# 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 160 mg tablets for dogs
Carprofen

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

**Active substance:**
Carprofen 160 mg

## 3. PHARMACEUTICAL FORM

Tablet.

[redacted]
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

## 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 41821/4025

## 17. MANUFACTURER'S BATCH NUMBER

Lot

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

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

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carporal 160 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 160 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 160 mg tablets for dogs
carprofen

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

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.

## 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 2 mg carprofen/kg bodyweight/day given as a single

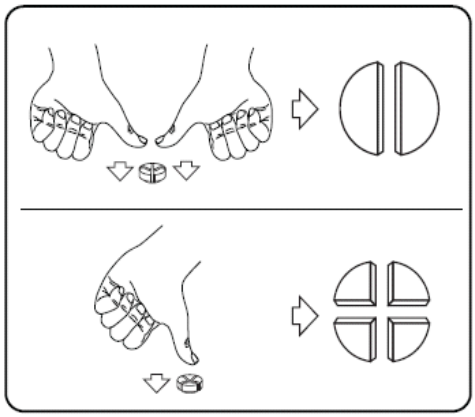
dose. Duration of treatment depends on the response observed in the patient. For treatment beyond 14 days the dog should be regularly examined by a veterinarian. Do not exceed the recommended dosage.
To extend analgesic and anti-inflammatory cover postoperatively, parenteral preoperative treatment with 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 | ¼ | | | |
| >5 kg - 7.5 kg | ½ | ¼ + ¼ | | |
| >7.5 kg - 10 kg | ¾ | ¼ + ¼ | | |
| >10 kg - 12.5 kg | 1 | ¼ + ¼ | | |
| >12.5 kg - 15 kg | 1 + ¼ | ½ + ¼ | | |
| >15 kg - 17.5 kg | 1 + ½ | ½ + ½ | | |
| >17.5 kg - 20 kg | 1 + 1 | ½ + ½ | | |
| >20 kg - 25 kg | 1 + 1 | ½ + ½ | ½ | ¼ + ¼ |
| >25 kg - 30 kg | 1 + 1 + ½ | ½ + ¼ + ½ + ¼ | | |
| >30 kg -35 kg | 1 + 1 + 1 | ½ + ¼ + ½ + ¼ | 1 | ¼ + ¼ |
| >35 kg - 40 kg | 1 + 1 + 1 + ½ | ½ + ½ + ½ + ½ | | |
| >40 kg - 50 kg | 1 + 1 + 1 + 1 | ½ + ½ + ½ + ½ | 1 | ¼ + ¼ |
| >50 kg - 60 kg | | | 1 + ¼ | ½ + ¼ |
| >60 kg - 70 kg | | | 1 + ½ | ½ + ½ |
| >70 kg - 80 kg | | | 1 + 1 | ½ + ½ |

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

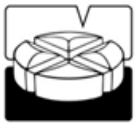
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

## 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 31 July 2020