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:

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

(UK)
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

MANUFACTURER RESPONSIBLE FOR BATCH RELEASE:

Norbrook Manufacturing Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synuclav 250 mg Tablets for Dogs

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

Active Substance:	mg per tablet
Amoxicillin	200
(as amoxicillin trihydrate)	229.5
Clavulanic acid	50
(as Potassium clavulanate)	59.5
Excipients:	
Carmoisine Lake (E122)	1.225

4. INDICATION(S)

Synuclav 250 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 animals with known cases of hypersensitivity to penicillin or other substances of the beta-lactam group.
Do not use in rabbits, guinea pigs, hamsters or gerbils.
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

None Known. 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

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 table is intended as a guide to dispensing Synuclav 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

Inappropriate use of the product may increase the prevalence of bacteria resistance 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.
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.

The product is of a low order of toxicity and is well tolerated by the oral route.

In a tolerance study a tested dose of 3 times the recommended dose of 12.5mg of the combined actives administered twice daily for 8 days did not demonstrate adverse effects.

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 any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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

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 Synuclav 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

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 4, 10, 20 and 50 blister strips (aluminium-aluminium) each containing 5 tablets per strip.

Not all pack sizes may be marketed.

Vm 02000/3006

ManA: 2000

Distributed by:
MiGroup, CVS House
Owen Road
Diss
Norfolk
IP22 4ER
United Kingdom

DRAFT LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synuclav 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

Tablet.

4. PACKAGE SIZE

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

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

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 REACH AND SIGHT OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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Norbrook Laboratories (Ireland) Ltd.
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(UK)

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

16. MARKETING AUTHORISATION NUMBER

Vm 02000/3006

17. MANUFACTURER'S BATCH NUMBER

BN:

Approved 25 July 2024
Gavin Hall