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

Per ml:
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 pale straw coloured liquid

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

i. 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 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.

ii. 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 to the physician.

4.6 Adverse reactions (frequency and seriousness)

Studies in cattle have shown that in very rare cases a transient local reaction may form at the site of the injection.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

In the absence of any specific studies in pregnant cattle, use only after a risk/benefit assessment has been performed by the attending veterinary surgeon.

4.8 Interaction with other medicinal products and other forms of interactions

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 penicllins 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 drugs, such that concomitant administration may result in toxic effects.

4.9 Amounts to be administered and administration route

Single subcutaneous or intravenous injection at a dosage of 1.4 mg carprofen/ kg body weight (1 ml/35 kg) in combination with antibiotic therapy, as 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 or IMMUNOLOGICAL 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 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, pyrexic 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 chlorbutyl rubber stopper retained by an aluminium crimped seal in a cardboard box.

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

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
Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA10475/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th April 2013
Date of latest renewal: 11th April 2018

10 DATE OF REVISION OF THE TEXT

July 2018