PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Glass and Plastic)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norocillin 30% w/v Suspension for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A suspension for injection containing Procaine Penicillin. 300 mg per ml (30% w/v). Also contains Methyl Parahydroxybenzoate 0.112% w/v, Ethyl Parahydroxybenzoate 0.023% w/v and Propyl Parahydroxybenzoate 0.016% w/v.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

50 ml / 100 ml/ 250 ml/ 500 ml

5. TARGET SPECIES

CattleSheep

Pigs

6. INDICATION(S)

Norocillin is indicated for use in cattle, sheep and pigs in the treatment of systemic infections caused by or associated with organisms sensitive to penicillin. *In vitro* tests have shown the following organisms to be sensitive:
Arcanobacterium (Actinomyces) pyogenes, Erysipelothrix rhusiopathiae, Listeria, *Mannheima haemolytica, Pasteurella multocida, Staphylococcus* spp (non-penicillinase producing) and *Streptococcus* spp.

Norocillin is recommended, therefore, in the treatment of diseases caused by susceptible organisms including:
erysipelas; navel/joint-ill; respiratory tract infections including pneumonia and atrophic rhinitis; listeriosis; septicaemia; urogenital tract infections and the control of secondary bacterial invaders in diseases of primary viral origin.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The recommended dose rate is:

10 mg/kg bodyweight (1 ml/30 kg) daily for three to five days.

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

8. WITHDRAWAL PERIOD

Cattle:	Meat – 7 Days.
	Milk – 84 Hours.
Pigs:	Meat – 7 Days.
Sheep:	Meat – 7 Days.

Do not use in sheep producing milk for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

Do not inject intravenously or intrathecally. Care should be taken not to overdose. Norocillin is contraindicated in known cases of hypersensitivity to penicillins.

Penicillins/cephalosporins may occasionally cause severe allergic reactions. See package leaflet for operator warning.

10. EXPIRY DATE

Exp: dd/mm/yyyy

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C – 8°C). Protect from light. Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

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.

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

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Newry
BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4099

ManA 2000

17. MANUFACTURER'S BATCH NUMBER

BN:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE(GLASS AND PLASTIC)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norocillin 30% w/v Suspension for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

300 mg per ml Procaine Penicillin in an aqueous suspension. Also contains Methyl Parahydroxybenzoate 0.112% w/v, Ethyl Parahydroxybenzoate 0.023% w/v and Propyl Parahydroxybenzoate 0.016% w/v.

3. PHARMACEUTICAL FORM

Suspension for Injection

4. PACKAGE SIZE

50 ml / 100 ml/ 250 ml/ 500 ml

5. TARGET SPECIES

Cattle, Sheep and Pigs

6. INDICATION(S)

For the treatment of infections caused by, or associated with organisms sensitive to penicillin.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Recommended dose rate in cattle, sheep and pigs is 10 mg Procaine Penicillin per kg bodyweight (1 ml per 30 kg) for 3-5 days.

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

8. WITHDRAWAL PERIOD

Cattle:	Meat – 7 Days.
	Milk – 84 Hours.
Pigs:	Meat – 7 Days.
Sheep:	Meat – 7 Days.

Do not use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Do not inject intravenously or intrathecally. Care should be taken not to overdose. Norocillin is contraindicated in known cases of hypersensitivity to penicillins.

Penicillins/cephalosporins may occasionally cause severe allergic reactions. See package leaflet for operator warning.

10. EXPIRY DATE

Exp:dd/mm/yyyy

Discard date: _____

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C – 8°C). Protect from light. Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

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

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 SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Newry
BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4099

ManA 2000

17. MANUFACTURER'S BATCH NUMBER

Distributed by:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

PACKAGE LEAFLET FOR: NOROCILLIN 30% W/V SUSPENSION FOR INJECTION (GLASS AND PLASTIC)

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
BT35 6JP

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norocillin 30% w/v Suspension for Injection

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

A suspension for injection containing Procaine Penicillin. 300 mg per ml (30% w/v). Also contains Methyl Parahydroxybenzoate 0.112% w/v, Ethyl Parahydroxybenzoate 0.023% w/v and Propyl Parahydroxybenzoate 0.016% w/v.

4. INDICATION(S)

Norocillin is indicated for use in cattle, sheep and pigs in the treatment of systemic infections caused by or associated with organisms sensitive to penicillin. *In vitro* tests have shown the following organisms to be sensitive:
Arcanobacterium (Actinomyces) pyogenes, Erysipelothrix rhusiopathiae, Listeria, *Mannheima haemolytica, Pasteurella multocida, Staphylococcus* spp (non-penicillinase producing) and *Streptococcus* spp.

Norocillin is recommended, therefore, in the treatment of diseases caused by susceptible organisms including:
erysipelas; navel/joint-ill; respiratory tract infections including pneumonia and atrophic rhinitis; listeriosis; septicaemia; urogenital tract infections and the control of secondary bacterial invaders in diseases of primary viral origin.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.

5. CONTRAINDICATIONS

Norocillin is contraindicated in known cases of hypersensitivity to penicillins.
Do not inject intravenously or intrathecally.
Not to be used on very small herbivores such as guinea pigs, gerbils and hamsters.

Operator Warning - Penicillin/Cephalosporin Sensitivity:

Care should be taken to avoid accidental self-injection

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross-reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

2. Handle this type of product with great care to avoid exposure, taking all recommended precautions.

3. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

6. ADVERSE REACTIONS

Very rarely, in sucking and fattening pigs administration of such products may cause a transient pyrexia, vomiting, shivering, listlessness and in-coordination.

In very rare cases, hypersensitivity reactions may occur. Such reactions may evolve to a more severe condition (anaphylaxis), which may be life-threatening. Potentially fatal reactions associated with the administration of procaine penicillin in horses have been observed.

The frequency of adverse reactions is defined using the following convention:

- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle
Sheep
Pigs

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

The recommended dose rate is:

10 mg/kg bodyweight (1 ml/30 kg) daily for three to five days.

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

9. ADVICE ON CORRECT ADMINISTRATION

Norocillin should be administered by the intramuscular route after shaking to ensure resuspension. Normal aseptic precautions should be observed.

10. WITHDRAWAL PERIOD(S)

Cattle:	Meat – 7 Days.
	Milk – 84 Hours.
Pigs:	Meat – 7 Days.
Sheep:	Meat – 7 Days.

Do not use in sheep producing milk for human consumption

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).

Protect from light.

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

When the container is broached (opened) 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 on the space provided on the label.

12. SPECIAL WARNING(S)

Care should be taken not to overdose

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

October 2022

15. OTHER INFORMATION

Packaging Quantities:

50 ml and 100 ml multidose type II clear glass vials closed with bromobutyl rubber bungs and aluminium caps.

50 ml, 100 ml, 250 ml and 500 ml multidose clear polyethylene terephthalate (PET) vials closed with bromobutyl rubber bungs and aluminium caps.

Not all pack sizes may be marketed.

Legal Category: POM-V

To be supplied only on veterinary prescription.

Marketing Authorisation Number:

Vm 02000/4099
ManA 2000

Manufactured by:

Norbrook Laboratories Limited
Station Works
Newry
Northern Ireland
BT35 6JP

Distributed by:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

FOR ANIMAL TREATMENT ONLY LOGO

Approved: 28 October 2022