

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard box**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Carporal 40 mg tablets for dogs  
carprofen



**2. STATEMENT OF ACTIVE SUBSTANCES**

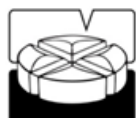
Each tablet contains:

**Active substance:**

Carprofen 40.0 mg

**3. PHARMACEUTICAL FORM**

Tablet.



Divisible tablet

**4. 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

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For oral use.  
Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP:  
A divided tablet should be used within 3 days.

**11. SPECIAL STORAGE CONDITIONS**

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

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only.  
To be supplied only on veterinary prescription

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 41821/4024

<b>17. MANUFACTURER'S BATCH NUMBER</b>
--

Lot

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Alu-PA/ALU/PVC blisters**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Carporal 40 mg tablets  
carprofen



**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Le Vet. Beheer B.V.

**3. EXPIRY DATE**

EXP:

**4. BATCH NUMBER**

Lot.

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

## **B. PACKAGE LEAFLET**

## **PACKAGE LEAFLET:**

### **Carporal 40 mg tablets for dogs**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER  
AND OF THE MANUFACTURING AUTHORISATION HOLDER  
RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:

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

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Carporal 40 mg tablets for dogs  
carprofen

**3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS**

Each tablet contains:

**Active substance:**

Carprofen 40.0 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.

**4. INDICATION(S)**

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 known 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. ADVERSE REACTIONS**

Typical undesirable effects associated with NSAIDs (non-steroidal anti-inflammatory drugs) such as vomiting, soft faeces/diarrhea, faecal occult blood (blood in stool that is not visibly apparent), loss of appetite and lethargy (lack of energy) 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 (kidney) or idiosyncratic hepatic (liver) 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).

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 inform your veterinary surgeon.

## **7. TARGET SPECIES**

Dogs

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 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 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

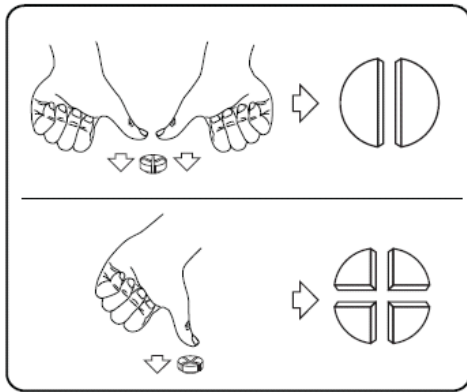
 = ½ Tablet

 = ¾ Tablet

 = 1 Tablet

## 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 PERIOD(S)**

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 WARNING(S)**

Special warnings for each target species

See sections “Contraindications” and “Special precautions for use in animals”.

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 (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 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 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.

Pregnancy and lactation

Studies in laboratory species (rat and rabbit) have shown evidence of foetotoxic effects (harmful effects on the foetus) 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 also section "Contraindications"

Interaction with other medicinal products and other forms of interaction:

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.

Overdose (symptoms, emergency procedures, 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.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

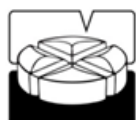
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

July 2020

**15. OTHER INFORMATION**

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



Divisible tablet



Approved 29 July 2020