# SUMMARY OF PRODUCT CHARACTERISTICS

## 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:**
Benzyl alcohol (E1519) 15.0 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Solution for injection.
Clear brownish-yellow solution.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Dogs and cats.

### 4.2 Indications for use, specifying the 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.

### 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 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 4.7, as the veterinary medicinal product is contraindicated during pregnancy and lactation.

## 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.
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.

## 4.6 Adverse reactions (frequency and seriousness)

Dogs and cats

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

## 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 and lactation. Do not use in dogs or cats during pregnancy or lactation.

Lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use in dogs or cats during pregnancy or 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 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 4.5). 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.

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

There is no specific antidote for carprofen overdosage. General symptomatic treatment, as is usual for 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, non-steroids

**ATC Vet Code:** QM01AE91

### 5.1 Pharmacodynamic properties

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.

### 5.2 Pharmacokinetic particulars

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.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Benzyl alcohol (E1519)
Arginine
Glycocholic acid
Lecithin
Sodium hydroxide (for pH adjustment)
Hydrochloric acid 10% (for pH adjustment)
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: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

## 6.4 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.

## 6.5 Nature and composition of immediate packaging

20 ml amber glass vials (Type I) with bromobutyl rubber stopper, covered with an aluminum cap.
The vials are packed singly in a cardboard box.
Multi-packs of 5 x 20 ml and 10 x 20 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 products should be disposed of in accordance with local requirements.

# 7. MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

# 8. MARKETING AUTHORISATION NUMBER

Vm 41821/5007

# 9. DATE OF FIRST AUTHORISATION

16 August 2013

## 10. DATE OF REVISION OF THE TEXT

November 2023

## PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

## 11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

For animal treatment only - to be supplied only on veterinary prescription.
POM-V

Veterinary medicinal product subject to prescription.
For administration only by a veterinarian.

Approved 09 January 2024