

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Carprodolor 50 mg/ml solution for injection for cattle

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

Each ml contains:

**Active substance:**

Carprofen 50 mg

**Excipients:**

<b>Qualitative composition of excipients and other constituents</b>	<b>Quantitative composition if that information is essential for proper administration of the veterinary medicinal product</b>
Ethanol 96%	0.1 ml
Macrogol 400	
Poloxamer 188	
Ethanolamine (for pH adjustment)	
Water for injections	

Clear yellowish solution

### **3. CLINICAL INFORMATION**

#### **3.1 Target species**

Cattle.

#### **3.2 Indications for use for each target species**

The product is indicated as an adjunct to antimicrobial therapy to reduce clinical signs in acute infectious respiratory disease and acute mastitis in cattle.

#### **3.3 Contraindications**

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in animals suffering from cardiac, hepatic or renal impairment.

Do not use in animals suffering from gastro-intestinal ulceration or bleeding.

Do not use where there is evidence of a blood dyscrasia.

### 3.4 Special warnings

None.

### 3.5 Special precautions for use

#### Special precautions for safe use in the target species:

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic drugs should be avoided.

Do not exceed the stated dose or the duration of treatment.

Do not administer other NSAID's (non-steroidal anti-inflammatory drugs) concurrently or within 24 hours of each other.

As NSAID therapy can be accompanied by GI or renal impairment, adjunctive fluid therapy should be considered especially in the case of acute mastitis treatment.

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

Carprofen, in common with other NSAIDs, has been shown to exhibit photosensitising potential in laboratory studies. Avoid contact with skin and eyes. Should this occur, wash the affected areas immediately. Seek medical attention if irritation persists.

Care should be taken to avoid accidental self-injection. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

#### Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction <sup>a</sup>
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<sup>a</sup> transient

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

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

Pregnancy:

The safety of the veterinary medicinal product has not been established during pregnancy.

Use only according to the benefit-risk assessment by the responsible veterinarian.

### **3.8 Interaction with other medicinal products and other forms of interaction**

No specific significant drug interactions have been reported for carprofen. During clinical studies in cattle four different antibiotic classes were used, macrolides, tetracyclines, cephalosporins and potentiated penicillins without known interactions. However, in common with other NSAIDs, carprofen should not be administered simultaneously with another veterinary medicinal product of the NSAID or glucocorticoid class. Animals should be carefully monitored if carprofen is administered simultaneously with an anticoagulant.

NSAID's are highly bound to plasma proteins and may compete with other highly bound medicines, such that concomitant administration may result in toxic effects.

### **3.9 Administration routes and dosage**

For subcutaneous or intravenous use.

Single injection of 1.4 mg of carprofen/ kg of body weight (corresponding to 1 ml of the product /35 kg bodyweight) in combination with antibiotic therapy where appropriate.

The stopper should not be punctured more than 20 times.

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

In clinical studies, no adverse signs were reported after intravenous and subcutaneous administration of up to 5 times the recommended dose.

There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAID's, should be applied.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

### **3.12 Withdrawal periods**

Meat and offal: 21 days

Milk: Zero hours

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QM01AE91

### 4.2 Pharmacodynamics

Carprofen is a member of the 2-arylpropionic acid group of non-steroidal anti-inflammatory drugs (NSAID's), and possesses anti-inflammatory, analgesic and antipyretic activity.

Carprofen, like most other NSAID's 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 is unclear.

Studies have shown that carprofen has potent antipyretic activity and significantly reduces the inflammatory response in lung tissue in cases of acute, pyrexia infectious respiratory disease in cattle. Studies in cattle with experimentally induced acute mastitis have shown that carprofen administered intravenously has potent antipyretic activity and improves heart rate and rumen function.

### 4.3 Pharmacokinetics

Absorption: Following a single subcutaneous dose of 1.4 mg carprofen/kg the maximum plasma concentration ( $C_{max}$ ) of 15.4 µg/ml was reached after ( $T_{max}$ ) 7-19 hours.

Distribution: The highest carprofen concentrations are found in bile and plasma and more than 98% of carprofen is bound to plasma proteins. Carprofen was well distributed in the tissues with the highest concentrations found in kidney and liver followed by fat and muscle.

Metabolism: Carprofen (parent) is the main component in all tissues. Carprofen (parent compound) is slowly metabolised primarily by ring hydroxylation, hydroxylation at the  $\alpha$ -carbon and by conjugation of the carboxylic acid group with glucuronic acid. The 8-hydroxylated metabolite and unmetabolized carprofen predominate in the faeces. Bile samples are comprised of conjugated carprofen.

Elimination: Carprofen has a plasma elimination half-life of 70 hours. Carprofen is primarily excreted in the faeces, indicating that the biliary secretion plays an important role.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

## **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 3 years  
Shelf life after first opening the immediate packaging: 28 days

## **5.3 Special precautions for storage**

Do not refrigerate or freeze.  
Keep the vial in the outer carton in order to protect from light.

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

50 ml amber glass (Type I) vials capped with chlorobutyl rubber stopper retained by an aluminium crimped seal in a cardboard box.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## **6. NAME OF THE MARKETING AUTHORISATION HOLDER**

Le Vet Beheer B.V.

## **7. MARKETING AUTHORISATION NUMBER**

Vm 41821/3002

## **8. DATE OF FIRST AUTHORISATION**

07 May 2013

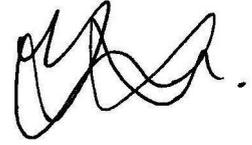
## **9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

September 2023

## **10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

A handwritten signature in black ink, consisting of several loops and a final flourish.

Approved: 31 January 2024