PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Folding carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox Palatable Tablets 500 mg

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 100 mg of clavulanic acid as **Potassium clavulanate** and 400 mg amoxicillin as **Amoxicillin trihydrate** in a palatable base.

clavulanate-potentiated amoxicillin

3. PHARMACEUTICAL FORM

Palatable Tablets

4. PACKAGE SIZE

100 tablets

5. TARGET SPECIES

Dogs (as icon)

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage Guide: Dose rate 12.5 mg/kg bodyweight *twice daily*.

Bodyweight (kg)	Number of tablets per dose *twice daily*
	500 mg
20	
40	
60	
80	

For further directions see enclosed package leaflet.

8. WITHDRAWAL PERIOD

-

9. SPECIAL WARNING(S), IF NECESSARY

Operator Warnings:
Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reaction 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 may require urgent medical attention.

Wash hands after use.

Synulox Palatable Tablets should not be given to rabbits, guinea pigs, hamsters or gerbils. Caution is advised in their use in any other very small herbivores.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in a dry place.

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

-

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4146

17. MANUFACTURER'S BATCH NUMBER

Batch No:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {Foil blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox 500 mg tablet

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis

3. EXPIRY DATE

Printed on line

4. BATCH NUMBER

Printed on line

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

PACKAGE LEAFLET FOR: Synulox Palatable Tablets 500 mg

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Batch release site not stated

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox Palatable Tablets 500 mg

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

Synulox Palatable Tablets are presented as circular, pink tablets with a break line on one face and 'SYNULOX' engraved on the other. Each tablet contains 100 mg clavulanic acid as Potassium clavulanate and 400 mg amoxicillin as Amoxicillin trihydrate in a palatable base.

clavulanate-potentiated amoxicillin

4. INDICATION(S)

Synulox Palatable Tablets have a broad spectrum of bactericidal activity against bacteria commonly found in dogs. *In vitro* Synulox is active against a wide range of clinically important aerobic and anaerobic bacteria including:

Gram-positive: Staphylococci (including ß-lactamase producing strains)
Clostridia
Actinomyces
Peptostreptococcus spp.
Streptococci
Enterococci

Gram-negative: *Bacteroides* spp. (including ß-lactamase producing strains)
Escherichia coli (including most ß-lactamase producing strains)
Salmonellae (including ß-lactamase producing strains)
Bordetella bronchiseptica
Campylobacter spp.
Fusobacterium necrophorum
Klebsiellae

Pasteurellae
Proteus spp.

Clinically Synulox has been shown to be effective in treating a wide range of diseases of dogs including:

- Skin disease (including deep and superficial pyodermas)
- Soft tissue infections (abscesses and anal sacculitis)
- Dental infections (e.g. gingivitis)
- Urinary tract infections
- Respiratory disease (involving upper and lower respiratory tract)
- Enteritis

5. CONTRAINDICATIONS

Synulox Palatable Tablets should not be given to rabbits, guinea pigs, hamsters or gerbils. Caution is advised in their use in any other very small herbivores.

6. ADVERSE REACTIONS

Very rarely hypersensitivity reactions (allergic skin reactions, anaphylaxis) may occasionally occur. If allergic reactions occur, the product should be discontinued immediately. Appropriate symptomatic treatment should be initiated.

In very rare cases the use of the product may result in instances of gastro-intestinal disorders (vomiting, diarrhoea, anorexia).

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))

- common (more than 1 but less than 10 animals in 100 animals treated)

- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)

- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage Guide: The recommended dose rate is 12.5 mg/kg twice daily. The table below is intended as a guide only.

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

The majority routine cases will respond to between 5 and 7 days therapy. Because of the low toxicity profile of Synulox the dose can be double if desired at the discretion of the veterinary surgeon for severe infection.

In certain indications, for example canine pyoderma and chronic cystitis, bacterial infection may be secondary to other pathology.

For such cases longer courses of antibacterial therapy may be required, in addition to diagnosis and treatment of the underlying condition.

In such circumstances overall treatment length must be at the clinician's discretion, but should be long enough to ensure complete resolution of the bacterial disease.

9. ADVICE ON CORRECT ADMINISTRATION

Administration: For oral administration only. Synulox Palatable Tablets are often accepted from the hand even by sick dogs. Alternatively, the tablets may be crushed and added to a little food.

10. WITHDRAWAL PERIOD(S)

-

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Store in a dry place.

12. SPECIAL WARNING(S)

For animal treatment only.

Keep out of the sight and reach of children.

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.

Operator Warnings
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Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and may require urgent medical attention.

Wash hands after use.

Interactions with other medicinal products and other forms of interaction

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

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

Penicillins may increase the effects of aminoglycoside.

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

March 2022

15. OTHER INFORMATION

POM-V

To be supplied only on veterinary prescription.

Vm 42058/4146

Resistance to many antibiotics is caused by ß-lactamase enzymes which destroy the antibiotic before it can act on the bacteria themselves.

The clavulanate in Synulox counteracts this defence mechanism by inactivating the ß-lactamases, thus rendering the organisms sensitive to amoxicillin' s rapid bactericidal effect, at concentrations readily attainable in the body.

Synulox is effective against *Klebsiella* infections but is not indicated for cases involving *Pseudomonas* species.

Concomitant administration of any bacteriostatic antibiotic is not recommended.

PRODUCT SUMMARY

• **Extended Spectrum of Activity** - clavulanate extends the spectrum of amoxicillin by making it active against resistant (ß-lactamase producing) strains of Staphylococci, *E. coli*, *Bacteroides* and Salmonellae, as well as adding *Klebsiella* species to the list of susceptible organisms.

• **Kills Bacteria Rapidly** - increases the likelihood of a rapid clinical cure.

• **Excellent Absorption and Penetration** - ensures sufficiently high levels of Synulox at the common infection sites to achieve clinical success.

• **Easy to Administer** - exceptional palatability makes the tablets readily acceptable to dogs.

• **Simple Twice Daily Dosage** - easy to remember.

• **Convenient Foil Packaging** - easy to dispense.

• **Highly Effective** - the unique formulation of Synulox increases the high cure rates achieved with amoxicillin alone.

Approved 04 March 2022