Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Norocarp Large Animal 5 %w/v Solution for Injection for young cattle, horses and ponies

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Carprofen	5.00 % w/v

Excipients

Ethanol (anhydrous)	10.00 % v/v (as preservative)
Sodium Formaldehyde Sulphoxylate	0.20 % w/v (as antioxidant)

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

Young cattle (under 12 months of age), horses and ponies.

4.2 Indications for use, specifying the target species

In young cattle (under 12 months old) Norocarp Large Animal Injection is indicated as adjunctive therapy for the control of acute inflammation associated with respiratory disease. The cause of the condition should be determined and treated with an appropriate antimicrobial.

In horses and ponies it is indicated for analgesic and anti-inflammatory action in musculo-skeletal disorders and after surgery.

4.3 Contraindications

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.
Do not use in animals with known hypersensitivity to the product.
Do not use in pregnant animals.
Not permitted for use in lactating cattle producing milk for human consumption.

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 potential nephrotoxic drugs should be avoided.

For specific information about the time which must elapse between treatment and equine competition, veterinary surgeons are required to consult the authority responsible for the competition in question.

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

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

In the absence of any specific studies in pregnant target animals such use is not indicated.
Not for use in cattle producing milk for human consumption.

4.8 Interaction with other medicinal products and other forms of interactions

Do not administer 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.
Concurrent administration of potential nephrotoxic drugs should be avoided.

4.9 Amounts to be administered and administration route

In young cattle the recommended dosage is 1.4 mg Carprofen per kilogram (1 ml/35 kg) bodyweight once, administered by intravenous or subcutaneous injection.
In horses and ponies the recommended dosage is 0.7 mg Carprofen per kilogram (1 ml/70 kg) bodyweight by intravenous injection as a single dose. This can be repeated after 24 hours.

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

This product is well tolerated at doses up to 3 times the recommended dose for cattle and at doses up to 2 times the recommended dose for horses. 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)

Cattle
Meat and offal: 21 days.
Do not use in cows producing milk for human consumption.

Horses
Meat and offal: 4 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC vet code: QM01AE91
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.

5.1 Pharmacodynamic properties

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 Norocarp Large Animal Injection in cattle, 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 7.2 hours (T_{max}).

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 primarily excreted in the faeces, indicating that the biliary secretion plays an important role.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Sodium Formaldehyde Sulphoxylate
Polyethylene Glycol 600
Polyethylene Glycol 4000
L-Arginine
Water for Injection

6.2 Major incompatibilities

In the absence of incompatibility 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 container: 28 days.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

50 ml multidose amber glass vials (grade 1), sealed with 20 mm 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 product 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)

VPA22664/074/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09 September 2005
Date of last renewal: 08 September 2010

10 DATE OF REVISION OF THE TEXT

February 2019