SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SYNULOX PALATABLE DROPS, Powder for Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:	mg per bottle	mg/ml when reconstituted
Amoxicillin	648.0	40.0
(as Amoxicillin Trihydrate)	743.8	
Clavulanic acid	162.0	10.0
(as Potassium Clavulanate)	193.0	

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

3. PHARMACEUTICAL FORM

Powder for oral suspension. An off-white coloured powder for reconstitution.

4. CLINICAL PARTICULARS

4.1 Target species

Cats and dogs.

4.2 Indications for use, specifying the target species

The product is indicated for the treatment of a wide range of diseases of cats and dogs including: skin diseases (including deep and superficial pyodermas); urinary tract infections; respiratory diseases (involving upper and lower respiratory tract); enteritis; soft tissue infections (abscesses and anal sacculitis); dental infections (e.g. gingivitis).
The product is effective against *Klebsiella* infections found in veterinary practice, but it is not indicated for cases involving *Pseudomonas* species.

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

None.

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)

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

In very rare cases hypersensitivity (allergy, allergic skin reactions) may occur after use. Allergic reactions may occasionally be serious (anaphylaxis). If allergic reactions occur, the product should be discontinued immediately. Appropriate symptomatic treatment should be initiated.

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

It is not advisable to use bacterial and bacteriostatic antibiotics in combination.

4.9 Amounts to be administered and administration route

Reconstitution: Add 15 ml water. Shake the bottle before use.
Administration: by the oral route.
Dosage rate: 12.5 mg/kg bodyweight (i.e. 0.25 ml/kg). For the accurate dosing of particularly small patients it is valuable to note that one drop from the pipette provided contains 2.3 mg clavulanate-potentiated amoxicillin. Therefore 5-6 drops/kg twice daily are recommended as a guide.
Dosage frequency: Dogs and cats should be dosed at the rate of 0.25 ml of reconstituted product per kg bodyweight twice daily.
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 those of the respiratory tract, have shown improved cure rates by doubling the dose to 25 mg/kg bodyweight, twice daily (i.e. 0.5 ml of reconstituted product 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 may be 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 - 20 days
Chronic cystitis	10 - 28 days
Respiratory disease	8 - 10 days

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 product has a notably broad spectrum of bactericidal activity against bacteria commonly found in cats and dogs.
In vitro the product is active against a wide range of clinically important aerobic and anaerobic bacteria including:
Gram-positive
Staphylococci (including ß-lactamase producing strains)
Clostridia
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.
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 the product 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.

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6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xanthan Gum
Saccharin Sodium
Succinic Acid
Silica Colloidal Anhydrous
Silicon Dioxide (Silica Gel)
Strawberry Dry Flavour
Peach Dry Flavour
Lemon Dry Flavour

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after dilution or reconstitution according to directions: 7 days.

6.4 Special precautions for storage

Do not store above 25˚C.
Store the reconstituted product in a refrigerator (2˚C - 8˚C). Any reconstituted product remaining 7 days after preparation should be discarded.

6.5 Nature and composition of immediate packaging

Ph. Eur. Type III clear glass bottle with nominal volume of 15 ml, closed with a metal screw cap fitted with a grey liner with a wrinkled surface composed of a chlorobutyl based compound. A dropper with graduations of 0.25 ml up to 1 ml is included. The dropper is manufactured from low density polyethylene and contains no additives.

Pack size: Cardboard box containing one 15 ml vial and one graduated dropper.

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
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KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4144

9. DATE OF FIRST AUTHORISATION

20 August 1990

10. DATE OF REVISION OF THE TEXT

March 2021

Approved 04 March 2022