SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Carprofen 50 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)	10 mg
Arginine	
Glycocholic acid	
Hydrochloric acid, dilute (for pH adjustment)	
Lecithin	
Sodium hydroxide	
Water for injections	

Clear, pale yellow coloured 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 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, or hypersensitivity to carprofen or any other NSAIDs or any excipients of this veterinary medicinal 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.

See also section 3.7.

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 any 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

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

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):	Renal disorder Hepatic disorder[1]
Undetermined frequency (cannot be estimated from the available data):	Vomiting [2], loose stool [2], diarrhoea [2], blood in faeces [2,3], appetite loss [2] Lethargy [2] Injection site reaction [4]

[1] Idiosyncratic reaction.
[2] Generally occur 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.
[3] Occult
[4] 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 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 and lactation:
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.

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

Intravenous and subcutaneous use.

Dogs: The recommended dosage is 4.0 mg carprofen/kg bodyweight (1 ml/12.5 kg bodyweight). 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), 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.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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. When puncturing more than 20 times, use a draw-off needle.

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

There is no specific antidote for carprofen overdosage 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 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

Type I glass vial (amber glass): 1 vial of 20 ml solution for injection with bromobutyl 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.

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

Vm 01656/4174

8. DATE OF FIRST AUTHORISATION

03 March 2014

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

September 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 22 January 2025