BLISTER PACKAGING

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NOROCLAV 50 mg TABLETS FOR DOGS AND CATS
40 mg Amoxicillin
10 mg Clavulanic acid

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

BN.

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

FOR ANIMAL TREATMENT ONLY

DRAFT LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclav 50mg Tablets for dogs and cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:
Amoxicillin (as Amoxicillin Trihydrate) 40 mg
Clavulanic Acid (as Potassium Clavulanate) 10 mg
Excipient: Carmoisine Lake (E122) 0.245 mg.

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

100 Tablets
500 Tablets

5. TARGET SPECIES

Dogs
Cats

6. INDICATION(S)

See package leaflet for indications

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet for user warnings.

10. EXPIRY DATE

DOM:
EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store in the original package in order to protect from moisture.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

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

FOR ANIMAL TREATMENT ONLY

UK – POM-V
To be supplied only on veterinary prescription.

IE- POM
Prescription only medicine.

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

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

Distributed in the UK by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

Distributed in IE by:
Norbrook Laboratories (Ireland) Limited,
Rossmore Industrial Estate,
Monaghan.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/3002

17. MANUFACTURER'S BATCH NUMBER

BN.:

DRAFT PACK OUTER CARTON TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclav 50 mg Tablets for dogs and cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:
Amoxicillin (as amoxicillin trihydrate) 40 mg,
Clavulanic acid (as Patassium clavulanate) 10 mg,
Excipient: Carmoisine Lake (E122) 0.245 mg.

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

20 /100 / 500 Tablets

5. TARGET SPECIES

Dogs
Cats

6. INDICATION(S)

See package leaflet for indications

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet for user warnings.

10. EXPIRY DATE

D.O.M.:
EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store in the original package in order to protect from moisture.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

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

FOR ANIMAL TREATMENT ONLY

UK – POM-V
To be supplied only on veterinary prescription.

IE- POM
Prescription only medicine.

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

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufacturing Authorisation Holder:
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

DISTRIBUTED IN THE UK BY:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

Distributed in IE by:
Norbrook Laboratories (Ireland) Limited,
Rossmore Industrial Estate,
Monaghan.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/3002

17. MANUFACTURER'S BATCH NUMBER

BN.

FURTHER INFORMATION - **See package leaflet.**

DRAFT INSERT TEXT

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

Manufacturing Authorisation Holder:
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

Manufacturer Responsible for Batch Release
Norbrook Laboratories Limited
Rossmore Industrial Estate
Monaghan
Ireland

Norbrook Laboratories Limited
Station Works
Newry
Co. Down,
BT35 6JP

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

NOROCLAV 50MG TABLETS FOR DOGS AND CATS

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

Noroclav 50 mg Tablets are for oral administration to dogs and cats. Each Noroclav 50 mg Tablet contains Amoxicillin 40 mg (as Amoxicillin Trihydrate) and Clavulanic Acid 10 mg (as Potassium Clavulanate). Carmosine Lake (E122) 0.245 mg

4. INDICATION(S)

Noroclav 50 mg Tablets are indicated for 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.

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. ADVERSE REACTIONS

Hypersensitivity reactions unrelated to dose can occur with these agents.

Gastrointestinal symptoms (diarrhoea, vomiting) may occur after administration of the product.
Allergic reactions (e.g. skin reactions, anaphylaxia) may occasionally occur.
In case of occurrence of allergic reaction, the treatment should be withdrawn.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 Noroclav 50mg Tablets 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 re assessed.
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 re-assessed.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Not Applicable

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Store in the original package in order to protect from moisture.
Do not use after the expiry date stated on the blister or tub.
Keep out of the reach and sight of children.

12. SPECIAL WARNINGS

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

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

Operator Warnings:
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.

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

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

14. 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.

15. OTHER INFORMATION

FURTHER INFORMATION

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

In vitro potentiated amoxicillin is active against a wide range of clinically important aerobic and anaerobic bacteria including:

Gram-positive:
Staphylococci (including β-lactamase producing strains)
Clostridia
Streptococci

Gram-negative:

Escherichia coli (including most β-lactamase producing strains)
Campylobacter spp
Pasteurellae
Proteus spp

Resistance is shown among *Enterobacter* spp, *Pseudomonas aeruginosa* and methicillin-resistant *Staphylococcus aureus*. A trend in resistance of *E. coli* is reported.

PACKAGE QUANTITIES:

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

Vm 02000/3002

UK – POM-V
To be supplied only on veterinary prescription.

IE- POM
Prescription only medicine.

FOR ANIMAL TREATMENT ONLY

LOGO

DISTRIBUTED IN THE UK BY:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

Distributed in IE by:
Norbrook Laboratories (Ireland) Limited,
Rossmore Industrial Estate,
Monaghan.

Approved 25 July 2024
Gavin Hall