

## BLISTER PACKAGING

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NOROCLAV 250 mg TABLETS FOR DOGS.  
200 mg Amoxicillin  
50 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 250mg Tablets for dogs.

### 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:

Amoxicillin (as Amoxicillin Trihydrate)	200mg
Clavulanic Acid (as Potassium Clavulanate)	50 mg
Carmoisine Lake (E122)	1.225 mg

### 3. PHARMACEUTICAL FORM

Tablet

### 4. PACKAGE SIZE

100 Tablets  
250 Tablets

### 5. TARGET SPECIES

Dogs

### 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  
Newry  
Co. Down,  
BT35 6JP

**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)**

ManA 2000  
UK – Vm: 02000/4212  
IE – VPA No: 10999/101/2

**17. MANUFACTURER'S BATCH NUMBER**

B.N.:

## DRAFT PACK OUTER CARTON TEXT

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclav 250 mg Tablets for dogs

### 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each Tablet contains:

Amoxicillin (as Amoxicillin Trihydrate)	200 mg
Clavulanic Acid (as Potassium Clavulanate)	50 mg
Excipient:	
Carmoisine Lake (E122)	1.225 mg

### 3. PHARMACEUTICAL FORM

Tablets

### 4. PACKAGE SIZE

10/20/50/100/ 250 Tablets

### 5. TARGET SPECIES

Dogs

### 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**

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**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.

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**16. MARKETING AUTHORISATION NUMBER(S)**

ManA 2000  
UK - Vm: 02000/4212

**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

Marketing Authorisation Holder:  
Norbrook Laboratories Limited  
Newry,  
Co. Down  
Northern Ireland  
BT35 6JP

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 250 MG TABLETS FOR DOGS

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

Noroclav 250 mg Tablets are for oral administration to dogs. Each Noroclav 250 mg Tablet contains Amoxicillin 200 mg (as Amoxicillin Trihydrate), Clavulanic Acid 50 mg (as Potassium Clavulanate) and Carmoisine Lake (E122) 1.225 mg

### 4. INDICATION(S)

Noroclav 250 mg Tablets are indicated for treatment of the following infections caused by  $\beta$ -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.

## 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

## 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 250 mg tablet per 20 kg bodyweight.

**Dosage frequency:** The following tables are intended as a guide to dispensing Noroclav 250mg Tablets at the standard dose rate of 12.5 mg/kg twice daily.

	Number of tablets per dose twice daily
Bodyweight (kg)	250 mg
19-20	●
21-30	● ◐
31-40	● ●
41-50	● ● ◐
more than 50	● ● ●

Duration of therapy: Routine cases involving all indications: The majority of cases respond to between 5 and 7 days therapy.

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

#### 9. **ADVICE ON CORRECT 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; Keep the container in the outer carton.

#### 12. **SPECIAL WARNINGS**

##### (i) **Special precautions for use in animals**

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.

Do not administer to horses and ruminating animals.

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

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.

Do not administer to horses and ruminating animals.

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

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

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

### **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. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

October 2022

**15. 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 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  $\beta$ -lactamase producing strains)

Clostridia

Streptococci

Gram-negative:

*Escherichia coli* (including most  $\beta$ -lactamase producing strains)

*Campylobacter* spp

*Pasteurellae*

*Proteus* spp

**PACKAGE QUANTITIES:**

The product is supplied in high-density polyethylene tubs with a polyethylene screw cap lid containing 100 and 250 tablets. A sachet of desiccant is included in each container. The product is also presented in packs of 2, 4, 10, 20 and 50 blister strips (aluminium-aluminium) each containing 5 tablets per strip.

Not all pack sizes may be marketed.

ManA 2000

UK - Vm: 02000/4212

UK – POM-V

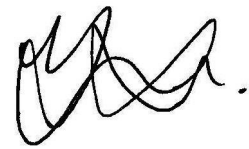
To be supplied only on veterinary prescription.

**FOR ANIMAL TREATMENT ONLY**

LOGO

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A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 28 October 2022