

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**BOX**

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

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

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

Active substance:  
Carprofen 50 mg

**3. PHARMACEUTICAL FORM**

Solution for injection.

**4. PACKAGE SIZE**

20 ml

**5. TARGET SPECIES**

Dogs and cats.

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.  
Intravenous and subcutaneous use.

**8. WITHDRAWAL PERIOD(S)**

**9. SPECIAL WARNING(S), IF NECESSARY**

**10. EXPIRY DATE**

EXP:

Once opened, use by:  
Shelf-life after first opening the immediate packaging: 28 days.

**11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator (2°C – 8°C).  
Do not freeze.  
Once opened, do not store above 25°C.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Dispose of waste material in accordance with local requirements.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary prescription.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

KRKA, d.d., Novo mesto  
Šmarješka cesta 6  
8501 Novo mesto  
Slovenia

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

Vm 01656/4174

**17. MANUFACTURER’S BATCH NUMBER**

Lot:

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**LABEL**

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

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

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

50 mg/ml

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

20 ml

**4. ROUTE(S) OF ADMINISTRATION**

Intravenous and subcutaneous use.

**5. WITHDRAWAL PERIOD**

**6. BATCH NUMBER**

Lot:

**7. EXPIRY DATE**

EXP:

Once opened, use by:

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

## PACKAGE LEAFLET:

**Rycarfa 50 mg/ml solution for injection for dogs and cats**  
**Carprox vet 50 mg/ml solution for injection for dogs and cats**  
**Rycarfa vet solution for injection for dogs and cats**  
**Carprofen Krka 50 mg/ml solution for injection for dogs and cats**

### 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

KRKA, d.d., Novo mesto  
Šmarješka cesta 6  
8501 Novo mesto  
Slovenia

Manufacturer responsible for batch release:

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia  
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

### 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:

Carprofen 50 mg

Excipient:

Benzyl alcohol (E1519) 10 mg

Clear, pale yellow coloured solution.

### 4. INDICATION(S)

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.

### 5. 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, or hypersensitivity to carprofen or any other NSAIDs 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.

## **6. ADVERSE REACTIONS**

Typical undesirable effects associated with NSAIDs such as vomiting, soft faeces/diarrhoea, faecal occult blood, loss of appetite and lethargy have been reported. These adverse reactions occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

If adverse reactions occur, even those not already listed in this package leaflet, use of the product should be stopped and the veterinary surgeon should be informed. As with other NSAIDs there is a risk of rare renal or idiosyncratic hepatic adverse events.

Occasionally reactions at the injection site may be observed following subcutaneous injection.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

## **7. TARGET SPECIES**

Dogs and cats.

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

For intravenous or subcutaneous administration

Dogs: The recommended dosage is 4.0 mg carprofen/kg bodyweight (1 ml/12.5 kg bodyweight). The 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), best given pre-operatively at the time of induction of anaesthesia. 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. 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.

The weight of treated animals should be accurately determined before administration.

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.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Do not administer by intramuscular injection.

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

The cap can be punctured up to 20 times. When puncturing more than 20 times, use a draw-off needle.

## **10. WITHDRAWAL PERIOD(S)**

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.

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

Shelf-life after first opening the immediate packaging: 28 days.

Once opened, do not store above 25°C.

## **12. SPECIAL WARNING(S)**

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.

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 product. Should this occur, wash the affected area immediately.

People with known hypersensitivity to carprofen or to any of the excipients should avoid contact with the veterinary medicinal product.

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.

Do not administer other NSAIDs and glucocorticoids concurrently or within 24 hours of administration of the 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.

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

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

### **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

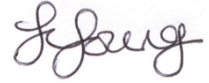
### **15. OTHER INFORMATION**

Type I amber glass vial of 20 ml solution for injection with bromobutyl rubber stopper and aluminium closure, in a box is available.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Revised February 2019  
AN:00133/2018

Approved: 13 February 2019

A handwritten signature in black ink, appearing to be 'J. Long', written in a cursive style.