Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 50 mg/ml Solution for Injection for Cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active Substance:
Carprofen 50 mg

Excipients:
Ethanol (anhydrous) 100 mg
Sodium Formaldehyde Sulphoxylate 2 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for Injection.
A clear colourless to pale yellow 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 pyrexia in acute cases of infectious respiratory disease in cattle.

4.3 Contraindications

Do not use in animals suffering from cardiac, hepatic or renal impairment.
Do not use in animals suffering from gastrointestinal ulceration or bleeding.
Do not use where there is evidence of a blood dyscrasia.
Do not use in animals with known hypersensitivity to the product.
For use in pregnant animals refer to section 4.7.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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

Do not administer other NSAIDs concurrently or within 24 hours of each other. Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs, which can lead to toxic effects.

Use in any animal less than 6 weeks of age, or in aged animals, may involve additional risk. If such use cannot be avoided animals may require a reduced dosage and careful clinical management.

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.

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 skin contact with the product. Wash off any splashes immediately. Take care to avoid accidental self-injection.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicnal 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 interactions

In common with other NSAIDs, carprofen should not be administered simultaneously with another product of the NSAID or glucocorticoid class. Animals should be carefully monitored if carprofen is administered simultaneously with an anticoagulant. NSAIDs are highly bound to plasma proteins and may compete with other highly bound drugs, which can lead to toxic effects.

Concurrent administration of potential nephrotoxic drugs should be avoided.

4.9 Amounts to be administered and administration route

Single subcutaneous or intravenous injection at a dosage of 1.4 mg carprofen per kilogram (1 ml/35 kg) bodyweight in combination with antibiotic therapy, as appropriate.

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

Carprofen is well tolerated at doses up to 3 times the recommended dose for cattle. There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAIDs should be applied.

4.11 Withdrawal period(s)

Milk: Zero days.

Meat and offal: 21 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and anti-rheumatic products, Propionic acid derivatives.
ATCvet code: QM01 AE91

5.1 Pharmacodynamic properties

Carprofen (CPF), (±)-6-chloro-a-methylcarbazole-2-acetic acid, is a non-steroidal anti-inflammatory drug (NSAID) with analgesic and anti-pyretic properties. It is a derivative of phenylpropionic acid and a member of the arylpropionic acid class of NSAIDs. As a representative of the 2-arylpropionic family, it contains a chiral center at C_2 of the propionic moiety and therefore, exists in 2 sterioisomeric forms, the (+)-S and (-)-R enantiomers.

In vitro studies have shown carprofen to be a cyclo-oxygenase inhibitor. 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 disease in cattle.

5.2 Pharmacokinetic particulars

In a pharmacokinetic study using the product, following a single subcutaneous dose of 1.4 mg carprofen per kilogram bodyweight the maximum plasma concentration (C_{max}) of 10.4 microgram/ml was reached after (T_{max}) 7.2 hours.

Carprofen is highly bound to plasma proteins. It is well distributed in the tissues with the highest concentrations found in kidney and liver followed by fat and muscle. Elimination is slow. Carprofen is eliminated primarily in the faeces, indicating that the biliary secretion plays an important role.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (anhydrous)
Sodium formaldehyde sulphoxylate
Polyethylene glycol 600
Polyethylene glycol 4000
L-Arginine
Water for Injection

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: 2 years
Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Protect from light.

6.5 Nature and composition of immediate packaging

50ml multidose amber glass (Type I) vials, sealed with 20mm bromobutyl bungs and 20mm aluminium seals.

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

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/080/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 May 2007
Date of last renewal: 03 May 2012

10 DATE OF REVISION OF THE TEXT

January 2019