

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprofen KRKA 50 mg/ml solution for injection for dogs and cats

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substance:

Carprofen for veterinary use 50 mg

### Excipients:

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

Clear, pale yellow coloured solution.

## 3. CLINICAL PARTICULARS

### 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 intraocular) 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 known cases of hypersensitivity to the active substance or any other NSAIDs or any excipients of this veterinary medicinal product.

As with other NSAIDs there is a risk of rare renal or idiosyncratic hepatic adverse events.

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.

### 3.4 Special warnings

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 use of a 1 ml graduated syringe is recommended to measure the dose accurately.

### 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 any 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:

Care should be taken to avoid accidental self-injection.

Carprofen, in common with other NSAIDs, has been shown to exhibit photosensitising potential in laboratory animals. Avoid skin contact with the veterinary medicinal product. Should this occur, wash the affected area immediately.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse reactions

Dogs and cats:

|   |   |
|---|---|
| Rare<br>(1 to 10 animals / 10,000 animals treated):                     | renal disorder.<br>hepatic disorder (idiosyncratic).  |
| Undetermined frequency<br>(cannot be estimated from the available data) | vomiting <sup>1</sup> , loose stool <sup>1</sup> , diarrhoea <sup>1</sup> , blood in faeces (occult) <sup>1</sup> , appetite loss <sup>1</sup> lethargy <sup>1</sup><br>Injection site reactions <sup>2</sup> |

<sup>1</sup>Generally occur within the first treatment week and are in most cases transient and disappear following termination of treatment. In very rare cases may be serious or fatal.

<sup>2</sup>Following subcutaneous injection.

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 the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

### **3.7 Use during pregnancy, lactation or lay**

Fertility:

Laboratory studies in laboratory animals (rat, rabbit) have shown evidence of foetotoxic effects of carprofen at doses close to the therapeutic dose.

Pregnancy and 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.

### **3.8 Interaction with other medicinal products and other forms of interaction**

Do not administer other NSAIDs and glucocorticoids concurrently or within 24 hours of administration of the veterinary medicinal product. Carprofen is highly bound to plasma proteins and may compete with other highly bound drugs, which can lead to toxic effects.

Concurrent administration of potential nephrotoxic drugs should be avoided.

### **3.9 Administration routes and dosage**

**Dogs:** The recommended dosage is 4.0 mg carprofen/kg bodyweight (1 ml/12.5 kg bodyweight), by intravenous or subcutaneous injection. The veterinary medicinal product is best given pre-operatively, either at the time of premedication or induction of anaesthesia.

**Cats:** The recommended dosage is 4.0 mg/kg (0.24 ml/3.0 kg bodyweight), by subcutaneous or intravenous injection, best given pre-operatively at the time of induction of anaesthesia. The use of a 1 ml graduated syringe is recommended to measure the dose accurately.

Clinical trial evidence in dogs and cats suggests only a single dose of carprofen is required in the first 24 hours perioperatively; if further analgesia is required in this period a half dose (2 mg/kg) of carprofen may be given to dogs (but not to cats) as necessary.

In dogs, 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.

For administration of the veterinary medicinal product a 21-gauge needle should be used.

The cap can be punctured up to 20 times. If more than twenty broachings is likely, use a draw-off needle.

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

There is no specific antidote for carprofen overdose 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 or IMMUNOLOGICAL INFORMATION**

### **4.1 ATCvet code:**

QM01AE91

### **4.2 Pharmacodynamics**

Carprofen possesses anti-inflammatory, analgesic and antipyretic activity. Like most other NSAID's, carprofen is an inhibitor of the enzyme cyclo-oxygenase of the arachidonic acid cascade. However, the inhibition of prostaglandin synthesis by carprofen is slight in relation to its anti-inflammatory and analgesic potency. The precise mode of action of carprofen is not clear.

Carprofen is a chiral drug with the S(+) enantiomer being more active than the R(-) enantiomer. There is no chiral inversion between the enantiomers *in-vivo*.

### **4.3 Pharmacokinetics**

Carprofen is well absorbed after subcutaneous administration with peak plasma concentrations achieved within 3 h after administration.

The volume of distribution is small. Carprofen is highly protein bound.

Carprofen is characterized by a half-life of approximately 10 hours in dogs. In cats, the elimination half-life is longer ranging from 9 to 49 hours after intravenous administration (mean of ~ 20 hrs).

## **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: 3 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.

Once broached, do not store above 25°C.

### **5.4 Nature and composition of immediate packaging**

Glass vial (amber glass): 1 vial of 20 ml solution for injection with rubber stopper and aluminium seal, in a box.

### **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**

KRKA, d.d., Novo mesto

**7. MARKETING AUTHORISATION NUMBER(S)**

VPA10774/019/001

**8. DATE OF FIRST AUTHORISATION**

21/06/2013

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

29/07/2024

**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) (<https://medicines.health.europa.eu/veterinary>).