SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SYNULOX PALATABLE TABLETS 250 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:	mg per tablet
Amoxicillin	200.0
(as Amoxicillin Trihydrate)	229.5
Clavulanic acid	50.0
(as Potassium Clavulanate)	59.5
Erythrosine Lake (E127)	17.50

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

3. PHARMACEUTICAL FORM

Tablet.
(Circular pink scored tablets).

4. CLINICAL PARTICULARS

4.1 Target species

Cats and dogs.

4.2 Indications for use, specifying the target species

The product has been shown to be effective in treating a wide range of diseases of cats and 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.

4.3 Contraindications

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) 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.

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 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)

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction 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.

4.9 Amounts to be administered and administration route

Administration: by the oral route.
Dosage rate: 12.5 mg/kg bodyweight.
Dosage frequency: The following table is intended as a guide to dispensing at the standard dose rate of 12.5 mg/kg, twice daily.

Bodyweight (kg)	Number of tablets per dose, twice daily	
	50 mg	250 mg
1 - 2	½	-
3 - 5	1	-
6 - 9	2	-
10 - 13	3	-
14 - 18	4	-
19 - 25	-	1
26 - 35	-	1 ½
36 - 49	-	2
50	-	3

For the majority of infections including those of the skin, urinary tract and gastrointestinal tract, the above dosage regime is effective. Refractory cases however particularly of the respiratory tract have shown improved cure rates by doubling the dose to 25mg/kg bodyweight twice daily.
Duration of therapy:
Routine cases involving all indications:
The majority of these 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 maybe required in that it allows sufficient time for damaged tissue to repair. Based on clinical trials, the following durations are suggested as guidelines:

Chronic skin disease 10 – 12 days
Chronic cystitis 10 – 28 days

Respiratory disease 8 – 10 days

The product is effective against *Klebsiella* infections found in veterinary practice, but it is not indicated for cases involving *Pseudomonas* species. Tablets are often accepted from the hand, even by sick dogs and cats. Alternatively, the tablets may be crumbled and added to a little food.

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

The product is of low order toxicity to the target species. No adverse side effects are to be expected from accidental overdose.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

The ingredients have a notably broad spectrum of bactericidal activity against bacteria commonly found in cats and dogs.
Resistance to many antibiotics is caused by ß-lactamase enzymes which destroy the antibiotic before it can act on the bacteria themselves. The clavulanate 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.
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; Arcanobacteria (Corynebacteria); *Peptostreptococcus* spp; Streptococci.

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.

ATCvet Code: QJ01CR02

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Erythrosine Lake (E127)
Magnesium Stearate
Sodium Starch Glycollate, Type A
Silica Colloidal Anhydrous

Yeast Dried
Microcrystalline Cellulose

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

Tablets are packed in laminated aluminium foil strips containing 5 x 2 tablets.
250 mg tablets are in packs of 100 and 250.

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
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Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4145

9. DATE OF FIRST AUTHORISATION

20 August 1990

10. DATE OF REVISION OF THE TEXT

March 2022

Approved 04 March 2022