SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Norocarp 20 mg tablets
Norocarp 50 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

One tablet contains 20 mg or 50 mg carprofen

Excipients

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
White/off white round tablet

4 CLINICAL PARTICULARS

4.1 Target species

Dog.

4.2 Indications for use, specifying the target species

Anti-inflammatory and analgesic treatment of disorders in muscles, joints and skeleton and the treatment of post surgical pain in dogs.

4.3 Contraindications

Do not use for animals that are suffering from gastrointestinal disorders (including invasive GI tract surgery), haemostatic disorders, kidney disorders, moderate/severe liver or heart disorders or for animals showing signs of individual hypersensitivity to the product.
Do not use in cats.

4.4 Special Warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Caution is required when used to treat dogs less than 6 weeks of age, or very old dogs. Special precaution should be taken when medicating dehydrated, hypovolaemic animals or

animals suffering from heart or, liver diseases or infections. Refer to Section 4.3. Simultaneous use of potent nephrotoxic drugs or other NSAIDs should be avoided.
Response to long term therapy should be monitored at regular intervals by a veterinary surgeon.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

None.

4.6 Adverse reactions (frequency and seriousness)

Undesirable effects of using NSAID-products include vomiting, diarrhoea, gastrointestinal bleeding, inappetence, lethargy and liver and kidney disorders. These effects are usually temporary but can in rare cases be serious and in few cases be lethal.
As with other NSAIDs there is risk of rare renal or idiosyncratic hepatic adverse effects.

4.7 Use during pregnancy, lactation or lay

In the absence of specific studies in pregnant bitches, such use is not indicated. Carprofen passes to milk and should not be administered to lactating bitches.

4.8 Interaction with other medicinal products and other forms of interaction

Carprofen should not be administered simultaneous to or within 24 hrs of administration with other NSAIDs or steroids or together with anticoagulants. Carprofen is highly protein bound and may therefore compete with other highly protein bound drugs.

4.9 Amounts to be administered and administration route

For oral use.

The dose is 4 mg/kg bodyweight per day. The dose should be split and administered on two occasions in equal amounts. At treatment periods exceeding 14 days the dog should be regularly examined by a veterinary surgeon.

In order to prolong the anti-inflammatory and analgetic effect post operatively, parenteral treatment can be followed by peroral Norocarp Tablets at a dose of 4 mg per kg per day, split in two doses and administered on two occasions in equal amounts, for up to 5 days.

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

Symptomatic treatment should be initiated. For further information, see section 4.6.

4.11 Withdrawal period

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Non-steroidal anti-inflammatory/antireumatic drug (NSAID)
ATCvet-code: QM01AE91

5.1 Pharmacodynamic properties

Carprofen (CPF), (±)-6-chloro-α-methylcarbazole-2-acetic acid, is a non steroidal anti-inflammatory drug (NSAID) with analgesic and antipyretic effect belonging to the group of propionic acid derivatives. It is a derivate of phenylpropionic acid and belongs to the NSAID-group of arylpropionic acids. As a representative of the 2-arylpropionic family it contains a chiral center at C2 of the propionic moiety and is available in two different stereoisomeric forms. – (+)-S- and (-)-R-enantiomers.
The mechanism of action is not fully understood. Carprofen inhibits the enzyme cyclo-oxygenase in the prostaglandin synthesis. However the inhibition is weak in relation to its anti-inflammatory and analgesic effect. At therapeutic doses for dogs the inhibition of cyclo-oxygenase (prostaglandin or thromboxane) and lipoxygenase (leucotriene) is negligible or absent.

5.2 Pharmacokinetic properties

Carprofen is rapidly absorbed and maximal serum concentration (ca 20-30 microgram/ml) is reached within 2 hrs following oral administration of 4 mg/kg bodyweight. The bioavailability is >90% and the protein binding level is >99%. The $t_{½}$ is approximately 6 hrs (4,1-7,9). Excretion is mainly via the bile, 70% of an i.v. dose is excreted in a metabolised way via the faecal route and 8-15% via urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose
Lactose Monohydrate
Crosscarmellose Sodium
Povidone K30
Sodium Lauril Sulphate
Magnesium Stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Tablet container of polypropylene sealed with a polyethylene cap
20 mg: 100 and 500 tablets.
50 mg: 100 and 500 tablets.

Blister of PVC/aluminium:
20 mg: 10, 20 and 100 tablets.
50 mg: 10, 20, 100 and 500 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused medicinal product or waste materials, derived from the use of such products

Not applicable.

7 MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8 MARKETING AUTHORISATION NUMBER(S)

20 mg: 17689
50 mg: 17690

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 March 2005
Date of latest renewal: 11 March 2010

10 DATE OF REVISION OF THE TEXT

2019-05-03