

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Canidryl 50 mg Tablets for dogs.

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### **Active Ingredient**

Carprofen 50.0 mg/tablet

#### **Excipients**

For a full list of excipients, see section 6.1

### **3. PHARMACEUTICAL FORM**

Tablet

A plain round flat bevelled edge white to off white tablet with a breakline on one side. The tablets 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 musculo-skeletal disorders and degenerative joint disease. As a follow up to parenteral analgesia in the management of post-operative pain following soft tissue surgery.

#### **4.3 Contra-indications**

Do not use in cats.

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 gastro-intestinal ulceration or bleeding, or where there is evidence of a blood dyscrasia.

Refer to section 4.7.

#### **4.4 Special Warnings for each target species**

Refer to Sections 4.3 and 4.5

#### **4.5 Special precautions for use**

i. Special precautions for use in animals

Use in dogs less than 6 weeks of age, or 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.

Concurrent administration of potential nephrotoxic drugs should be avoided. 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.

Do not administer other 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.

ii. 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/diarrhea, 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 and 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 and other forms of interaction**

Carprofen must not be administered with glucocorticoids.  
Refer also to section 4.5

#### **4.9 Amounts to be administered and administration route**

For oral administration.

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 dependant 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 4mg/kg/day for 2 days.

Do not exceed the stated dose.

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

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 Periods**

Not applicable.

### **5. PHARMACOLOGICAL PROPERTIES**

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

**ATC Vet Code:** QM01AE91.

#### **5.1 Pharmacodynamic Properties**

Carprofen is a member of the 2-arylpropionic acid group of non-steroidal anti-inflammatory drugs (NSAIDs), and possesses anti-inflammatory, analgesic and antipyretic activity. Carprofen is a chiral drug with the S(+) enantiomer being more active than the R(-) enantiomer. Carprofen, like most other NSAIDs 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.

## **5.2 Pharmacokinetic particulars**

After oral administration, carprofen is well absorbed in the dogs. Following the administration of Rofeniflex tablets in dogs, a mean C<sub>max</sub> (maximum concentration in serum) of 15.8 µg/ml and 12.2 µg/ml was achieved at approximately 2 hours and 1.7 hours for Carprofen R(-) and Carprofen S(+), respectively. For both enantiomers, the mean half-life was approximately 6 hours. The analgesic effect from each dose persists for at least 12 hours. Carprofen has a small volume of distribution and a low systemic clearance. It is highly bound to plasma protein. Carprofen is metabolised in the liver by conjugation and oxidation. The excretion of the glucuronide conjugate is mainly faecal after biliary excretion.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Lactose Monohydrate  
Microcrystalline Cellulose  
Silica Colloidal anhydrous  
Magnesium Stearate  
Grilled Meat Flavour

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf-life**

Shelf-life of the veterinary medicinal product packaged in blister packs: 4 years  
Shelf-life of the veterinary medicinal product packaged in HDPE containers: 3 years

Any divided and unused tablets should be discarded immediately.

### **6.4 Special Precautions for Storage**

Store in a dry place in the original package. Protect from light.

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

- i) White High Density Polyethylene (HDPE) Twist-off plastic containers with child proof tamper evident Polypropylene white twist-off closures.
- ii) Blister packs made up of a PVC/PVdC (250µm/40g/m<sup>2</sup>) with a 20µm Hard Temper Aluminium Foil.

**Pack sizes: Blisters**

Pack size: 6 tablets: A box of 1 blister. Each blister contains 6 tablets  
Pack size: 10 tablets: A box of 1 blister. Each blister contains 10 tablets  
Pack size: 14 tablets: A box of 1 blister. Each blister contains 14 tablets  
Pack size: 20 tablets: A box of 2 blisters. Each blister contains 10 tablets  
Pack size: 28 tablets: A box of 2 blisters. Each blister contains 14 tablets  
Pack size: 30 tablets: A box of 3 blisters. Each blister contains 10 tablets  
Pack size: 42 tablets: A box of 3 blisters. Each blister contains 14 tablets  
Pack size: 50 tablets: A box of 5 blisters. Each blister contains 10 tablets  
Pack size: 56 tablets: A box of 4 blisters. Each blister contains 14 tablets  
Pack size: 60 tablets: A box of 6 blisters. Each blister contains 10 tablets  
Pack size: 70 tablets: A box of 5 blisters with each blister containing 14 tablets  
or a box of 7 blisters with each blister containing 10 tablets  
Pack size: 84 tablets: A box of 6 blisters. Each blister contains 14 tablets  
Pack size: 98 tablets: A box of 7 blisters. Each blister contains 14 tablets  
Pack size: 100 tablets: A box of 10 blisters. Each blister contains 10 tablets  
Pack size: 140 tablets: A box of 10 blisters with each blister containing 14  
tablets or a box of 14 blisters with each blister containing 10 tablets  
Pack size: 180 tablets: A box of 18 blisters. Each blister contains 10 tablets  
Pack size: 200 tablets: A box of 20 blisters. Each blister contains 10 tablets  
Pack size: 250 tablets: A box of 25 blisters. Each blister contains 10 tablets  
Pack size: 280 tablets: A box of 28 blisters with each blister containing 10  
tablets or a box of 20 blisters with each blister containing 14 tablets  
Pack size: 300 tablets: A box of 30 blisters. Each blister contains 10 tablets  
Pack size: 500 tablets: A box of 50 blisters. Each blister contains 10 tablets  
Pack size: 1000 tablets: A box of 100 blisters. Each blister contains 10 tablets

**Pack sizes for containers:**

The container pack sizes and volumes are as follows:

**50mg:**

<b>Pack size</b>	<b>Container volume</b>
6, 10, 14, 20, 28, 30	15ml
42, 50	30ml
60, 70	50ml
84, 98, 100	75ml
140, 180, 200	100ml
250, 280	150ml
300	200ml
500	300ml

Not all pack sizes may be marketed.

**6.6 Special Precautions for the Disposal or Unused Medicinal Product or Waste Materials, if any**

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**

Chanelle Pharmaceuticals Manufacturing Ltd.,  
Loughrea,  
Co. Galway,  
Ireland

**8. MARKETING AUTHORISATION NUMBER**

Vm 08749/4010

**9. DATE OF FIRST AUTHORISATION**

12 December 2006

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

September 2011