SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
Carprofen 50 mg

Excipients:
Benzyl alcohol 10 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
A clear, yellow coloured solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dog and cat

4.2 Indications for use, specifying the target species

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.

4.3 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 4.7.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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.

Special precautions for the protection of the environment:

Not applicable.

Other precautions

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Dogs and cats:

Rare (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] Renal disorder. Hepatic disorder (idiosyncratic). Injection site reactions[3]
Undetermined frequency (cannot be estimated from the available data)	Lethargy. [1,2] 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

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.

4.8 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.

4.9 Amount(s) to be administered and administration route

For intravenous or subcutaneous use.

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

Dog:
The recommended dose is 4 mg carprofen/kg bodyweight (equivalent to 1 ml of the veterinary medicinal 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 medicinal 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Not Applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and Anti-rheumatic products, nonsteroids

ATC Vet Code: QM01AE91

5.1 Pharmacodynamic properties

Carprofen is a member of the 2-arylpropionic acid group of NSAIDs, and possesses anti-inflammatory, analgesic and antipyretic properties.
As with most other NSAIDs, carprofen is an inhibitor of the enzyme cyclo-oxygenase of the arachidonic acid cascade. However, the inhibition of prostaglandin synthesis by carprofen is slight compared to its anti-inflammatory and analgesic properties. At therapeutic doses in the dog and cat, inhibition of the products of cyclo-oxygenase (prostaglandins and thromboxanes) or lipoxygenase (leucotrienes) has been absent or slight.

5.2 Pharmacokinetic particulars

Following a single subcutaneous dose of 4 mg carprofen/kg in dogs, the maximum plasma concentration (Cmax) of 16.0 µg /ml was reached after (Tmax) 4-5 hours.
In cats the maximum plasma concentration (Cmax) of 26.0 µg /ml was reached after approximately (Tmax) 3-4 hours. The bioavailability is 85% in dogs and more than 90% in cats.
Carprofen has a plasma elimination half-life of 10 hours in dogs and 20 hours in cats.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Sodium hydroxide
Glycocholic acid
Lecithin
L-arginine
Hydrochloric acid, diluted
Water for injections

6.2 Major Incompatibilities

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

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 30 months
Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

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.

6.5 Nature and composition of immediate packaging

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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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.

7. MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 36408/5028

9. DATE OF FIRST AUTHORISATION

02 May 2024

10. DATE OF REVISION OF THE TEXT

May 2024

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Approved 02 May 2024