

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve Tablets 50mg

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

#### Active Substance:

Each tablet contains:

Carprofen 50 mg

#### Excipients:

For a full list of excipients, see section 6.1

### 3. PHARMACEUTICAL FORM

Tablet

A white/off white circular tablet of diameter 8 mm, 50 embossed on one side and a single break line on the other side.

### 4. CLINICAL PARTICULARS

#### 4.1 Target species

Dogs

#### 4.2 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.

#### 4.3 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.

#### **4.4 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.

#### **4.5 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.

#### **4.6 Adverse reactions (frequency and seriousness)**

None.

#### **4.7 Use during pregnancy, lactation or lay**

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

#### **4.8 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.

#### **4.9 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.

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

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**

Not applicable

### **5. PHARMACOLOGICAL PROPERTIES**

**Pharmacotherapeutic group:** Non-steroidal anti-inflammatory drug

**ATC Vet Code:** QM01AE91

#### **5.1 Pharmacodynamic properties**

Carprofen, ( $\pm$ )-6-chloro- $\alpha$ -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 C<sub>2</sub> of the propionic moiety and therefore, exists in 2 stereoisomeric forms, the (+)-S and (-)-R enantiomers.

#### **5.2 Pharmacokinetic properties**

Following oral administration of 4mg carprofen/kg to dogs, peak plasma concentrations (mean C<sub>max</sub> = 28.51  $\mu$ g/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.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Microcrystalline cellulose  
Lactose monohydrate  
Croscarmellose sodium  
Poly-vinyl pyrrolidone K 30  
Sodium laurilsulfate  
Magnesium stearate  
Purified water

#### **6.2 Incompatibilities**

None.

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale:

Tubs: 36 months

Blister strips: 24 months

### **6.4 Special precautions for storage**

Do not store above 25°C.

Store in a dry place.

Protect from light.

### **6.5 Nature and composition of immediate packaging**

Carprieve Tablets are supplied in:

Polypropylene Snap Secure Tubs, containing 100 or 500 tablets, sealed with a white Polyethylene Snap Secure Cap.

Alu/Alu blister strips of 2 x 5 tablets

### **6.6 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.

## **7. MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories Limited

Station Works

Newry

Co. Down, BT35 6JP

Northern Ireland

## **8. MARKETING AUTHORISATION NUMBER(S)**

ManA: 2000

Vm: 02000/4221

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

5<sup>th</sup> September 2003/ 5<sup>th</sup> September 2008

## **10. DATE OF REVISION OF THE TEXT**

January 2009