

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SYNULOX PALATABLE DROPS 40 mg/ml + 10 mg/ml, Powder for Oral Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

After reconstitution, each ml contains:

Amoxicillin 40 mg

Clavulanic acid 10 mg

3. PACKAGE SIZE

1 x 15 ml after reconstitution

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

Reconstitute with 15 ml water.

Shake well before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 7 days.

Use by...

9. SPECIAL STORAGE PRECAUTIONS

Powder: Do not store above 25°C.
Suspension: Store in a refrigerator

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5213

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SYNULOX PALATABLE DROPS 40 mg/ml + 10 mg/ml, Powder for Oral Suspension

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

After reconstitution, each ml contains:

Amoxicillin 40 mg

Clavulanic acid 10 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 7 days.

Use by...

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Synulox Palatable Drops 40 mg/ml + 10 mg/ml, Powder for Oral Suspension

2. Composition

Active substance:

Each bottle of powder contains:

648 mg amoxicillin (equivalent to 743,8 mg amoxicillin trihydrate).

162 mg clavulanic acid (equivalent to 193 mg potassium clavulanate)

Each ml of reconstituted oral suspension contains:

Amoxicillin 40 mg

Clavulanic acid 10 mg

Powder: Off-white.

After reconstitution: Off-white suspension.

3. Target species

Dogs and cats.

4. Indications for use

Dogs:

For the treatment of

- Skin infections (including deep and superficial pyoderma).
- Soft tissue infections (including anal sacculitis and abscesses).
- Urinary tract infections.
- Respiratory infections.
- Intestinal infections.
- Periodontal infections (infections of the tissues surrounding the teeth) in addition to mechanical or surgical periodontal therapy.

Cats:

For the treatment of

- Skin infections (including superficial pyoderma).
- Soft tissue infections (including abscesses).
- Urinary tract infections.
- Respiratory infections.
- Intestinal infections.
- Periodontal infections (infections of the tissues surrounding the teeth) in addition to mechanical or surgical periodontal therapy.

5. Contraindications

Do not use in rabbits, guinea pigs, hamsters, gerbils, chinchillas or other small herbivores.

Do not use in cases of hypersensitivity to the active substances, other substances of the beta-lactam group or to any of the excipients.

Do not administer to horses or ruminating animals.

Do not use in animals with severe renal impairment with no or decreased urine production (anuria or oliguria).

6. Special warnings

Special warnings:

Cross-resistance has been shown between amoxicillin/clavulanic acid and other antibiotics belonging to the beta-lactam group. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to other antimicrobials in the beta-lactam group because its effectiveness may be reduced.

The veterinary medicinal product has no effect against infections caused by *Pseudomonas* spp. due to its inherent resistance.

Special precautions for safe use in the target species:

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Pharmacokinetic of the active substances in the target tissue might be considered as well.

The routine use of systemic antibiotics for intestinal infections is not recommended.

Oral treatment with antibiotics can result in disturbance of gastrointestinal flora, especially in case of long-term treatment.

In case of renal or hepatic insufficiency, the use of the veterinary medicinal product should be subject to a benefit-risk assessment by the responsible veterinarian.

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 can lead to cross-reactions with cephalosporins and vice versa. Allergic reactions caused by these substances may occasionally be serious.

People with known hypersensitivity to the active substance should avoid contact with the veterinary medicinal product. Wear gloves when handling this product to avoid skin contact.

In case of accidental spillage onto skin or eyes, immediately wash the affected area with plenty of water.

If you develop symptoms such as a skin rash and persistent eye irritation after exposure to the veterinary medicinal product, seek medical advice immediately and show the package leaflet or label to the physician. Swelling of the face, lips, or eyes, or difficulty breathing are more serious symptoms that require urgent medical attention.

Wash hands after use.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

In laboratory studies (rat, mouse), signs of embryotoxicity or teratogenicity could only be detected at high doses.

Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

The bactericidal effect of amoxicillin may be inhibited by the concomitant use of bacteriostatic antimicrobials.

Penicillins may increase the effect of aminoglycosides.

Overdose:

Doses up to 40 mg amoxicillin and 10 mg clavulanic acid/kg and 60 mg amoxicillin and 15 mg clavulanic acid/kg administered twice daily for 5 days were tolerated well in young dogs and young cats respectively.

