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Synulox Palatable Tablets 50 mg and 250 mg

Species: Cats, Dogs

Therapeutic indication:Pharmaceuticals: Antimicrobials: Oral preparations: Tablets

Active ingredient: Amoxicillin Trihydrate, Clavulanic Acid

Product: Synulox® Palatable Tablets

Product index: Synulox Palatable Tablets

Incorporating:

Presentation

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. The composition of the two tablet sizes is as follows:

50 mg

40 mg amoxicillin and 10 mg clavulanic acid.

250 mg

200 mg amoxicillin and 50 mg clavulanic acid.

Uses

Synulox Palatable Tablets have a notably broad spectrum of bactericidal activity against bacteria commonly found in cats and dogs.

In vitro Synulox is active against a wide range of clinically important aerobic and anaerobic bacteria including:

Gram-positive: Staphylococci (including β-lactamase producing strains); Clostridia; Corynebacteria; *Pept*

Gram-negative:	Bacteroides spp (including β-lactamase producing strains); *Escherichia coli* (including most β-lac Salmonellae (including β-*lactamase* producing strains); *Bordetella bronchiseptica*; *Campylobacte necrophorum*; Klebsiellae; Pasteurellae; *Proteus* spp.

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.

Dosage and administration

Administration

By the oral route. Synulox palatable tablets are often accepted from the hand even by sick cats and dogs. Alternatively, the tablets may be crushed and added to a little food.

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.

For the majority of infections, including those of the skin, urinary tract and gastrointestinal tract, the above dosing 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. (Note that the smallest animals of 1 kg bodyweight when dosed with ½ tablet will already be receiving the doubled (25 mg/kg) dose rate.)

Duration of therapy

Routine cases involving all indications: The majority of these cases respond to between 5 and 7 days therapy.

	Number of tablets per dose, twice daily
Bodyweight (kg)	50 mg
1– 2	½
3– 5	1
6– 9	2
10–13	3

14–18	4
19–25	—
26–35	—
36–49	—
50	—

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 d
Chronic cystitis	10–28 d
Respiratory disease	8–10 day

Contra-indications, warnings, etc

For animal treatment only. 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.

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).

Operator warning

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.

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reaction to cephalosporins and vice-versa. Allergic reaction 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. Wash hands after use.

Handle this product with great care to avoid exposure, taking all recommended precautions.

If you develop symptoms following exposure such as 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 may require urgent medical attention.

Pharmaceutical precautions

Do not store above 25°C. Store in a dry place. Keep out of the sight and reach of children.

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

Legal category

Legal category:POM-V

Packaging quantities

Both size tablets are packed in foil strips containing 5 x 2 tablets. 50 mg tablets are supplied in packs of 100 and 500, 250 mg tablets are in packs of 100 and 250. Not all pack sizes may be marketed.

Further information

Resistance to many antibiotics is caused by beta-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 beta-lactamases, thus rendering the organisms sensitive to amoxicillin's rapid bactericidal effect, at concentrations readily attainable in the body.

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.

Synulox Palatable Tablets can safely be used during pregnancy and lactation.

Synulox Palatable Drops are available as an alternative presentation for treating small individuals.

Marketing Authorisation Number

50 mg	Vm 42058/4147
250 mg	Vm 42058/4145

Significant changes

GTIN

GTIN description:100 x 50 mg:

GTIN:05013457076929

GTIN description:500 x 50 mg:

GTIN:05013457076936

GTIN description:100 x 250 mg:

GTIN:05013457076943

GTIN description:250 x 250 mg:

GTIN:05013457076950