

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cartaxx 100 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Carprofen 100 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

Store in the original package in order to protect from light.
Store the tablet parts in the blister and the blister in the outer carton in order to protect from light.
Remaining tablet fraction(s) should be used at the next administration(s).

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 36408/3059

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Aluminium blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cartaxx



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Carprofen 100 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

Cartaxx 20 mg chewable tablets for dogs
Cartaxx 50 mg chewable tablets for dogs
Cartaxx 100 mg chewable tablets for dogs

2. Composition

Each tablet contains:

Cartaxx 20 mg

Active substance:

Carprofen 20 mg

White to off-white round and convex chewable tablet with a cross-shaped break line on one side, size 7 mm.

Cartaxx 50 mg

Active substance:

Carprofen 50 mg

White to off-white round and convex chewable tablet with a cross-shaped break line on one side, size 10 mm.

Cartaxx 100 mg

Active substance:

Carprofen 100 mg

White to off-white round and convex chewable tablet with a cross-shaped break line on one side, size 13 mm.

The tablets can be divided into 2 or 4 equal parts.

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.

The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

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

Carprofen is a non-steroidal anti-inflammatory drug.

People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

Direct skin contact by the user with the active substance should be avoided, as phototoxic reactions may occur in humans or there is a risk of developing a photoallergy, which may persist for years as severe photo/light sensitivity with redness, swelling and blistering of the skin. Laboratory studies have shown photosensitizing properties for carprofen, as well as for other NSAIDs.

Accidental ingestion of the veterinary medicinal product may cause gastrointestinal effects, such as nausea and gastric pain. Care should be taken to avoid accidental ingestion by children. To avoid accidental ingestion, unused tablet parts should be returned to the open blister space and into the cardbox.

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:

Laboratory studies in laboratory animals (rat, rabbit) 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 or lactation. 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 NSAIDs, 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 |
|---|---|

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 <{national system details}>.

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

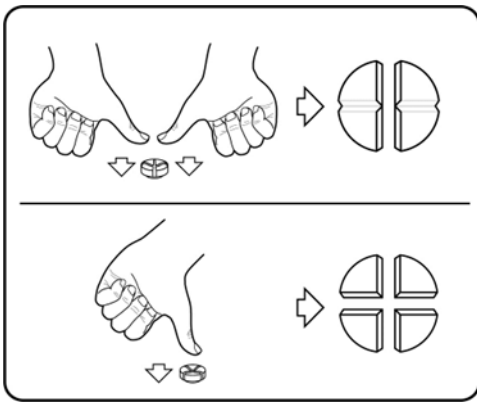
Oral use

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

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.



Two equal parts: press down with your thumbs on both sides of the tablet.
Four equal parts: press down with your thumb in the middle of the tablet.
Remaining tablet fraction(s) should be used at the next administration(s).

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original package in order to protect from light.

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

Store the tablet parts (halves/ quarters) in the blister and the blister in the outer carton in order to protect from light. 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 36408/3057 (20mg)

Vm 36408/3058 (50mg)

Vm 36408/3055 (100mg)

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: 16 December 2025