

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carpcoat 8 mg film-coated tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Carprofen 8 mg

3. PACKAGE SIZE

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

4. TARGET SPECIES

Dogs



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

Alfasan Nederland B.V.

14. MARKETING AUTHORISATION NUMBER

Vm 36408/3053

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Aluminium blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carpcoat



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Carprofen 8 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

Carpcoat 8 mg film-coated tablets for dogs
Carpcoat 20 mg film-coated tablets for dogs
Carpcoat 40 mg film-coated tablets for dogs
Carpcoat 80 mg film-coated tablets for dogs

2. Composition

Each tablet contains:

Carpcoat 8 mg

Active substance:

Carprofen 8 mg

Excipients:

Iron oxide black (E172) 0.001 mg
Iron oxide red (E172) 0.002 mg
Pink film-coated tablet with a biconvex shape (size 5 mm).

Carpcoat 20 mg

Active substance:

Carprofen 20 mg

Excipients:

Iron oxide red (E172) 0.0004 mg
Iron oxide yellow (E172) 0.157 mg
Yellow film-coated tablet with a modified ball shape (size 6 mm).

Carpcoat 40 mg

Active substance:

Carprofen 40 mg

Excipients:

Iron oxide red (E172) 0.070 mg
Iron oxide yellow (E172) 0.616 mg
Orange film-coated tablet with a modified ball shape (size 8 mm).

Carpcoat 80 mg

Active substance:

Carprofen 80 mg

Excipients:

Iron oxide black (E172) 1.036 mg
Iron oxide red (E172) 1.829 mg
Iron oxide yellow (E172) 0.942 mg

Brown film-coated tablet with a modified ball shape (size 10 mm).

3. Target species

Dogs

4. Indications for use

Reduction of inflammation and pain in acute and chronic diseases of the musculoskeletal system (e.g. osteoarthritis).

For the reduction of postoperative pain following soft tissue surgery after previous parenteral analgesia.

5. Contraindications

Do not use in cases of hypersensitivity to carprofen or to any of the excipient(s).

Do not use in dogs suffering from severe cardiac, hepatic or renal disease, or where there is a possibility of gastrointestinal ulceration or bleeding.

Do not use in dehydrated, hypovolemic and hypotensive animals.

Do not use in cats.

Do not use on pregnant or lactating bitches.

6. Special warnings

Special precautions for safe use in the target species:

Use in dogs younger than 6 weeks or in aged dogs may involve additional risk. If such a use cannot be avoided, use only according to the benefit-risk assessment by the responsible veterinarian and treated dogs may require careful clinical management. 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Carprofen is a non-steroidal anti-inflammatory drug. Accidental ingestion of the veterinary medicinal product may cause gastrointestinal effects, such as nausea and gastric pain and hypersensitivity reactions. Care should be taken to avoid accidental ingestion by children. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Wash hands after use.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Laboratory studies in laboratory animals (rat, rabbit) have shown evidence of foetotoxic effects of carprofen at doses close to the therapeutic dose.

Do not use in dogs during pregnancy or lactation.

Interaction with other medicinal products and other forms of interaction:

Carprofen must not be administered together with glucocorticoids and other NSAIDs.

If pre-treatment with steroidal or non-steroidal anti-inflammatory drugs, a treatment-free period should be strictly observed, otherwise possible side effects may worsen.

Carprofen is highly bound to plasma proteins and competes with other highly bound

drugs, which can lead to toxic effects. It should therefore not be administered simultaneously with other substances that also have a high plasma protein binding. Concurrent administration of anticoagulants should be avoided because of the increased tendency to bleeding.

Concurrent administration of potentially nephrotoxic drugs should be avoided.

Overdose:

No signs of toxicity were observed when dogs were administered carprofen at levels up to 9 mg/kg once daily for 14 days.

There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAIDs, should be applied.

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Allergic reaction Elevated liver enzymes, hepatopathy, hepatic disorder Diarrhoea ¹ , melaena ¹ , soft stool ¹ , vomiting ¹ Elevated renal parameters ¹ , increased urine volume ¹ , Oliguria ¹ Appetite loss ¹ , lethargy ¹ , polydipsia ¹
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¹Typical side effects associated with NSAIDs; temporary, usually occur during the first week of treatment and disappear after treatment is stopped, but in very rare cases they can be very serious or even fatal. If side effects occur, treatment should be stopped immediately and the dog should be taken to a veterinarian without delay.

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 its local representative using the contact details at the end of this leaflet, or via your national reporting system.

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

Oral use.

Administer the dose of 4 mg carprofen per kg body weight once daily. The specified dosage should not be increased.

The duration of treatment depends on the clinical course of the disease and should be determined by the responsible veterinarian. Long-term treatment should only be carried out under veterinary supervision. To ensure a correct dosage, body weight should be determined as accurately as possible.

9. Advice on correct administration

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister/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

Vm 36408/3053 (8mg)

Vm 36408/3054 (20mg)

Vm 36408/3054 (40mg)

Vm 36408/3054 (80mg)

PVC/PE/PVDC-aluminium blisters, containing 10 tablets each.

Cardboard box of 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120 or 250 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 manufacturer responsible for batch release and contact details to report suspected adverse events:

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands
Tel: +31(0)348 416945

Manufacturer responsible for batch release:

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

Local representatives and contact details to report suspected adverse reactions>:

17. Other information

Gavin Hall
Approved: 15 December 2025