SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SYNULOX PALATABLE TABLETS 500 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:	mg per tablet
Amoxicillin	400.0
(as Amoxicillin Trihydrate)	460.0
Clavulanic acid	100.0
(as Potassium Clavulanate)	119.2
Erythrosine Lake (E127)	35.0

For the full list of all other excipients see section 6.1.

3. PHARMACEUTICAL FORM

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 clavulanic acid as potassium clavulanate and amoxicillin as Amoxicillin Trihydrate. in a palatable base.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

In vitro the product is active against a wide range of clinically important aerobic and anaerobic bacteria, including:
Gram-positive: Staphylococci (including β-lactamase-producing strains) Clostridia; Actinomyces; Peptostreptococcus spp; Streptococci; Enterococci.
Gram-negative: Bacteroides spp. (including β-lactamase-producing strains); *Escherichia coli* (including β-lactamase-producing strains); Salmonellae (including β-lactamase-producing strains); *Bordetella bronchiseptia*; Campylobacter spp; *Fusobacterium necrophorum*; Klebsiellae; Pasteurellae; Proteus spp.

Clinically, amoxicillin has been shown to be effective in treating a wide range of diseases of dogs including: skin disease (including deep and superficial pyoderma); urinary tract infection; respiratory disease

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involving upper and lower respiratory tract; enteritis; dental infections (e.g. gingivitis); soft tissue infections (e.g. abscesses and anal sacculitis).
Note: The product is not indicated for cases involving Pseudomonas spp.

4.3 Contraindications

In common with other penicillins, amoxicillin should not be administered orally to rabbits, guinea pigs or gerbils, and should be used with care on other small herbivores.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) Special precautions for use in animals

Do not use this product on animals known to be sensitive to penicillin.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

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.

1) Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2) Handle this product with great care to avoid exposure, taking all recommended precautions.
3) 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.
4) Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

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4.7 Use during pregnancy, lactation or lay

The tablets can be safely used in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

Should not be administered concomitantly with bacteriostatic antibiotics, which are incompatible.

4.9 Amounts to be administered and administration route

Dosage Rate:
Recommended dose rate is 12.5 mg/kg, twice daily.
Dosage guide:
For oral administration only. The tablets are often accepted from the hand, even by sick dogs. Alternatively, the tablets may be crushed and added to a small quantity of food.
The majority of routine cases will respond to between 5 and 7 days therapy. Because of the low toxicity profile, the dose can be doubled if desired in refractory cases.
In certain indications, for example canine pyoderma and chronic cystitis, bacterial infection may be secondary to other pathology. For such cases long 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Amoxicillin is of a low order of toxicity and is well tolerated by the oral route in the dogs. Limited overdose normally produces no adverse effect. If signs do occur, for example of gastro-intestinal disturbance, treatment should be symptomatic.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Amoxicillin is a broad-spectrum antibiotic active against a wide range of Gram-positive and Gram-negative bacteria. However, many clinically important bacteria product β-lactamase enzymes, which destroy this antibiotic. Clavulanic acid inactivates these enzymes, making the organisms susceptible to the amoxicillin.

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ATCvet Code: QJ01CR02.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Erythrosine Lake (E127)
Magnesium Stearate
Sodium Starch Glycollate, Type A (dried)
Silica Colloidal Anhydrous
Yeast, Dried
Microcrystalline Cellulose (dried)

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Laminated, aluminium foil packs with 2 tablets in each blister card, - packed in an outer carton box.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
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Springfield Drive
Leatherhead
Surrey
KT22 7LP

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8. MARKETING AUTHORISATION NUMBER

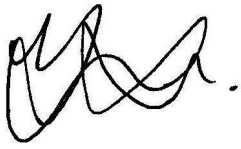
Vm 42058/4146

9. DATE OF FIRST AUTHORISATION

19 October 1995

10. DATE OF REVISION OF THE TEXT

August 2020



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