PARTICULARS TO APPEAR ON THE OUTER PACKAGE {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NOROCARP 5.0% w/v LARGE ANIMAL SOLUTION FOR INJECTION

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Norocarp 5.0% w/v Large Animal Solution for Injection is a solution for injection, containing 5% w/v carprofen, 10% v/v ethanol (as preservative) and 0.2% w/v sodium formaldehyde sulphoxylate (as antioxidant).

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 ml multidose amber glass vials.

5. TARGET SPECIES

Young cattle (under 12 months of age)

6. INDICATION(S)

Carprofen is a non-steroidal anti-inflammatory drug (NSAID) with analgesic and anti-pyretic properties. 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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In young cattle, the recommended dosage is 1.4 mg Carprofen per kilogram (1ml/35kg) bodyweight once, administered by subcutaneous injection.

8. WITHDRAWAL PERIOD

Cattle meat and offal: 10 days.
Do not use in cows producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY CONTRAINDICATIONS, WARNINGS, ETC:

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

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.
In the absence of any specific studies in pregnant target animals such use is not indicated.

Avoid use in any dehydrated, hypovolemic or hypotensive animal, as there is a potential risk of increased renal toxicity.
There is no specific antidote for Carprofen overdose but general supportive therapy as applied to clinical overdose with NSAIDs should be applied. If adverse reactions occur, use of the product should be stopped and the advice of a veterinarian should be sought.

Typical undesirable effects associated with NSAID administration such a 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 treatment, but in rare cases may be serious or fatal. Transient injection site reactions may be observed in young cattle after subcutaneous administration. These resolve within 24 hours.

USER WARNINGS:
Avoid skin contact. Wash off any splashes immediately. Take care to avoid accidental self-injection. Wash hands after use.

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.
Keep container in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

FOR ANIMAL TREATMENT ONLY

POM - V

To be supplied only on veterinary prescription.

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

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

KEEP OUT OF THE REACH AND SIGHT 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 02000/4246

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NOROCARP 5.0% w/v LARGE ANIMAL SOLUTION FOR INJECTION
(Carprofen 5 % w/v)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A solution for injection containing 5% w/v Carprofen, 10% v/v ethanol (as preservative) and 0.2% w/v 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)

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In young cattle the recommended dosage is 1.4 mg Carprofen per kilogram (1ml/35kg) bodyweight once, administered by subcutaneous injection.

8. WITHDRAWAL PERIOD

Cattle meat and offal: 10 days.
Do not use in cows producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

For details on contraindications, warnings and user warnings, see package leaflet.

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.
Keep container in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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

FOR ANIMAL TREATMENT ONLY

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

POM - V

To be supplied only on veterinary prescription.

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

KEEP OUT OF THE REACH AND SIGHT 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)

Vm 02000/4246
ManA 2000

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

PACKAGE LEAFLET FOR:
NOROCARP 5.0% w/v LARGE ANIMAL SOLUTION FOR INJECTION

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

Norbrook Laboratories Limited
Station Works
Newry
Co. Down
Northern Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

NOROCARP 5.0% w/v LARGE ANIMAL SOLUTION FOR INJECTION

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

Norocarp 5.0% w/v Large Animal Solution for Injection is a solution for injection, containing 5% w/v carprofen, 10% v/v ethanol (as preservative) and 0.2% w/v sodium formaldehyde sulphoxylate (as antioxidant).

4. INDICATION(S)

Carprofen is a non-steroidal anti-inflammatory drug (NSAID) with analgesic and anti-pyretic properties. 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.

5. CONTRAINDICATIONS

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. Gastrointestinal tract ulceration may be exacerbated by corticosteroids in patients given NSAIDs.
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.
This product should not be used in cattle producing milk for human consumption.

6. ADVERSE REACTIONS

If adverse reactions occur, use of the product should be stopped and the advice of a veterinarian should be sought. Typical undesirable effects associated with NSAID administration such a 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 treatment, but in rare cases may be serious or fatal. 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)

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

In young cattle, the recommended dosage is 1.4 mg Carprofen per kilogram (1ml/35kg) bodyweight once, administered by subcutaneous injection.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

Cattle meat and offal: 10 days.
Do not use in cows producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.
Keep container in outer carton.
Following withdrawal of the first dose, use the remainder of the product within 28 days.
Keep out of reach and sight of children.

When the container is broached for the first time, using the in-use shelf-life which is specified on this package insert, 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.

12. SPECIAL WARNING(S)

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.
In the absence of any specific studies in pregnant target animals such use is not indicated.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

There is no specific antidote for Carprofen overdose but general supportive therapy as applied to clinical overdose with NSAIDs should be applied.

User Warnings:
Avoid skin contact with the product. Wash off any splashes immediately. Take care to avoid accidental self-injection.
Wash hands after use.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2012

15. OTHER INFORMATION

PACKAGE QUANTITIES:

50 ml multidose amber glass vials.

MARKETING AUTHORISATION NO.:

Vm 02000/4246
ManA 2000

FOR ANIMAL TREATMENT ONLY

UK AUTHORISED VETERINARY MEDICINAL PRODUCT
Keep out of the reach and sight of children.

POM - V

To be supplied only on veterinary prescription.

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

Approved: 30/08/2017