# PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton box}

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cartaxx 50 mg/ml solution for injection

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Carprofen 50 mg/ml

Benzyl alcohol 10 mg/ml

## 3. PACKAGE SIZE

10 ml
20 ml
50 ml

## 4. TARGET SPECIES

Dog and cat

## 5. INDICATION(S)

## 6. ROUTES OF ADMINISTRATION

IV, SC

## 7. WITHDRAWAL PERIODS

## 8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.
Once broached use by…

## 9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton 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

Alfasan Nederland B.V.

## 14. MARKETING AUTHORISATION NUMBERS

Vm 36408/5028

## 15. BATCH NUMBER

Lot {number}

## 16. SPECIAL WARNING(S), IF NECESSARY

## 17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

## 18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

To be supplied only on veterinary prescription
POM-V

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {glas vials}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cartaxx

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Carprofen 50 mg/ml

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

## 5. ROUTE(S) OF ADMINISTRATION

IV, SC

## 6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

# PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cartaxx 50 mg/ml solution for injection for dogs and cats

## 2. COMPOSITION

Each ml contains:
Active substances

| | |
|---|---|
| Carprofen | 50 mg |

Excipients:

| | |
|---|---|
| Benzyl alcohol (E1519) | 10 mg |

Solution for injection
A clear, yellow coloured solution.

## 3. TARGET SPECIES

Dog and cat

## 4. INDICATIONS FOR USE

Dog: for the control of post-operative pain and inflammation following orthopaedic and soft tissue (including intra-ocular) surgery.
Cat: for the control of post-operative pain following surgery.

## 5. CONTRAINDICATIONS

Do not use in animals suffering from cardiac, hepatic or renal disease or gastrointestinal problems, where there is a possibility of gastrointestinal ulceration or bleeding.
Do not use in cases of hypersensitivity to the active substance or any other non-steroidal anti-inflammatory drugs (NSAIDs) or any excipients of this veterinary medicinal product.
Do not administer by intramuscular injection.
Do not use after surgery which was associated with considerable blood loss.
Do not use in cats on repeated occasions.
Do not use in cats less than 5 months of age.
Do not use in dogs less than 10 weeks of age.
Do not use during pregnancy and lactation, see also section ‘special warnings’.

## 6. SPECIAL WARNING(S)

Special precautions for safe use in the target species:
Do not exceed the recommended dose or duration of treatment.

Use in aged dogs and cats, may involve additional risk. If such use cannot be avoided, such animals may require a reduced dosage and careful clinical management.
Avoid use in dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.
NSAIDs 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, in common with other NSAIDs, has been shown to exhibit photosensitising potential in laboratory studies. Benzyl alcohol may cause hypersensitivity (allergic) reactions. People with known (hyper)sensitivity to carprofen, NSAIDs or benzyl alcohol should administer the veterinary medicinal product with caution. Avoid contact with skin. Wash off any splashes immediately with clean, running water. Seek medical attention if irritation persists.
Take care to avoid self-injection. In case of accidental self-injection, seek medical advice and show the package leaflet or the label to the physician.

Pregnancy:
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. Do not use in dogs or cats during pregnancy.

Lactation:
The safety of the veterinary medicinal product has not been established during lactation. Do not use in dogs or cats during lactation.

Interaction with other medicinal products and other forms of interaction:
Carprofen should not be administered concurrently, or within 24 hours of another NSAID, or in conjunction with glucocorticosteroids. Carprofen is highly bound to plasma proteins and may compete with other highly bound drugs which can lead to toxic effects. Hence, concurrent administration with potentially nephrotoxic drugs should be avoided.

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

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

## 7. ADVERSE EVENTS

Dogs and cats:

| | |
|---|---|
| Rare<br>(1 to 10 animals / 10,000 animals treated): | Digestive tract disorder: loss of appetite, vomiting, gastric-intestinal ulceration, loose stool, blood in faeces (occult), diarrhoea [1,2]<br>Renal disorder.<br>Hepatic disorder (idiosyncratic).<br>Injection site reactions[3] |
| Undetermined frequency (cannot be estimated from the available data) | Lethargy. [1,2]<br>Anaemia. |

[1] in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.
[2] If adverse reactions occur, use of the veterinary medicinal product should be stopped and the advice of a veterinarian should be sought.
[3] following subcutaneous injection

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, the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system <{national system details}.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For intravenous or subcutaneous use.

Dog:
The recommended dose is 4 mg carprofen/kg bodyweight (equivalent to 1 ml of the veterinary product/12.5 kg bodyweight). To extend analgesic and anti-inflammatory treatment post-operatively, parenteral therapy may be followed after 24 hours with carprofen tablets at 4 mg/kg/day for up to 5 days.

Cat:
The recommended dose is 4 mg carprofen /kg bodyweight (equivalent to 0.08 ml of the veterinary product/1.0 kg bodyweight). Due to the longer half-life in cats and narrower therapeutic index particular care should be taken not to exceed or repeat the recommended dose and the use of a 1 ml graduated syringe is recommended to measure the dose accurately.
The parenteral therapy may not be followed with carprofen tablets.

The stoppers should not be broached more than 30 times.

## 9. ADVICE ON CORRECT ADMINISTRATION

The veterinary medicinal product is best given pre-operatively, either at the time of premedication or induction of anaesthesia.

## 10. WITHDRAWAL PERIOD(S)

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the vial in the outer carton in order to protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days.

## 12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

## 13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

To be supplied only on veterinary prescription.

## 14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 36408/5028

One clear glass (type I) vial with a grey bromobutyl rubber stopper and aluminium cap in a cardboard box.
Pack sizes:
Cardboard box with 1 vial of 10 ml.
Cardboard box with 1 vial of 20 ml.
Cardboard box with 1 vial of 50 ml.
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:
Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

Local representatives and contact details to report suspected adverse reactions:

## 17. OTHER INFORMATION

Approved 02 May 2024