DRAFT BLISTER LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synuclav Palatable Tablets 500 mg for Dogs

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

3. EXPIRY DATE

XX/XX/XXXX

4. BATCH NUMBER

XXXX-XX

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

FOR ANIMAL TREATMENT ONLY

Do not store above 25ºC

DRAFT CARTON TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synuclav Palatable Tablets 500 mg for Dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Synuclav Palatable Tablets 500mg for Dogs are for oral administration to dogs: each tablet contains Amoxicillin 400 mg (as Amoxicillin Trihydrate) ,Clavulanic Acid 100 mg (as Potassium Clavulanate) and Lake Carmoisine (E122) 2.45mg.

3. PHARMACEUTICAL FORM

Tablets.
The tablet can be divided into equal halves.

4. PACKAGE SIZE

10/20/25/100 Tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

For the 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 when initiating the treatment. The treatment should only proceed if sensitivity is proven to the combination.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing. Read the package leaflet before use.

Administration is via the oral route. The dosage rate is 12.5 mg combined actives/kg bodyweight twice daily. The tablets may be crushed and added to a little food.

The following table is intended as a guide to dispensing Synuclav Palatable Tablets at the standard dose rate of 12.5 mg/kg twice daily.

Bodyweight (kg)	Number of tablets per dose twice daily
20 kg	½
40 kg	1
60 kg	1½
80 kg	2

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.

8. WITHDRAWAL PERIOD

Not Applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in animals with known cases of hypersensitivity to penicillins 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 or oliguria.
Do not use where resistance to the combination is known to occur.
Do not administer to horses and ruminating animals.

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.
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.

10. EXPIRY DATE

XX/XX/XXX

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in a dry place.
Divided tablets should be stored in the blister pack.
Any divided tablet portion remaining after 24 hours should be discarded.
Keep the blister in the outer carton.

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

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

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

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

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

16. MARKETING AUTHORISATION NUMBER

Vm: 02000/4264
ManA 2000

17. MANUFACTURER'S BATCH NUMBER

XXXX-XX

<Supply category to be completed nationally>

FURTHER INFORMATION

Amoxicillin is a broad-spectrum antibiotic active against a wide range of Gram-positive and Gram-negative bacteria. However, many clinically important bacteria produce beta-lactamase enzymes which destroy this antibiotic. Clavulanic acid inactivates these enzymes, rendering the organisms susceptible to the amoxicillin. Synuclav Palatable Tablets are safe for use during pregnancy and lactation. Studies in laboratory animals have not produced any evidence of teratogenic effects. Use only according to the risk/benefit assessment by the responsible veterinarian.

DRAFT INSERT TEXT

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

MARKETING AUTHORISATION HOLDER:

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

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

MANUFACTURER RESPONSIBLE FOR BATCH RELEASE:

Norbrook Manufacturing Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

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

DISTRIBUTED BY:

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synuclav Palatable Tablets 500 mg for Dogs

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Synuclav Palatable Tablets 500mg for Dogs are for oral administration to dogs. Each Synuclav
Palatable Tablet 500 mg for Dogs contains Amoxicillin 400 mg (as Amoxicillin Trihydrate),
Clavulanic Acid 100 mg (as Potassium Clavulanate)and Lake Carmoisine (E122) 2.45mg.
The tablet can be divided into equal halves.

4. INDICATION(S)

For the 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 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 penicillins 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 or oliguria.
Do not use where resistance to the combination is known to occur.
Do not administer to horses and ruminating animals.

6. ADVERSE REACTIONS

Hypersensitivity 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, ROUTES AND METHOD OF ADMINISTRATION

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

Administration is via the oral route. The dosage rate is 12.5 mg combined actives/kg bodyweight twice daily. The tablets may be crushed and added to a little food.

The following table is intended as a guide to dispensing Synuclav Palatable Tablets at the standard dose rate of 12.5 mg/kg twice daily.

Bodyweight (kg)	Number of tablets (500 mg) per dose twice daily
20 kg	½
40 kg	1
60 kg	1½
80 kg	2

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

10. WITHDRAWAL PERIOD

Not Applicable

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C; store in a dry place.
Divided tablets should be stored in the blister pack.
Any divided tablet portion remaining after 24 hours should be discarded.
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 or renal failure, the dosing regimen should be carefully evaluated.
Use of the product should be based on susceptibility testing and take into account local antimicrobial policies. Narrow spectrum antibacterial therapy should be used for first line treatment where susceptibility testing suggests likely efficacy of this approach.
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 contraindications.
Chloramphenicol, macrolides, sulphonamides 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.
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. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

LEGAL CATEGORY:

<Supply category to be completed nationally>

PACKAGE QUANTITIES:
Aluminium/aluminium blister strips, each containing 5 tablets.
The product is presented as follows:
Carton box containing 2 strips,each containg 5 tablets (10 tablets)
Carton box containing 4 strips,each containg 5 tablets (20 tablets)
Carton box containing 5 strips,each containg 5 tablets (25 tablets)
Carton box containing 20 strips,each containg 5 tablets (100 tablets)
Not all pack sizes may be marketed.

FURTHER INFORMATION
Amoxicillin is a broad-spectrum antibiotic active against a wide range of Gram-positive and Gram-negative bacteria. However, many clinically important bacteria produce beta-lactamase enzymes which destroy this antibiotic. Clavulanic acid inactivates these enzymes, rendering the organisms susceptible to the amoxicillin. Synuclav Palatable Tablets are safe for use during pregnancy and lactation. Studies in laboratory animals have not produced any evidence of teratogenic effects. Use only according to the risk/benefit assessment by the responsible veterinarian.

ManA 2000

FOR ANIMAL TREATMENT ONLY.

Approved: 03 June 2019