Norbrook Laboratories Ltd

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Carprieve 20 mg Tablets for Dogs

Species: Dogs

Therapeutic indication:Pharmaceuticals: Anti-inflammatory preparations: Oral: Other NSAIDs

Active ingredient: Carprofen

Product: Carprieve 20 mg Tablets for Dogs

Product index: Carprieve Tablets 20 mg

Incorporating:

Qualitative and quantitative composition

Each tablet contains:

Active Substance: :

Carprofen

Excipients:

For a full list of excipients, see section "*Pharmaceutical Particulars*"

Pharmaceutical form

Tablet.

A white/off white circular tablet of diameter 8 mm, 20 embossed on one side and a single break line on the other side.

Clinical particulars

Target species

Dogs

Indications for use, specifying the target species

For analgesia and reduction of chronic inflammation, for example in degenerative joint disease, in dogs.

Carprieve Tablets can also be used in the management of post-operative pain.

Contraindications

The use of Carprieve Tablets is contraindicated in the cat, and the inadvertent administration of oral carprofen tablets may induce life-threatening conditions in this species.

Do not exceed the stated dose.

Do not administer NSAIDs concurrently or within 24 hours of each other. Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs, which can lead to toxic effects.

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 or hypersensitivity to the product.

In the absence of any specific studies in pregnant bitches such use is not indicated.

Special Warnings for each target species

Use in dogs less than 6 weeks of age, or in aged animals, may involve additional risk. If such use cannot be avoided, such dogs may require a reduced dosage and 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 for use

Special precautions for use in animals

None.

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

None.

Adverse reactions (frequency and seriousness)

None.

Use during pregnancy, lactation or lay

In the absence of any specific studies in pregnant bitches such use is not indicated.

Interaction with other medicinal products and other forms of interaction

Do not administer NSAIDs concurrently or within 24 hours of each other. Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs, which can lead to toxic effects.

Concurrent administration of potential nephrotoxic drugs should be avoided.

Amounts to be administered and administration route

For oral administration.

An initial dose of 2 to 4 mg carprofen/kg bodyweight/day is recommended to be given in 2 equally divided doses. The dose may be reduced to 2 mg carprofen/kg bodyweight/day administered as a single daily dose after 7 days, subject to clinical response.

Duration of treatment will be dependent upon the response seen. Long term treatment should be under regular veterinary supervision.

To extend analgesic cover post-operatively, parenteral administration of carprofen, may be followed with Carprieve Tablets.

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

Not applicable.

Withdrawal period

Not applicable.

Pharmacological particulars

Pharmacotherapeutic group: Non-steroidal anti-inflammatory drug

ATC Vet Code: QM01AE91

Pharmacodynamic properties

Carprofen, (±)-6-chloro-α-methylcarbazole-2-acetic acid, is a non-steroidal anti-inflammatory drug (NSAID). It is a derivative of phenylpropionic acid and a member of the arylpropionic acid class of NSAIDs. As a representative of the 2-arylpropionic family, it contains a chiral center at C2 of the propionic moiety and therefore, exists in 2 sterioisomeric forms, the (+)-S and (-)-R enantiomers.

Pharmacokinetic properties

Following oral administration of 4mg carprofen/kg to dogs, peak plasma concentrations (mean Cmax = 28.51 µg/ml) were achieved in 4 hours.

Absorption of carprofen is rapid and complete in the dog. The volume of distribution is small with the highest drug concentrations occurring in plasma. Ratios of tissue to plasma concentration are less than one, which is consistent with a high level of binding of carprofen to plasma proteins.

Pharmaceutical particulars

List of excipients

•Microcrystalline cellulose

•Lactose monohydrate

•Croscarmellose sodium

•Poly-vinyl pyrrolidone K 30

•Sodium laurilsulfate

•Magnesium stearate

•Purified water

Incompatibilities

None.

Shelf life

Tubs: 36 months

Blister strips: 24 months

Special precautions for storage

Do not store above 25°C.

Store in a dry place.

Protect from light.

Nature and composition of immediate packaging

Carprieve Tablets are supplied in:

Polypropylene Snap Secure Tubs, containing 100 tablets, sealed with a white Polyethylene Snap Secure Cap.

Alu/Alu blister strips of 2 x 5 tablets.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

Marketing Authorisation Holder (if different from distributor)

Norbrook Laboratories Limited, Station Works, Newry, Co. Down, BT35 6JP, Northern Ireland

Marketing Authorisation Number

Vm 02000/4220

Significant changes

Date of the first authorisation or date of renewal

5th September 2003/ 5th September 2008

Date of revision of the text

January 2009

Any other information

Nil.

Legal category

Legal category:POM-V

GTIN

GTIN description: Carprieve 20mg (Blisters X 100)

GTIN:5023534008286

GTIN description: Carprieve 20mg (100 Tablets)

GTIN:5023534008309