

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SYNULOX PALATABLE TABLETS 500 mg

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<i>Active ingredients:</i>	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  $\beta$ -lactamase-producing strains) Clostridia; Actinomyces; Peptostreptococcus spp; Streptococci; Enterococci.

*Gram-negative:* Bacteroides spp. (including  $\beta$ -lactamase-producing strains); *Escherichia coli* (including  $\beta$ -lactamase-producing strains); Salmonellae (including  $\beta$ -lactamase-producing strains); *Bordetella bronchiseptica*; 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

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.

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.

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)**

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 gastrointestinal 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).

#### **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.

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.

#### **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 produce  $\beta$ -lactamase enzymes, which destroy this antibiotic. Clavulanic acid inactivates these enzymes, making the organisms susceptible to the amoxicillin.

**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  
1st Floor, Birchwood Building  
Springfield Drive  
Leatherhead  
Surrey  
KT22 7LP

## **8. MARKETING AUTHORISATION NUMBER**

Vm 42058/4146

## **9. DATE OF FIRST AUTHORISATION**

19 October 1995

## **10. DATE OF REVISION OF THE TEXT**

March 2022

Approved 04 March 2022

A handwritten signature in black ink, consisting of a stylized initial followed by the name "Hunter." with a period.