times the highest recommended dose rate of 4 mg/kg bw) and 6 mg/kg bw once daily for a further 7 days (1.5 times the highest recommended dose rate of 4 mg/kg bw).

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

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti inflammatory and antirheumatic products, non-steroids. Propionic acid derivatives, Carprofen.
ATCvet code: QM01AE91

5.1 Pharmacodynamic properties

Carprofen is a non-steroidal anti-inflammatory drug (NSAID). It is derived from phenylpropionic acid and belongs to the 2-arylpropionic acid class of NSAIDs. It contains a chiral center at the C_2 of the propionic half and therefore exists in two stereo isomeric forms, the (+)-S and (-)-R enantiomers. In dogs there is no chiral inversion between the enantiomers *in-vivo*.

Carprofen possesses anti-inflammatory, analgesic and antipyretic activity. Like most other NSAID's, carprofen 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. The precise mode of action of carprofen is not clear.

5.2 Pharmacokinetic particulars

In dogs the absorption of carprofen is rapid (T_{max} =2.0 h) after oral administration. C_{max} is 28.67 µg/ml. The volume of distribution is small and carprofen is highly bound to plasma proteins. The biotransformation of carprofen takes place in the liver the ester glucuronide and two 1-O-acyl-β-D-glucuronide diastereoisomers are formed. These are secreted into the bile duct and excreted in the faeces.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Sodium Starch Glycolate (Type A)
Maize Starch
Talc
Cellulose, powdered
Starch, pregelatinised
Silica, colloidal anhydrous
Calcium Behenate
Yeast, deactivated
Artificial beef flavour

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
A divided tablet should be used within 3 days.

6.4 Special precautions for storage

Any unused tablet portions should be returned to the open blister in order to protect from light.

The unopened blister does not require any special storage condition.

6.5 Nature and composition of immediate packaging

Aluminium - PA/ALU/PVC blister
Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 25 or 50 blisters of 10 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/national requirements.

7 MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA10475/019/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 July 2015
Date of last renewal: 09 July 2020

10 DATE OF REVISION OF THE TEXT

July 2020