PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprox vet 20 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Active substance:
Carprofen 20 mg

3. PACKAGE SIZE

20 tablets
50 tablets
100 tablets
500 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Return any halved tablet to the opened blister and use within 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Keep the blister in the outer carton in order to protect from light and moisture.

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 01656/4010

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprox vet

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

20 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Carprox vet 20 mg tablets for dogs

2. Composition

Each tablet contains:

Active substances:
Carprofen 20 mg

Excipients:
Ferric oxide red (E172) 0.61 mg
Ferric oxide black (E172) 0.38 mg

Round, dark brown, marbled tablets with visible darker spots, one-side scored and bevel-edged.
The tablets can be divided into two equal parts.

3. Target species

Dogs.

4. Indications for use

Reduction of inflammation and pain caused by musculoskeletal disorders and degenerative joint disease. As a follow up to parenteral analgesia in the management of post operative pain.

5. Contraindications

Do not use in cats.
Do not use in pregnant or lactating bitches.
Do not use in dogs less than 4 months of age.
Do not use in cases of hypersensitivity to active substance or to any of the excipients.
Do not use in dogs suffering from cardiac, hepatic or renal disease, where there is a possibility of gastrointestinal ulceration or bleeding, or where there is evidence of a blood dyscrasia.

6. Special warnings

Special precautions for safe use in the target species:
Use in aged dogs, may involve additional risk. If such a use cannot be avoided, dogs may require careful clinical management.

Avoid use in any dehydrated, hypovolaemic or hypotensive dog, 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:
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Wash hands after handling the product.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Laboratory studies in rats and rabbits have shown evidence of foetotoxic effects of carprofen at doses close to the therapeutic dose. Do not use in pregnant or lactating bitches.

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.

Overdose:
Although studies investigating the safety of carprofen at overdose have been performed, no signs of toxicity appeared when dogs were treated with carprofen at levels up to 6 mg/kg twice daily for 7 days (3 times the recommended dose rate of 4 mg/kg) and 6 mg/kg once daily for a further 7 days. (1.5 times the recommended dose rate of 4 mg/kg).
There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAIDs should be applied.

7. Adverse events

Dogs:

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].

[1] Idiosyncratic reaction.
[2] Transient. Generally, occur within the first treatment week and in most cases disappear following termination of the treatment but in very rare cases may be serious or fatal.

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 marketing

authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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

For oral use.

An initial dose of 2 to 4 mg carprofen per kg bodyweight per day is recommended to be given as a single or in two equally divided doses. Subject to clinical response, the dose may be reduced after 7 days to 2 mg carprofen/kg bodyweight/day given as a single dose.
In order to adjust the dosage, the tablets can be divided into two equal parts.

Duration of treatment will be dependent upon the response seen, but the dog's condition should be re-appraised by the veterinary surgeon after 14 days therapy.

9. Advice on correct administration

To extend analgesic cover post-operatively, parenteral therapy with solution for injection may be followed with tablets at 4 mg/kg/day for up to 5 days.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.
Keep the blister in the outer carton in order to protect from light and moisture.

Return any halved tablet to the opened blister and use within 24 hours.

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

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

Vm 01656/4010

20 mg tablets are available in boxes of 20, 50, 100 and 500 tablets in blisters of 10 tablets.
Not all pack sizes may be marketed.

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

Manufacturer responsible for batch release:
KRKA - FARMA d.o.o., V. Holjevca 20/E, 10450 Jastrebarsko, Croatia
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Local representatives and contact details to report suspected adverse events:
Virbac Ltd
Suffolk, IP30 9UP - UK
Tel: +44 (0)-1359 243243

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

17. Other information

POM-V

Gavin Hall
Approved: 22 October 2025