Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprofen flavour KRKA 20 mg tablets for dogs.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Carprofen 20 mg

Excipients:
Ferric oxide red (E172) 0.61 mg

Ferric oxide black (E172) 0.38 mg

For a 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 tablet can be divided into equal halves.

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.

Non-steroid anti-inflammatory drug **(**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

Do not use in pregnant or lactating bitches.
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.

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.
Do not administer the product together with anticoagulants.
Concurrent administration of potential nephrotoxic drugs should be avoided

4.9 Amounts to be administered and administration route

For oral administration.
2 to 4 mg carprofen per kg bodyweight per day.
An initial dose of 4 mg carprofen per kg bodyweight per day given as a single daily dose or in two equally divided doses may, subject to clinical response, be reduced after 7 days to 2 mg carprofen/kg bodyweight/day given as a single dose.
Duration of treatment will be dependent upon the response seen. Long term treatment should be under regular veterinary supervision.
To extend analgesic and anti-inflammatory cover post-operatively, parenteral preoperative treatment may be followed with Carprofen tablets at 4 mg/kg/day for up to 5 days.

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

Do not exceed the stated dose.
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 or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: non-steroid antiinflammatory product (NSAID*)*
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 properties

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 feces (70-80%) and urine (10-20%). Some enterohepatic circulation has been detected.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Ferric oxide red (E172)
Ferric oxide black (E172)
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.
Store in the original package 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 products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Krka, d.d. Novo mesto
Smarjeska cesta 6,
8501 Novo mesto,
Slovenia.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10774/018/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

3rd February 2012

10 DATE OF REVISION OF THE TEXT

January 2013