1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Karprovet 50 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active substance:
Carprofen 50 mg

Excipients:
Ferric oxide red (E172) 1.52 mg
Ferric oxide black (E172) 0.95 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the 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.

4.3 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 case 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.

4.4 Special warnings for each target species

Refer to Sections 4.3 and 4.5.

4.5 Special precautions for use

Special precautions for use in animals

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 the event of accidental ingestion of the tablets, seek medical advice and show the doctor the package leaflet. Wash hands after handling the product.

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.

4.7 Use during pregnancy, lactation or lay

Studies in laboratory species (rat and 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 pregnant or lactating bitches.

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

For oral administration.

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.

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.

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

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 4mg/kg) and 6mg/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.

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 oral administration (>90%) and is highly protein bound. Peak plasma concentrations are achieved between 1 h and 3 h 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 feces (70-80%) and urine (10-20%). Some enterohepatic circulation has been detected.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Not applicable.

6.3 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.

6.4. 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.

6.5 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.

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

8. MARKETING AUTHORISATION NUMBER(S)

VPA 10774/006/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10th December 2010

10. DATE OF REVISION OF THE TEXT

15 October 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.