Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Norocarp 50 mg/ml Solution for Injection for Cattle (AT, BE, ES, FI, IE, PT)
Carprieve 50 mg/ml Solution for Injection for Cattle (DE, IT, UK)
Carprogesic 50 mg/ml Solution for Injection for Cattle (FR)
Norodyl Vet. Solution for Injection (DK, NO)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance Carprofen	50 mg/ml
Excipients	
Ethanol (anhydrous)	0.1 ml/ml
Sodium Formaldehyde Sulphoxylate	2.0 mg/ml

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

Reduction of pyrexia in acute cases of infectious respiratory disease in cattle, in combination with appropriate anti-infective therapy.

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 refer to section 4.7.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) 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. Also refer to section 4.8.

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 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, however this should disappear within 24 hours after the injection.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

4.8 lnteraction 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 (1ml/35kg) 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.

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

No systemic adverse effects were reported after intravenous or subcutaneous administration of up to 3 times the recommended dose. 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 hours.
Meat and offal: 21 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and anti-rheumatic products, Propionic acid derivatives.
ATCvet code: QM01AE91

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

After a single subcutaneous administration of the product at 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.
Carprofen has a plasma elimination half-life of 70 hours. Carprofen is eliminated primarily in the faeces, indicating that the biliary secretion plays an important role.

Metabolism: Carprofen (parent) is the main component in all tissues. Carprofen (parent compound)

is slowly metabolised primarily by ring hydroxylation, hydroxylation at the a-carbon and by conjugation of the carboxylic acid group with glucuronic acid. The 8-hydroxylated metabolite and unmetabolised carprofen predominate in the faeces. Bile samples are comprised of conjugated carprofen.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (anhydrous)
Sodium formaldehyde sulphoxylate
Polyethylene glycol 600
Polyethylene glycol 4000
L-Arginine
5 % Sodium Hydroxide
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 immediate packaging: 28 days

6.4 Special precautions for storage

Protect from light.

6.5 Nature and composition of immediate packaging

Norocarp Injection for Cattle is available in 1 *x* 50ml, 5 *x* 50ml, 6 x 50ml, 10 x 50ml and 12 x 50ml multidose amber glass (Type I) vials, sealed with 20mm bromobutyl bungs and 20mm aluminium seals. Not all pack sizes may be marketed.

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

8 MARKETING AUTHORISATION NUMBER(S)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:
Date of last renewal:

10 DATE OF REVISION OF THE TEXT

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

Manufacturer Responsible for Batch Release:
Norbrook Manufacturing Ltd
Rossmore Industrial Estate
Monaghan
Ireland

Norbrook Laboratories Limited
Station Works, Camlough Road
Newry, Co. Down, BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norocarp 50 mg/ml Solution for Injection for Cattle

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Norocarp 50 mg/ml Solution for Injection for Cattle is a solution for injection containing 50 mg/ml carprofen, 100 mg/ml ethanol (as preservative) and 2.0 mg/ml sodium formaldehyde sulphoxylate (as antioxidant).

4. INDICATION(S)

Reduction of pyrexia in acute cases of infectious respiratory disease in cattle, in combination with appropriate anti-infective therapy.

5. CONTRAINDICATIONS

Do not use in animals suffering from cardiac, hepatic or renal impairment, where there is a possibility of gastrointestinal ulceration or bleeding, or where there is evidence of a blood dyscrasia or hypersensitivity to the product.

6. ADVERSE REACTIONS

Studies in cattle have shown that a transient local reaction may form at the site of subcutaneous injection, however this should disappear within 24 hours after the injection.

If you notice any serious side effects or any other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Milk: Zero hours.

Meat and offal: 21 days.

11. SPECIAL STORAGE PRECAUTIONS

Protect from light.
Shelf-life after first opening the container: 28 days.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.
Do not use after the expiry date which is stated on the vial and carton label after EXP:

Keep out of the reach and sight of children.

12. SPECIAL WARNINGS

Do not exceed the stated dose or the duration of treatment.
Do not administer other NSAIDs concurrently or within 24 hours of each other.
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.

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.
There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAIDs should be applied.
The safety of the veterinary medicinal product has not been established during pregnancy. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.
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.

USER WARNINGS

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

MARKETING AUTHORISATION NUMBER

Norocarp Injection for Cattle is available in 1 x 50ml, 5 x 50ml, 6 x 50ml, 10 x 50ml and 12 x 50ml multidose amber glass (Type I) vials, sealed with 20mm bromobutyl bungs and 20mm aluminium seals.
Not all pack sizes may be marketed.

POM

Prescription Only Medicine.