

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Outer carton}**

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

Carprodolor 50 mg/ml solution for injection

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each ml contains:

**Active substance:**

Carprofen 50 mg

**Excipient(s):**

Ethanol 96% 0.1 ml

**3. PACKAGE SIZE**

50 ml

**4. TARGET SPECIES**

Cattle



**5. INDICATION(S)**

**6. ROUTES OF ADMINISTRATION**

Subcutaneous use, intravenous use

The stopper should not be punctured more than 20 times.

**7. WITHDRAWAL PERIODS**

Withdrawal period:

Meat and offal: 21 days

Milk: Zero hours

## **8. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached, used within 28 days.

Once broached, use by...

## **9. SPECIAL STORAGE PRECAUTIONS**

Do not refrigerate or freeze

Keep the vial in the outer carton in order to protect from light.

## **10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

## **11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

## **12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

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

Le Vet Beheer B.V.

## **14. MARKETING AUTHORISATION NUMBERS**

Vm 41821/5008

## **15. BATCH NUMBER**

Lot {number}

## **16. SPECIAL WARNING(S), IF NECESSARY**

## **17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

POM-V. Veterinary medicinal product subject to prescription.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS {Amberg glass vial – 50 ml}**

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

Carprodolor

“ ”

**2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE  
SUBSTANCES**

Carprofen 50 mg/ml

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached, use within 28 days.

Once broached, use by...

**5. ROUTE(S) OF ADMINISTRATION**

For SC and IV use.

**6. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

## **PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

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

Carprodolor 50 mg/ml solution for injection for cattle

### **2. COMPOSITION**

Per ml:

**Active substance:**

Carprofen 50 mg

**Excipient(s):**

Ethanol 96% 0.1 ml

Clear yellowish solution

### **3. TARGET SPECIES**

Cattle.

### **4. INDICATIONS FOR USE**

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

### **5. 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.

### **6. SPECIAL WARNINGS**

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.

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.

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.

Overdose:

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.

Major incompatibilities:

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

## 7. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first

instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: <{national system details}>.

## **8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION**

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.

## **9. ADVICE ON CORRECT ADMINISTRATION**

The stopper should not be punctured more than 20 times.

## **10. WITHDRAWAL PERIODS**

Meat and offal: 21 days

Milk: Zero hours

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Do not refrigerate or freeze

Keep the vial in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the vial after Exp. The expiry date refers to the last day of the month.

Shelf life after first opening the immediate packaging: 28 days.

## **12. SPECIAL PRECAUTIONS FOR DISPOSAL**

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

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

Veterinary medicinal product subject to prescription.

## **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

Marketing authorisation numbers: Vm 41821/5008

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

## 15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

Find more product information by searching for the 'Product Information Database' or 'PID' on [www.gov.uk](http://www.gov.uk).

## 16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:

Le Vet Beheer B.V.  
Wilgenweg 7  
3421 TV Oudewater  
The Netherlands  
Tel.: +44 (0)1939 211200

Manufacturer responsible for batch release:

Produlab Pharma B.V.  
Forellenweg 16  
4941 SJ Raamsdonksveer  
The Netherlands

## 17. OTHER INFORMATION

POM-V. Veterinary medicinal product subject to prescription.

For animal treatment only.

Approved 16 November 2023

