1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Carprofen 50.0 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)	15.0 mg
Arginine	
Glycocholic acid	
Lecithin	
Sodium hydroxide (for pH adjustment)	
Hydrochloric acid 10% (for pH adjustment)	
Water for injections	

Clear brownish-yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

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

Cats: 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 NSAIDs (non-steroidal anti-inflammatory drugs) or to any of the excipients.
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.

See also section 3.7, as the veterinary medicinal product is contraindicated during pregnancy and lactation.

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.
Due to the longer half-life in cats and narrower therapeutic index, particular care should be taken not to exceed the recommended dose and the dose should not be repeated.

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 animals, 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:

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

Care should be taken to avoid accidental self-injection. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.
Carprofen, in common with other NSAIDs, has been shown to exhibit photosensitising potential in laboratory studies.
Avoid contact with skin and eyes. Wash off any splashes immediately with clean, running water.
Seek medical attention if irritation persists.

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)	Injection site reaction[a]
Very rare (<1 animal / 10,000 animals treated, including isolated reports)	Vomiting[bc], diarrhoea[bc], loose stool[bc], blood in faeces[bc] appetite loss[bc], lethargy[b]
Undetermined frequency (cannot be estimated from the available data)	Vomiting[bd], diarrhoea[bd], loose stool[bd], blood in faeces[bd] appetite loss[bd]

[a] following subcutaneous injection
[b] most cases are transient and disappear following termination of the treatment but in very rare cases may be serious or fatal

[c] In Dogs only.
[d] In Cats only.

As with other NSAIDs there is a risk of rare renal, idiosyncratic hepatic or gastro-intestinal tract adverse events.

If adverse reactions occur, use of the veterinary medicinal product should be stopped and the advice of a veterinarian should be sought.

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 and subcutaneous use..

Dogs:
4 mg/kg (1 ml/12.5 kg) bodyweight, by intravenous or subcutaneous injection, best given pre-operatively, either at the time of premedication or induction of anaesthesia.
To extend analgesic and anti-inflammatory cover post-operatively, parenteral therapy may be followed with Carprofen tablets at 4 mg/kg/day for up to 5 days.

Cats:
4 mg/kg (0.08 ml/1.0 kg) bodyweight by intravenous or subcutaneous injection, best given pre-operatively, either at the time of premedication or induction of anaesthesia. The use of a 1 ml graduated syringe is recommended to measure the dose accurately (see also section 3.5). The parenteral therapy may not be followed with Carprofen tablets.

The weight of treated animals should be accurately determined before administration.
The stopper should not be punctured more than 20 times.

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

There is no specific antidote for carprofen overdosage. General symptomatic treatment, as is usual for 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 non-steroidal anti-inflammatory drugs (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 (C_{max}) of 16.0 µg /ml was reached after (T_{max}) 4-5 hours.
In cats the maximum plasma concentration (C_{max}) of 26.0 µg /ml was reached after approximately (T_{max}) 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: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Store in a refrigerator (2°C - 8°C). Do not freeze.
Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

One amber glass (type I) vial with a coated bromobutyl rubber stopper and aluminium cap in a cardbox.

Pack sizes:
Cardboard box with 5 vials of 20 ml.
Cardboard box with 10 vials of 20 ml.
The vials are packed singly in a cardboard box.
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

Le Vet Beheer B.V.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10475/007/001

8. DATE OF FIRST AUTHORISATION

09 August 2013

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

25 October 2023

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.