No adverse events associated with overdoses other than those listed in section 'Adverse events' were detected in the respective studies (for information on symptomatic treatment see also section on adverse events).

Due to the toxic effect of penicillins on the nervous system, overdosing might result in central nervous system symptoms and convulsions. In these cases, treatment with the veterinary medicinal product should be discontinued immediately and symptomatic treatment should be initiated.

<Special restrictions for use and special conditions for use:>

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Dogs and cats:

Common (1 to 10 animals / 100 animals treated):
gastrointestinal disorder ¹ (e.g. vomiting, diarrhoea)
Uncommon (1 to 10 animals / 1 000 animals treated):
hypersalivation anorexia ^{1,2} , lethargy
Very rare (<1 animal / 10 000 animals treated, including isolated reports):
hypersensitivity reaction ³ (e.g. allergic skin reaction, anaphylaxis)

¹ Depending on the severity of the adverse event treatment should be discontinued and symptomatic treatment initiated based on the benefit-risk assessment by the responsible veterinarian.

² Very rare (<1 animal / 10 000 animals treated, including isolated reports) in cats.

³ May be serious. Immediate discontinuation of the veterinary medicinal product is required. Countermeasures to be taken by the veterinarian in case of an allergic reaction:

- anaphylaxis: administer epinephrine (adrenaline) and glucocorticoids.
- allergic skin reactions: administer antihistamines and/or glucocorticoids.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

E-mail: adverse.events@vmd.gov.uk

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

8. Dosage for each species, routes and method of administration

Oral use.

Dosage: 10 mg amoxicillin and 2.5 mg clavulanic acid/kg body weight every 12 hours equivalent to 0.25 ml reconstituted product/kg body weight every 12 hours or 5 drops per kg body weight 12 hours.

In refractory respiratory tract infections, the dose can be doubled to 20 mg amoxicillin and 5 mg clavulanic acid/kg body weight every 12 hours and the treatment can be prolonged for up to 10 days.

Dosing instructions:

Body weight (kg)	Quantity (ml) of reconstituted veterinary medicinal product every 12 hours per dose level	
	10 mg amoxicillin and 2.5 mg clavulanic acid/kg	20 mg amoxicillin and 5 mg clavulanic acid/kg
0.5 – 1	0.15 (3 drops*) to 0.25 (5 drops)	0.30 (6 drops) to 0.5 (10 drops)
>1 – 2	0.3 (6 drops) to 0.5 (10 drops)	0.6 (12 drops) to 1 (20 drops)
>2 – 3	0.55 (11 drops) to 0.75 (15 drops)	1.1 (22 drops) to 1.5 (30 drops)
>3 – 4	0.8 (16 drops) to 1 (20 drops)	1.6 (32 drops) to 2 (40 drops)

*1 drop delivers approximately 0.05 ml of the suspension.

Duration of treatment:

In most of the cases, a treatment duration of 5 to 7 days is sufficient.

For chronic cases, a longer course of therapy may be required.

Based on clinical trials, the following treatment durations are recommended:

Chronic skin infections, 10–20 days.

Chronic cystitis, 10–28 days.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.

Open the bottle. Discard the original aluminium cap. Reconstitute the powder with 15 ml of tap water. Close the bottle with the dropper cap and shake vigorously to obtain a milky suspension. Open the bottle and use the dropper (graduated from 0.25 to 1 ml) to extract the prescribed amount. If needed, gently squeeze the rubber portion of the dropper to drop the excess of the veterinary medicinal product back into the bottle.

Administer the veterinary medicinal product with the graduated dropper either directly into the animal's mouth or mixed with some food.

Shake the veterinary medicinal product well before each use.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C.

Store the reconstituted veterinary medicinal product in a refrigerator (2°C - 8°C).

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 7 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 42058/5213

Cardboard box containing 1 x 15 ml bottle and 1 x graduated dropper.

15.PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:

Haupt Pharma Latina S.r.l.
Strada Statale 156 Dei Monti Lepini Km 47,600
Latina
04100
Italy

17. Other information

POM-V

Gavin Hall
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