DRAFT LABEL

NOROCARP 50 MG/ML SOLUTION FOR INJECTION FOR CATTLE AND HORSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NOROCARP 50 MG/ML SOLUTION FOR INJECTION FOR CATTLE AND HORSES

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

50 mg/ml carprofen, 100 ml ethanol (as preservative) and 2 mg/ml sodium formaldehyde sulphoxylate (as antioxidant).

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 ml.

5. TARGET SPECIES

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

6. INDICATION(S)

In young cattle, 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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In young cattle, the recommended dosage is 1.4mg carprofen per kg (1ml/35kg) bodyweight once, administered 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.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle: Meat & offal - 21 days.
Milk - Not for use in cattle producing milk for human consumption.
Horses: Not for use in horses producing food or milk for human consumption.
See package leaflet for full advice.

9. SPECIAL WARNINGS

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

Following withdrawal of the first dose, use the remainder of the product within 28 days.

Date of broaching: --/--/--
Date to discard: --/--/--

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, if applicable

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

FOR ANIMAL TREATMENT ONLY

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufactured by:
Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

Distributed by:
Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4277

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

POM-V To be supplied only on veterinary prescription

DRAFT CARTON

NOROCARP 50 MG/ML SOLUTION FOR INJECTION FOR CATTLE AND HORSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NOROCARP 50MG/ML SOLUTION FOR INJECTION FOR CATTLE AND HORSES

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

50 mg/ml carprofen, 100 ml ethanol (as preservative) and 2 mg/ml sodium formaldehyde sulphoxylate (as antioxidant).

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 ml.

5. TARGET SPECIES

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

6. INDICATION(S)

In young cattle, 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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In young cattle, the recommended dosage is 1.4mg carprofen per kg (1ml/35kg) bodyweight once, administered 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.

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Cattle: Meat & offal - 21 days.
Milk - Not for use in cattle producing milk for human consumption.
Horses: Not for use in horses producing food or milk for human consumption.
See package leaflet for complete warnings.

9. SPECIAL WARNINGS

Read the package leaflet before use.

USER WARNINGS:
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

10. EXPIRY DATE

EXP:

Following withdrawal of the first dose, use the remainder of the product within 28 days.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, if applicable

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

FOR ANIMAL TREATMENT ONLY

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufactured by:
Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

Distributed by:
Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4277

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

POM-V To be supplied only on veterinary prescription

PACKAGE LEAFLET

NOROCARP 50 MG/ML SOLUTION FOR INJECTION FOR CATTLE AND HORSES

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

Norbrook Laboratories Limited
Newry, Co. Down,
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

NOROCARP 50MG/ML SOLUTION FOR INJECTION FOR CATTLE AND HORSES

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

50 mg/ml carprofen, 100 ml ethanol (as preservative) and 2 mg/ml sodium formaldehyde sulphoxylate (as antioxidant).

4. INDICATION(S)

In young cattle, 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.

5. CONTRAINDICATIONS

Do not use in animals suffering from cardiac, hepatic or renal disease, where there is a possibility of gastro-intestinal 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.

6. ADVERSE REACTIONS

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 reaction occurs, 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.

7. TARGET SPECIES

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

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

In young cattle, the recommended dosage is 1.4mg carprofen per kg (1ml/35kg) bodyweight once, administered 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 the treatment.

FOR INTRAVENOUS USE ONLY IN THE HORSE. For horses, specific information about the time which must elapse between 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).

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Cattle:
Meat - 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 national horse passport legislation.
Milk – Not for use in horses producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.
Following withdrawal of the first dose, use the remainder of the product within 28 days. The date of discard of the remaining product should be recorded on the label after first opening the immediate packaging.
Keep out of reach and sight of children.
For animal treatment only.

12. SPECIAL WARNINGS

Use in any animal less than 6 weeks of age, or in aged animals may involve additional risk. If such a use cannot be avoided, animals may require a reduced dosage and careful clinical management.
Avoid use in any dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.
In horses, concurrent administration of potential nephrotoxic drugs should be avoided.
In the absence of any specific studies the use in pregnant or lactating animals is not recommended.

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

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

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2017

15. OTHER INFORMATION

PACKAGE QUANTITIES:
50 ml multidose amber glass vials.

Vm 02000/4277 ManA 2000

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