

**ANNEX I**  
**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:

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

<sup>a</sup> following subcutaneous injection

<sup>b</sup> most cases are transient and disappear following termination of the treatment but in very rare cases may be serious or fatal

<sup>c</sup> In Dogs only.

<sup>d</sup> 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  $\mu\text{g}/\text{ml}$  was reached after ( $T_{max}$ ) 4-5 hours.

In cats the maximum plasma concentration ( $C_{max}$ ) of 26.0  $\mu\text{g}/\text{ml}$  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 cardboard box.

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)**

#### **8. DATE OF FIRST AUTHORISATION**

Date of first authorisation:<{DD/MM/YYYY}> <{DD month YYYY}>.

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

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month YYYY}>

#### **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>.

**ANNEX II**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**



**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARDBOARD BOX**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Carprofelican 50 mg/ml solution for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

Carprofen 50.0 mg

**3. PACKAGE SIZE**

20 ml

5 x 20 ml

10 x 20 ml

**4. TARGET SPECIES**

Dogs and cats



**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

For intravenous and subcutaneous use.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Shelf life after first opening the vial: 28 days.

Once broached, use by:

**9. SPECIAL STORAGE PRECAUTIONS**

Store in a refrigerator (2°C - 8°C). Do not freeze.

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**

Le Vet Beheer B.V.

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**  
**{20 ML GLASS VIAL}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Carprofelican

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Each ml contains:

Carprofen 50.0 mg

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Shelf life after first opening the vial: 28 days.

Once broached, use by:

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

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

### 2. Composition

Each ml contains:

**Active substance:**

Carprofen: 50.0 mg

**Excipients:**

Benzyl alcohol (E1519) 15.0 mg

Clear brownish-yellow solution.

### 3. Target species

Dogs and cats.



### 4. Indications for use

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.

### 5. Contraindications

Do not use in animals suffering from cardiac, hepatic or renal disease or gastrointestinal problems, where there is a possibility of gastro-intestinal ulceration or bleeding.

Do not use in cases of hypersensitivity to the active substance or any other NSAIDs (non-steroidal anti-inflammatory drugs) or any excipients of this 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 in dogs or cats during pregnancy or lactation.

### 6. Special warnings

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, 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.

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 overdose. General symptomatic treatment, as is usual for clinical overdose 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 (1 to 10 animals / 10,000 animals treated)	Injection site reaction <sup>a</sup>
Very rare (<1 animal / 10,000 animals treated, including isolated reports)	Vomiting <sup>bc</sup> , diarrhoea <sup>bc</sup> , loose stool <sup>bc</sup> , blood in faeces <sup>bc</sup> appetite loss <sup>bc</sup> , lethargy <sup>b</sup>
Undetermined frequency (cannot be estimated from the available data)	Vomiting <sup>bd</sup> , diarrhoea <sup>bd</sup> , loose stool <sup>bd</sup> , blood in faeces <sup>bd</sup> appetite loss <sup>bd</sup>

<sup>a</sup> following subcutaneous injection

<sup>b</sup> most cases are transient and disappear following termination of the treatment but in very rare cases may be serious or fatal

<sup>c</sup> In Dogs only.

<sup>d</sup> 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 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 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 or 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, routes and method of administration**

Dogs: For intravenous and subcutaneous use.

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: For intravenous and subcutaneous use.

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 6). The parenteral therapy may not be followed with Carprofen tablets.

## **9. Advice on correct administration**

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

## **10. Withdrawal periods**

Not applicable.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

Store in a refrigerator (2°C - 8°C). Do not freeze.

Keep the vial in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the vial and carton label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the vial: 28 days.

When the container is breached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

## **12. Special precautions for disposal**

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. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

### **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

### **14. Marketing authorisation numbers and pack sizes**

Marketing authorisation number(s):

Packaging:

Injection vial containing 20 ml.

Pack sizes:

Multi-packs of 5 x 20 ml and 10 x 20 ml.

Not all pack sizes may be marketed.

### **15. Date on which the package leaflet was last revised**

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month YYYY}>

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

### **16. Contact details**

Marketing authorisation holder and contact details to report suspected adverse reactions:

Le Vet Beheer B.V.

Wilgenweg 7

3421 TV Oudewater

The Netherlands

Phone number: +31 348 563434

Manufacturer responsible for batch release:

Produlab Pharma B.V.

Forellenweg 16

4941 SJ Raamsdonksveer

The Netherlands

### **17. Other information**

<national information>
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