PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprox vet 50 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Carprofen 50 mg

3. PACKAGE SIZE

20 ml

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

s.c., i.v.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.
Once broached use by …

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto

14. MARKETING AUTHORISATION NUMBERS

Vm 01656/4014

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprox vet

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

50 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:
Carprofen 50 mg

Excipient:
Benzyl alcohol (E1519) 10 mg

Clear, pale yellow coloured solution.

3. Target species

Dogs and cats.

4. Indications for use

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 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 ‘Pregnancy and lactation’.

6. Special warnings

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.

Pregnancy and lactation:
Laboratory studies in laboratory animals (rats and rabbits) 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.

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.

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

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

7. 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], appetite loss[2], lethargy[2] Injection site reaction[3]

[1] Idiosyncratic reaction.
[1] Transient. Generally within the first treatment week and are in most cases disappear following termination of the treatment but in very rare cases may be serious or fatal.
[2] 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine.

8. Dosage for each species, routes and method of administration

Intravenous and subcutaneous use.

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.

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.

9. Advice on correct administration

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.

10. Withdrawal periods

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.
Once broached, do not store above 25 ºC.

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

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

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

1 glass vial of 20 ml solution for injection with rubber and aluminium closure, in a box is available.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release :
Krka, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Local representatives and contact details to report suspected adverse reactions:
KRKA UK Ltd
United Kingdom
Tel: 02071 646 156
info.uk@krka.biz

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

17. Other information

POM-V
To be supplied only on veterinary prescription

Gavin Hall

Approved 11 February 2025