

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Karprovet 50 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

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
Ferric oxide red (E172)	1.52 mg
Ferric oxide black (E172)	0.95 mg
Lactose monohydrate	
Maize starch	
Povidone K30	
Sodium starch glycolate, type A	
Colloidal anhydrous silica	
Meat flavour 10022	
Talc	
Magnesium stearate	

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. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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.

3.3 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.

3.4 Special warnings

Refer to Sections 3.3 and 3.5.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use in aged dogs may involve additional risk. If such 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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 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:

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.

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 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

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.

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.

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.

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

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.

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 oral administration (>90%) and is highly protein bound. Peak plasma concentrations are achieved between 1 hour and 3 hours after administration.

Carprofen is characterized by a half-life of approximately 10 hours in dogs.

Carprofen is eliminated in dogs primarily by means of biotransformation in the liver, followed by rapid excretion of the resulting metabolites in faeces (70-80%) and urine (10-20%). Some enterohepatic circulation has been detected.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Return any halved tablet to the opened blister and use within 24 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Blister (OPA/Al/PVC-Al): 20, 50, 100 or 500 tablets (10 tablets/blister) in a box.
Not all pack sizes may be marketed.

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 or household waste.

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(S)

VPA10774/006/002

8. DATE OF FIRST AUTHORISATION

10/12/2010

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

06/08/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).