SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norocarp 50 mg/ml Solution for Injection for Cattle and Horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Carprofen	50 mg/ml

Excipients:

Ethanol	0.1 ml/ml (as preservative)
Sodium Formaldehyde Sulphoxylate	2 mg/ml (as antioxidant)

For the 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) the product 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 disease, where there is a possibility of gastrointestinal ulceration or bleeding, or where there is evidence of a blood dyscrasia or hypersensitivity to the product.

Do not administer by the intramuscular or subcutaneous routes in the horse (see 4.9)

4.4 Special Warnings for each target species

None

4.5 Special precautions for use

(i) Special precautions for use in animals

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.
In horses, concurrent administration of potential nephrotoxic drugs should be avoided.

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

(ii) Special Precautions to be taken by the person administering the veterinary medicinal product to animals

Care should be taken to avoid accidental self-injection. If accidental self-injection occurs, seek medical attention immediately
Avoid contact with skin and eyes. Wash off any splashes immediately with clean running water. Seek medical attention if irritation persists

4.6 Adverse reactions (frequency and seriousness)

Typical undesirable effects associated with NSAID administration such as faecal occult blood, loss of appetite and lethargy, have been reported. These adverse reactions occur generally within the first week and in most cases are transient and disappear following termination of the treatment, but in rare cases may be serious or fatal.

If adverse reactions occur, use of the product should be stopped and the advice of a veterinarian should be sought.

Transient injection site reactions may be observed in young cattle after subcutaneous administration. These resolve within 24 hours.

4.7 Use during pregnancy, lactation or lay

In the absence of any specific studies the use in pregnant or lactating animals is not recommended.

4.8 Interaction with other medicinal products and other forms of interaction

No significant drug interactions have been reported for Carprofen. During clinical studies in cattle four different antibiotic classes were used, macrolides, tetracyclines, cephalosporins and potentiated penicillins without

known interactions. The acute toxicity of Carprofen in animals was not significantly affected in tests with 15 concomitantly administered drugs.
These were acetylsalicylic acid, amphetamine, atropine, chloropromazine, diazepam, diphenhydramine, ethyl alcohol, hydrochlorothiazide, imipramine, meperidine, proxyphene, penobarbital, sulfisoxazole, tetracycline and tolbutaide.
Do not administer NSAIDs or glucocorticoids 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.

Gastrointestinal tract ulceration may be exacerbated by corticosteroids in patients given NSAIDs.

4.9 Amounts to be administered and administration route

In young cattle the recommended dosage is 1.4 mg Carprofen per kilogram (1ml/35kg) bodyweight once, administered by subcutaneously or intravenously.
In horses and ponies, the recommended dosage is 0.7mg/kg (1ml/70kg) bodyweight by intravenous injection as a single dose. This can be repeated after 24 hours, or followed by therapy with an oral formulation of carprofen, according to the duration of clinical signs. After this, further use should follow another clinical evaluation.

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

FOR INTRAVENOUS USE ONLY IN THE HORSE (see 4.3) For horses, specific information about the time which must elapse between the treatment and competition, veterinary surgeons are advised to consult the authority responsible for the competition in question (e.g the Jockey club in the case of racing in the UK)

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

Carprofen is well tolerated at doses up to 3 times the recommended dose for cattle and two 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

Cattle:
Meat and offal-21 days.
Milk- Not for use in cattle producing milk for human consumption

Horses:
Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.

The horse must have been declared as not intended for human consumption under the national horse passport legislation.
Milk- Not for use in horses producing milk for human consumption

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QM01AE91

Phamacotherapeutic group: Antiiflammatory and Antirheumatic Products, non-steroids, Propionic acid derivatives.

5.1 Pharmacodynamic properties

The mechanism of action of Carprofen has not been fully elucidated, however *in vitro* studies have shown it 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 properties

As a representative of the 2-arylpropionic family, carprofen contains a chiral center at C_2 of the propionic moiety and therefore, exists in 2 stereoisomeric forms, the (+)-S and (-)-R enantiomers.

The drug is available as a racemic mixture (i.e. equal quantities of both the R- and S+ enantiomers). All 2-arylpropionic acid NSAIDs (except Naproxen) are administered as a racemic mixture of 2 optical isomers with different anti-inflammatory activity as well as inter-species differences across the group.

For a racemic mixture, results have shown the predominance of R(-) over the S(+) enantiomer in cattle and horses, with a slow clearance, long half-life and low distribution volume of both enantiomers. 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 (T_{max}) 7.2 hours. Carprofen is eliminated primarily by metabolism. 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 Anhydrous
Sodium Formaldehyde Sulphoxylate
Macrogol 600
Macrogol 4000
L-Arginine
Water for Injection

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

The shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after opening the immediate packaging: 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

Available in 50ml multidose amber glass (grade I), sealed with 20mm bromobutyl bungs and 20mm aluminium seals.

Available in cartons of 1 x 50ml

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4277

9. DATE OF FIRST AUTHORISATION

22 May 2009

10. DATE OF REVISION OF THE TEXT

July 2017

Approved: 11 July 2017