

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carporal 40 mg tablets for dogs

(AT, BE, CY, CZ, EL, ES, FR, HR, HU, IE, IT, LU, NL, PT, RO, SI, SK, UK)

Canicaral vet 40 mg tablets for dogs

(DK, FI, IS, NO, SE, EE, LT, LV, PL)

## 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 <sup>b</sup>
Very Rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting <sup>a</sup> , Loose Stool <sup>a</sup> , Diarrhoea <sup>a</sup> , Blood in faeces <sup>a</sup> Lethargy <sup>a</sup> , Appetite Loss <sup>a</sup>

<sup>a</sup> 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.

<sup>b</sup> 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					

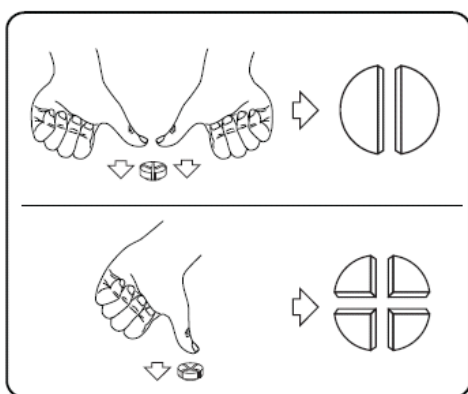
= ¼ Tablet

= 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<sub>2</sub> 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)**

## **8. DATE OF FIRST AUTHORISATION**

Date of first authorisation:> <{DD/MM/YYYY}> <{DD month YYYY}.

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

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month YYYY}>

## **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) (<https://medicines.health.europa.eu/veterinary>).

## **ANNEX II**

### **LABELLING AND PACKAGE LEAFLET**



## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE****Outer cardboard box****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Carporal 40 mg tablets

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each tablet contains: 40 mg carprofen

**3. PACKAGE SIZE**

10 tablets  
20 tablets  
30 tablets  
40 tablets  
50 tablets  
60 tablets  
70 tablets  
80 tablets  
90 tablets  
100 tablets  
250 tablets  
500 tablets

**4. TARGET SPECIES**

Dogs

**5. INDICATIONS****6. ROUTES OF ADMINISTRATION**

Oral use.

**7. WITHDRAWAL PERIODS****8. EXPIRY DATE**

Exp. {mm/yyyy}

A divided tablet should be used within 3 days.

<b>9. SPECIAL STORAGE PRECAUTIONS</b>
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Any unused tablet portions should be returned to the open blister in order to protect from light.

<b>10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”</b>
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Read the package leaflet before use.

<b>11. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b>
--

For animal treatment only.

<b>12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”</b>
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Keep out of the sight and reach of children.

<b>13. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
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Le Vet. Beheer B.V.

<b>14. MARKETING AUTHORISATION NUMBERS</b>
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<b>15. BATCH NUMBER</b>
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Lot {number}

<b>MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS</b>
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<b>Alu-PA/ALU/PVC blisters</b>
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<b>1. NAME OF THE VETERINARY MEDICINAL PRODUCT</b>
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Carporal



<b>2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES</b>
---

40 mg/tablet

<b>3. BATCH NUMBER</b>
------------------------

Lot {number}

<b>4. EXPIRY DATE</b>
-----------------------

Exp. {mm/yyyy}

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### **1. Name of the veterinary medicinal product**

Carporal 40 mg tablets for dogs

### **2. Composition**

Each tablet contains:

#### **Active substance:**

Carprofen 40 mg

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. Target species**

Dogs.

### **4. Indications for use**

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.

### **5. 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 heart-, liver-, or kidney disease where there is a possibility of gastrointestinal ulceration (ulceration of the stomach and intestine) or bleeding, or where there is evidence of blood dyscrasia (blood disorder).

### **6. Special warnings**

#### 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 (low blood volume) or hypotensive (low blood pressure) dogs, as there is a potential risk of increased renal toxicity (kidney damage).

Non-steroidal anti-inflammatory drugs (NSAID) like carprofen can cause inhibition of phagocytosis (one of the mechanisms of the immune system) 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 also the section on: Interaction with other medicinal products and other forms of interaction.

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.

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 “Contraindications”.

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.

Overdose:

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.

## **7. Adverse events**

Dogs:

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

<sup>a</sup> 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.

<sup>b</sup> 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

{< > to be adjusted nationally}

## 8. Dosage for each species, routes and method of administration

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 postoperatively, parenteral preoperative treatment with an injectable carprofen veterinary medicinal product may be followed by carprofen tablets at 4 mg/kg/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.

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>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				 	 

 = 1/4 Tablet

 = 1/2 Tablet

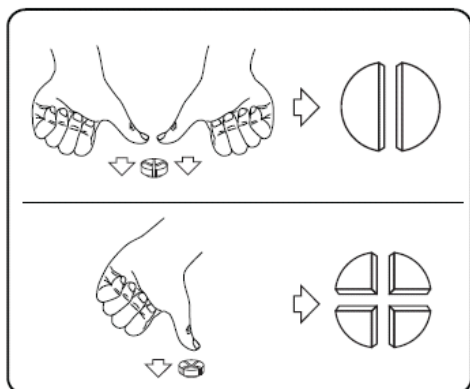
 = 3/4 Tablet

 = 1 Tablet



## **9. Advice on correct administration**

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.

## **10. Withdrawal periods**

Not applicable.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

A divided tablet should be used within 3 days.

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister and the carton after Exp.

The expiry date refers to the last day of that month.

## **12. Special precautions for disposal**

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. Marketing authorisation numbers and pack sizes**

Marketing authorisation number(s): {to be completed nationally}

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.

**15. Date on which the package leaflet was last revised**

<{MM/YYYY}>  
<{DD/MM/YYYY}>  
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).

**16. Contact details**

Marketing authorisation holder and contact details to report suspected adverse reactions:

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

Manufacturer responsible for batch release:

Artesan Pharma GmbH & Co KG  
Wendlandstrasse 1, Lüchow  
29439, Germany

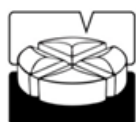
Lelypharma B.V.  
Zuiveringweg 42  
8243 PZ Lelystad  
The Netherlands

Genera d.d.  
Svetonedeljska cesta 2, Kalinovica  
10436 Rakov Potok  
Croatia

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

**17. Other information**



Divisible tablet