Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprosol 50 mg/ml solution for injection for cattle.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Carprofen 50 mg

Excipients:
Ethanol 96% 0.1 ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
Clear, light yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

An adjunct treatment to antimicrobial therapy to reduce clinical signs in acute infectious respiratory disease and in acute mastitis in cattle.

4.3 Contraindications

Do not use in animals suffering from cardiac, hepatic or renal disease.
Do not use in animals suffering from gastro-intestinal ulceration or bleeding.
Do not use if there is evidence of blood dyscrasia.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

- Avoid use in dehydrated or hypovolaemic animals or animals with hypotension, because there is a potential risk of increased renal toxicity.
- Concurrent administration of potentially nephrotoxic drugs should be avoided.
- The recommended dose and duration of treatment should not be exceeded.
- Do not administer other NSAIDs concurrently or within 24 hours after each administration.
- As treatment with NSAIDs may be accompanied by gastrointestinal or renal impairment, adjunctive fluid therapy should be considered, especially in the treatment of acute mastitis.

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

As with other NSAIDs, photosensitivity can also occur with carprofen. Avoid skin contact and accidental self-injection with the veterinary medicinal product. In case skin contact does occur, immediately wash with water and soap.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Studies in cattle have shown that a transient local reaction may occur at the injection site.

4.7 Use during pregnancy, lactation or lay

Use only according to the benefit/risk assessment of the responsible veterinarian, as specific studies on pregnant cattle are not available.

4.8 Interaction with other medicinal products and other forms of interaction

No specific interactions with other veterinary medicinal products have been reported for carprofen.
Four different classes of antibiotics have been used during clinical studies with cattle (macrolides, tetracyclines, cephalosporins and potentiated penicillins) with no known interactions. However, as is the case with other NSAIDs, carprofen should not be administered simultaneously with any other veterinary medicinal product from the NSAID group or with glucocorticoids. Animals that receive an anticoagulant simultaneously with carprofen should be carefully monitored.
NSAIDs have a high percentage of binding to plasma proteins and are competitive with other agents with high plasma protein binding, which can lead to toxic effects.

4.9 Amounts to be administered and administration route

Single subcutaneous or intravenous injection at a dose of 1.4 mg carprofen per kg of body weight (1 ml/35 kg) in combination with appropriate antibiotic therapy.

The stopper should not be punctured more than 20 times.

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

In clinical trials, no adverse effects were observed after intravenous or subcutaneous administration of up to 5 times the recommended dose.
There is no specific antidote for carprofen overdosage. General symptomatic treatment, as is usual for clinical overdosage with NSAIDs, should be established.

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 (NSAIDs), and possesses anti-inflammatory, analgesic and antipyretic properties.

As with most other NSAIDs, carprofen is an inhibitor of the enzyme cyclo-oxygenase of the arachidonic acid cascade. However, the inhibition of prostaglandin synthesis by carprofen is slight compared to its anti-inflammatory and analgesic properties. The exact mechanism of action is not clear.

Studies have demonstrated that carprofen exhibits strong antipyretic activity and provides a significant reduction of inflammation in lung tissue in acute infectious respiratory disease with fever in cattle. Studies on experimentally induced acute mastitis in cattle have shown that intravenously administered carprofen has a powerful antipyretic activity and improves heart rate and rumen function.

5.2 Pharmacokinetic properties

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 were found in bile and plasma, and more than 98% of the carprofen is bound to plasma proteins. Carprofen was well distributed among the tissues, with the highest concentrations found in kidneys and liver, followed by fat and muscle.

Metabolism: Carprofen (parent compound) is the main component in all tissues. Carprofen (parent compound) is metabolised slowly, mainly by ring hydroxylation, hydroxylation at the α-carbon site and by conjugation of the carboxylic acid group with glucuronic acid. The 8-hydroxyl metabolite and unmetabolised carprofen predominate in the faeces. Bile samples contain conjugated carprofen.

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96%
Macrogol 400
Poloxamer 188
Ethanolamine
Water for injections

6.2 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: 2 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 vial (Type I) with chlorobutyl rubber stopper, covered with an aluminum cap.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

CP-Pharma Handelsges. mbH
Ostlandring 13
31303 Burgdorf
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10810/006/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27th April 2012

10 DATE OF REVISION OF THE TEXT