SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprox vet 50 mg/ml solution for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Carprofen 50 mg

Excipient:
Benzyl alcohol (E1519) 10 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, pale yellow coloured solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the 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.

4.3 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 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.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

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

4.6 Adverse reactions (frequency and seriousness)

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, use of the product should be stopped and the advice of a veterinarian should be sought.

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.

4.7 Use during pregnancy, lactation or lay

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.

4.8 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 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.

4.9 Amounts to be administered and administration route

Dogs: The recommended dosage is 4.0 mg carprofen/kg bodyweight (1 ml/12.5 kg bodyweight), by intravenous or subcutaneous injection. 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), 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 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids, Propionic acid derivatives
ATCvet code: QM01AE91

5.1 Pharmacodynamic properties

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*.

5.2 Pharmacokinetic particulars

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).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Arginine

Glycocholic acid
Hydrochloric acid, dilute (for pH adjustment)
Lecithin
Sodium hydroxide
Water for injections

6.2 Incompatibilities

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

6.3 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.

6.4. Special precautions for storage

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

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 01656/4014

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19 November 2010

10. DATE OF REVISION OF THE TEXT

December 2015

Approved: 23 December 2015