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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Ethanol (anhydrous)	100 mg
Sodium Formaldehyde Sulphoxylate	2 mg
Polyethylene glycol 600	
Polyethylene glycol 4000	
L-Arginine	
5% sodium hydroxide	
Water for Injection	

A clear colourless to pale yellow solution for injection.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

The product is indicated as an adjunct to antimicrobial therapy to reduce pyrexia in acute cases of infectious respiratory disease in cattle.

3.3 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 cases of hypersensitivity to the active substance or to any of the excipients.
For use in pregnant animals refer to section 4.7.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction[1]

[1]Transient at the site of subcutaneous injection.

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.

3.7 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.

3.8 Interaction with other medicinal products and other forms of interaction

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.

3.9 Administration routes and dosage

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.

Do not exceed 3 broachings per vial. If more than 3 broachings are required, the use of a draw-off needle is recommended

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Milk: Zero days.

Meat and offal: 21 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QM01AE91

4.2 Pharmacodynamics

Carprofen (CPF), (±)-6-chloro-α-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.

4.3 Pharmacokinetics

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 μg/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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

Protect from light.

5.4 Nature and composition of immediate packaging

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

5.5 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 or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA 22664/080/001

8. DATE OF FIRST AUTHORISATION

04/05/2007

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

18/12/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).