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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	10 mg
Sodium hydroxide (for pH adjustment)	
Glycocholic acid	
Lecithin	
L-arginine	
Hydrochloric acid, diluted (for pH adjustment)	
Water for injections	

Clear, yellow coloured solution for injection.

3. CLINICAL INFORMATION

3.1 Target species

Dog and cat

3.2 Indications for use for each 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.

3.3 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 3.7.

3.4 Special warnings

None.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

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.

3.7 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.

3.8 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.

3.9 Administration routes and dosage

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AE91

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 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.

5.4 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.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 36408/3038

8. DATE OF FIRST AUTHORISATION

02 May 2024

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

May 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Approved 02 May 2024