1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox Palatable Tablets 50 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active ingredients

Amoxicillin (as trihydrate)	40.0	mg
Clavulanic acid (as Potassium clavulanate)	10.0	mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.
Speckled pink flat circular tablets with bevelled edges.
The tablet has a break line on one face and "SYNULOX" engraved on the other.

4 CLINICAL PARTICULARS

4.1 Target Species

Cats and dogs.

4.2 Indications for use, specifying the target species

Clinically Synulox 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 (eg gingivitis); urinary tract infections; respiratory disease (involving upper and lower respiratory tract); enteritis.

4.3 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.
Synulox is not indicated for cases involving *Pseudomonas* spp.
Do not use in animals with known hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
None.

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.
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 require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Very occasionally, hypersensitivity reactions to penicillins may occur in treated animals.
Use of the product may result in very rare instances of gastro-intestinal disorders (vomiting, diarrhoea, anorexia).

4.7 Use during pregnancy, lactation or lay

Synulox Palatable Tablets can be safely used in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

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 Synulox Palatable Tablets 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

Synulox is effective against Klebsiella infections found in veterinary practice, but it is not indicated for cases involving *Pseudomonas* species.

Synulox Palatable 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.
The majority of routine cases respond to between 5 and 7 days therapy. In chronic or refractory cases, a longer course of therapy may be required e.g. 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

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

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Synulox Palatable Tablets 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 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.
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; 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Stearate
Sodium Starch Glycollate
Colloidal Silica
Roller dried yeast
Erythrosine Lake (E127) Microcrystalline Cellulose

6.2 Major 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

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

6.5 Nature and composition of immediate packaging

The tablets are circular pink tablets with a break line on one surface and "SYNULOX" engraved on the other.
They are packed in laminated aluminium foil strips containing 5 x 2 tablets.
50 mg tablets are in packs of 100 and 500.
Not all pack sizes may be marketed.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
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8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/074/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1997
Date of last renewal: 30th September 2007

10 DATE OF REVISION OF THE TEXT

November 2017