

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclav 50 mg Tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Active Substance:

Amoxicillin (as amoxicillin trihydrate) 40 mg

Clavulanic acid (as Potassium clavulanate) 10 mg

3. PACKAGE SIZE

20 tablets

100 tablets

500 tablets

4. TARGET SPECIES

Dogs and Cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

To be given orally. The tablets may be crushed and added to a little food.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use immediately

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Store in the original package in order to protect from moisture.

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

Read the package leaflet before use.

User warnings:

Penicillins and cephalosporins may occasionally cause severe allergic reactions.

See package leaflet for user warnings.’

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

Vm 02000/5010

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclav 50 mg tablets.

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Active Substance:

Amoxicillin (as amoxicillin trihydrate) 40 mg

Clavulanic acid (as Potassium clavulanate) 10 mg

Excipient: Carmoisine Lake (E122) 0.245 mg

3. TARGET SPECIES

Dogs.

Cats.

4. ROUTES OF ADMINISTRATION

To be given orally.

Read the package leaflet before use.

User warnings:

Penicillins and cephalosporins may occasionally cause severe allergic reactions.

See package leaflet for user warnings.'

5. WITHDRAWAL PERIODS

Not applicable.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use immediately

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Store in the original package in order to protect from moisture.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

9. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {BLISTER PACKAGING}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclav (include pictograms of a dog and cat)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Amoxicillin (as amoxicillin trihydrate) 40 mg

Clavulanic acid (as Potassium clavulanate) 10 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use immediately

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Noroclav 50mg Tablets for dogs and cats.

2. Composition

Each tablet contains:

Active substance:

Amoxicillin (as Amoxicillin Trihydrate) 40 mg

Clavulanic Acid (as Potassium Clavulanate) 10 mg

Excipient : Carmoisine Lake (E122) 0.245 mg

“Round pink tablet with a score line and 50 embossed on opposing faces.”

3. Target species

Dogs and Cats

4. Indications for use

The veterinary medicinal product is indicated for the treatment of the following infections caused by β lactamase producing strains of bacteria sensitive to amoxicillin in combination with clavulanic acid:

- Skin infections (including superficial and deep pyodermas) caused by susceptible Staphylococci.
- Urinary tract infections caused by susceptible Staphylococci or Escherichia coli.
- Respiratory infections caused by susceptible Staphylococci.
- Enteritis caused by susceptible Escherichia coli.

It is recommended to carry out suitable tests for sensitivity testing when initiating the treatment. The treatment should only proceed if sensitivity is proven to the combination.

Penicillins and cephalosporins may occasionally cause severe allergic reactions.

5. Contraindications

Do not use in rabbits, guinea pigs, hamsters or gerbils.

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

Do not use in animals with serious dysfunction of the kidneys accompanied by anuria and oliguria.

Do not use where resistance to this combination is known to occur.

Do not administer to horses and ruminating animals.

6. Special warnings

Special warnings:

Inappropriate use of the product may increase the prevalence of bacteria resistant to amoxicillin/clavulanic acid.

Special precautions for safe use in the target species:

In animals with hepatic and renal failure, the dosing regimen should be carefully evaluated.

Use of the veterinary medicinal product should be based on susceptibility testing and take into account official and local antimicrobial policies. Narrow spectrum antibacterial therapy should be used for first line treatment where susceptibility testing suggests likely efficacy of this approach.

Dogs and cats diagnosed with Pseudomonas infections should not be treated with this antibiotic combination.

Studies in laboratory animals have not produced any evidence of teratogenic effects. Use only according to the benefit/risk assessment by the responsible veterinarian.

The potential for allergic cross-reactivity with other penicillins should be considered.

Penicillins may increase the effect of aminoglycosides.

Caution is advised in the use in small herbivores other than those reported in contradictions

Chloramphenicol, macrolides, sulfonamides and tetracyclines may inhibit the antibacterial effect of penicillins because of the rapid onset of bacteriostatic action.

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

Pregnancy:

Studies in laboratory animals have not produced any evidence of teratogenic effects. Use only according to the benefit/risk assessment by the responsible veterinarian.

7. Adverse events

Target species: Dogs & Cats

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Gastrointestinal disorders (Diarrhoea, Vomiting) Allergic reactions (e.g. skin reaction, anaphylaxis) ¹ Hypersensitivity reaction ²
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¹ In these cases, treatment should be withdrawn.

² Unrelated to dose

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

Dosage Rate: 12.5 mg combined actives/kg bodyweight twice daily. The recommended dose of 12.5 mg per kg bodyweight is equivalent to one 50 mg tablet per 4 kg bodyweight.

Dosage frequency: The following table is intended as a guide to dispensing the veterinary medicinal product at the standard dose rate of 12.5 mg/kg twice daily.

	Number of tablets per dose twice daily
Bodyweight (kg)	50 mg
1-2	●
3-4	●●
5-6	●●●
7-8	●●●●
9-10	●●●●●
11-12	●●●●●●
13-14	●●●●●●●
15-16	●●●●●●●●
17-18	●●●●●●●●●

Duration of therapy

Acute cases: 5 to 7 days of treatment.

If no improvement is observed after 5 to 7 days, the diagnosis should be reassessed.

Chronic or refractory cases: In these cases where there is considerable tissue damage, a longer course of therapy may be required so that it allows sufficient time for damaged tissue to repair.

If no improvement is observed after two weeks, the diagnosis should be reassessed.

9. Advice on correct administration

By the oral route. The tablets may be crushed and added to a little food.

10. Withdrawal periods

Not Applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C.

Store in the original package in order to protect from moisture.

Do not use the veterinary medicinal product after the expiry date which is stated on the blister or tub. The expiry date refers to the last day of the month.

Shelf life after first opening the immediate packaging: use immediately

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

Vm 02000/5010

The product is supplied in high-density polyethylene tubs with a polypropylene screw cap lid containing 100 tablets and in high-density polyethylene tubs with a polyethylene screw cap lid containing 500 tablets. A sachet of desiccant is included in each container. The product is also presented in packs containing 2, 10 and 50 blister strips (aluminium-aluminium) each containing 10 tablets per strip.

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 manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland
Tel: +44 28 3026 4435
Email: phvdept@Norbrook.co.uk

17. Other information

POM-V

Gavin Hall

Approved: 21 October 2025