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 160 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains: 160 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.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet. Beheer B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 41821/3004

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Alu-PA/ALU/PVC blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carporal

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

160 mg/tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Carporal 160 mg tablets for dogs

2. Composition

Each tablet contains:

Active substance:

Carprofen 160 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 [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 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: Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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 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.

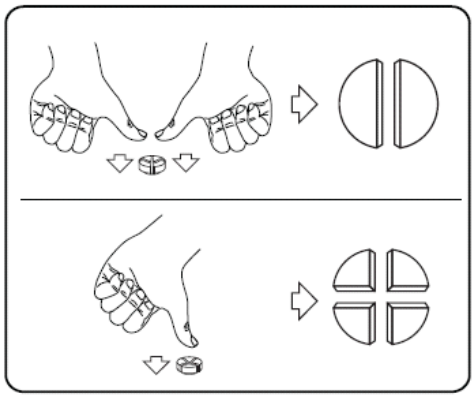
	Number of tablets for a dose rate of 4 mg/kg bw				
Body weight (kg)	Carporal 40 mg Once daily	Carporal 40 mg Twice daily		Carporal 160 mg Once daily	Carporal 160 mg Twice daily
>2.5kg - 5 kg					
>5 kg - 7.5 kg					

>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 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: Vm 41821/3004
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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

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

OR

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

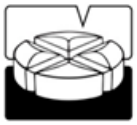
OR

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

Gavin Hall

Approved: 27 December 2024