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

Excipients:

Qualitative composition of excipients and other constituents
Lactose Monohydrate
Sodium Starch Glycolate (Type A)
Maize Starch
Talc
Cellulose, powdered
Starch, pregelatinised
Silica, colloidal anhydrous
Calcium Behenate
Yeast, deactivated
Artificial beef flavour

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.

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 dogs 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.

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, 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 (non-steroidal anti-inflammatory drugs) 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 3.8.

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

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Renal disorder Hepatic disorder [b]
Very Rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting[a], Loose Stool[a], Diarrhoea[a], Blood in faeces[a] Lethargy[a], Appetite Loss[a]

[a] 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.
[b] Idiosyncratic effect

If adverse reactions occur, use of the veterinary medicinal product should be stopped and the advice of a veterinarian should be sought.

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
Laboratory studies in rats and rabbits 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 3.3.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with other NSAIDs and glucocorticoids or within 24 hours of administration of the veterinary medicinal 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.

3.9 Administration routes and dosage

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 veterinary medicinal product may be followed by carprofen tablets at 4 mg/kg bw/day for up to 5 days.

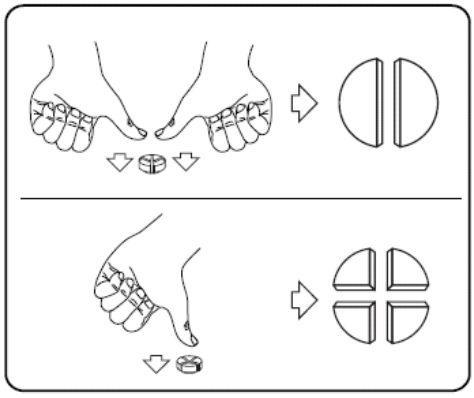
The following table is intended as a guide to dispensing the veterinary medicinal product at the dose rate of 4 mg per kg bodyweight per day.

	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				
>5 kg - 7.5 kg				
>7.5 kg - 10 kg				
>10 kg - 12.5 kg				
>12.5 kg - 15 kg				
>15 kg - 17.5 kg				
>17.5 kg - 20 kg				
>20 kg - 25 kg				
>25 kg - 30 kg				
>30 kg -35 kg				
>35 kg - 40 kg				

>40 kg - 50 kg					
>50 kg - 60 kg					
>60 kg - 70 kg					
>70 kg - 80 kg					

= ¼ Tablet = ½ Tablet = ¾ Tablet = 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

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 is a 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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

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

5.3 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.

5.4 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.

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

Le Vet. Beheer B.V.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10475/019/001

8. DATE OF FIRST AUTHORISATION

10/07/2015

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

13/02/2024

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).