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 25ºC.

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.

Approved: 13 February 2019