

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

Excipient(s):

Ethanol 96% 0.1 ml

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for Injection
Clear yellowish solution

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the 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.

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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.

Other precautions

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction ^a
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^a 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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

4.7 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.

4.8 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.

4.9 Amount(s) to be administered and administration route

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.

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

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.

4.11 Withdrawal period(s)

Meat and offal: 21 days

Milk: Zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and Anti-rheumatic products, non-steroids

ATCvet code: QM01AE91

5.1 Pharmacodynamic properties

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 cyclooxygenase 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.

5.2 Pharmacokinetic particulars

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 α -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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96%
Macrogol 400
Poloxamer 188
Ethanolamine (for pH adjustment)
Water for injections

6.2 Major incompatibilities

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

6.3 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

6.4 Special precautions for storage

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

6.5 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.

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

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

7. MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 41821/5008

9. DATE OF FIRST AUTHORISATION

07 May 2013

10. DATE OF REVISION OF THE TEXT

November 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Approved 16 November 2023

A handwritten signature in black ink, appearing to be 'M. M. M.', located below the approval date.