PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclav Injection for Cattle, Dogs and Cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Amoxycillin (as Amoxycillin trihydrate)	140mg
Clavulanic acid (as Potassium clavulanate)	35mg

3. PACKAGE SIZE

50 ml
100 ml

4. TARGET SPECIES

Cattle, Dogs and Cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use: Cattle
Subcutaneous use: Dogs
Intramuscular use and subcutaneous use: Cats

The recommended dosage rate of 8.75 mg/kg bodyweight (1 ml per 20 kg bodyweight) daily for 3-5 days.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle:
Meat and offal: 42 days
Milk: 80 hours.

Animals must not be slaughtered for human consumption during treatment.
Milk for human consumption must not be taken during treatment.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

At the time of first use insert the date to discard on the label.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 ºC.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

14. MARKETING AUTHORISATION NUMBERS

UK(GB) - Vm 02000/5021
UK(NI) – Vm 02000/3013

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclav Injection for Cattle, Dogs and Cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substances:

Amoxycillin (as Amoxycillin trihydrate)	140mg
Clavulanic acid (as Potassium clavulanate)	35mg

3. TARGET SPECIES

Cattle, Dogs and Cats.

4. ROUTES OF ADMINISTRATION

Intramuscular use: Cattle
Subcutaneous use: Dogs
Intramuscular use and subcutaneous use: Cats

The recommended dosage rate of 8.75 mg/kg bodyweight (1 ml per 20 kg bodyweight) daily for 3-5 days.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle:
Meat and offal: 42 days
Milk: 80 hours.

Animals must not be slaughtered for human consumption during treatment.
Milk for human consumption must not be taken during treatment.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
At the time of first use insert the date to discard on the label.
Use by ……..

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 ºC.
Once a vial has been broached the contents should be used within 28 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Noroclav Injection for Cattle, Dogs and Cats

2. Composition

Each ml contains:

Amoxycillin (as Amoxycillin trihydrate)	140mg
Clavulanic acid (as Potassium clavulanate)	35mg

An off-white suspension.

3. Target species

Cattle, Dogs and Cats.

4. Indications for use

The veterinary medicinal product has a notably broad spectrum of bactericidal activity against the bacteria commonly found in cattle, dogs and cats:

(a) *In vitro,* the veterinary medicinal product is active against a wide range of clinically important bacteria including:

Gram-positive: Staphylococci (including beta-lactamase producing strains), Streptococci, Corynebacteria, Clostridia, *Bacillus anthracis*, *Actinomyces bovis*.

Gram-negative: *Escherichia coli* (including beta-lactamase producing strains), *Salmonella* spp., (including beta-lactamase producing strains), *Campylobacter* spp., *Klebsiella* spp., *Proteus* spp., *Pasteurellae* spp., *Fusobacterium necrophorum*, *Bacteroides* spp. (including beta-lactamase producing strains), *Haemophilus* spp., *Moraxella* spp and *Actinobacillus lignieresi.*

(b) The veterinary medicinal product is indicated for the treatment of diseases including:

Cattle:
Respiratory infections
Soft tissue infections (e.g. joint/navel ill, abscesses etc.)
Metritis
Mastitis

Dogs and Cats:
Respiratory tract infections

Urinary tract infections
Skin and soft tissue infections (e.g. abscesses, pyoderma, anal sacculitis and gingivitis)

5. Contraindications

Do not administer to rabbits, guinea pigs, hamsters or gerbils. Caution is advised in its use in other very small herbivores.

6. Special warnings

Special warnings:
Cross-resistance has been shown between amoxicillin/clavulanic acid and other beta-lactam antibiotics. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to beta-lactam antibiotics because its effectiveness may be reduced.

Special precautions for safe use in the target species:

Do not use in cases hypersensitivity to penicillin or other substances of the beta-lactam group.

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
Do not handle this veterinary medicinal product if you know you are sensitised, or if you have been advised not to work with such preparations.
Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions.

If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention. Wash hands after use.

Pregnancy and lactation:

Can be used during pregnancy, subject to observance of the withholding time for milk and the withdrawal time for meat intended for human consumption.

Overdose:

Potentiated penicillin is of a low order of toxicity and is well tolerated by the parenteral route. Apart from occasional injection site reactions, which may occur at the recommended dose, no other adverse effects are to be expected from an accidental overdose.

7. Adverse events

Cattle, Dogs and Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Immediate pain upon injection, Injection site reaction. Allergic reaction[1] (e.g. allergic skin reaction, anaphylaxis).

[1] If allergic reactions occur, the product should be discontinued immediately. Appropriate symptomatic treatment should be initiated.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Intramuscular use: Cattle
Subcutaneous use: Dogs
Intramuscular use and subcutaneous use: Cats

Cattle: 8.75 mg/kg bodyweight (equivalent to 1 ml per 20 kg bodyweight) daily for 3 to 5 days.

Dogs: 8.75 mg/kg bodyweight (equivalent to 1 ml per 20 kg bodyweight) daily for 3 to 5 days.

Cats: 8.75 mg/kg bodyweight (equivalent to 1 ml per 20 kg bodyweight) daily for 3 to 5 days.

Shake the vial well before use. This veterinary medicinal product does not contain an antimicrobial preservative. Use a completely dry needle and syringe. Swab the septum before removing each dose. After injection massage the injection site.

9. Advice on correct administration

Care should be taken to avoid contaminating the remaining contents of a vial with water. Clavulanic acid is moisture sensitive. It is very important therefore, that a completely dry needle and syringe is used when extracting suspension for injection in order to avoid contaminating the remaining contents of the vial with drops of water. Contamination will result in obvious beads of dark, brown discolouration corresponding to the introduced water droplets. Material affected in this way should not be used as it may have significantly reduced potency.

10. Withdrawal periods

Cattle:
Meat and offal: 42 days
Milk: 80 hours

Animals must not be slaughtered for human consumption during treatment.
Milk for human consumption should not be taken during treatment.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 ºC.
Once a vial has been broached the contents should be used within 28 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

UK(GB) - Vm 02000/5021
UK(NI) – Vm 02000/3013

Pack sizes
The veterinary medicinal product will be supplied in clear colourless type II glass vials of 50 ml and 100 ml, complete with nitryl bungs and aluminium caps.

Not all pack sizes may be marketed.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

Norbrook Laboratories Limited.
Station Works,
Camlough Road,
Newry,
Co. Down,
Northern Ireland,
BT35 6JP
Tel: +44 (0)28 3026 4435
E-mail: phvdept@norbrook.co.uk

Manufacturer responsible for batch release:
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

Norbrook Laboratories (Ireland) Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

17. Other information

Resistance to many antibiotics is caused by beta-lactamase enzymes which destroy the antibiotic before it can act on the bacteria themselves. The clavulanic acid in the veterinary medicinal product counteracts this defence mechanism by inactivating the beta-lactamases, thus rendering the bacteria sensitive to amoxicillin's rapid bactericidal effect, at concentrations readily attainable in the body.

POM-V

Gavin Hall

Approved: 10 June 2026