PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox Palatable Drops Powder for Oral Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 193mg Potassium Clavulanate (equivalent to162mg clavulanic acid) and 743.8mg Amoxicillin Trihydrate (equivalent to 648mg amoxicillin). Upon reconstitution with 15ml water, the product provides 10mg/ml clavulanic acid and 40mg/ml amoxicillin.

3. PHARMACEUTICAL FORM

Powder for Oral Suspension

4. PACKAGE SIZE

15 ml after reconstitution

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dogs and cats: 0.25 ml per 1 kg twice daily. For further details see enclosed leaflet.

8. WITHDRAWAL PERIOD

-

9. SPECIAL WARNING(S), IF NECESSARY

Synulox Palatable Drops should not be administered to rabbits, guinea pigs, hamsters or gerbils. Caution is advised in their use in any other very small herbivores.

Operator warnings

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. 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.

Wash hands after use.

For further details please see package leaflet.

10. EXPIRY DATE

EXP {month/year}

Once reconstituted use by…

11. SPECIAL STORAGE CONDITIONS

Powder: Do not store above 25°C.

Suspension: Store in a refrigerator (2°C - 8°C).

Once reconstituted use within 7 days.

Shake the reconstituted product before use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4144

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Folding carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox Palatable Drops Powder for Oral Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 193mg Potassium Clavulanate (equivalent to162mg clavulanic acid) and 743.8mg Amoxicillin Trihydrate (equivalent to 648mg amoxicillin). Upon reconstitution with 15ml water, the product provides 10mg/ml clavulanic acid and 40mg/ml amoxicillin.

3. PHARMACEUTICAL FORM

Powder for Oral Suspension

4. PACKAGE SIZE

15 ml after reconstitution

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.

Dogs and cats: 0.25 ml per 1 kg twice daily.

Bodyweight	**Dosage** (twice daily)
½ kg	3 drops
1 kg	0.25 ml
2 kg	0.50 ml
3 kg	0.75 ml
4 kg	1.00 ml
5 kg	1.25 ml

8. WITHDRAWAL PERIOD

-

9. SPECIAL WARNING(S), IF NECESSARY

Synulox Palatable Drops should not be administered to rabbits, guinea pigs, hamsters or gerbils. Caution is advised in their use in any other very small herbivores.

Operator warnings

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. 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.

Wash hands after use.

For further details please see package leaflet.

10. EXPIRY DATE

EXP {month/year}

Once reconstituted use within 7 days

11. SPECIAL STORAGE CONDITIONS

Powder: Do not store above 25°C.

Suspension: Store in a refrigerator (2°C - 8°C).

Shake the reconstituted product before use.

Date of reconstitution:

Date to discard:

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4144

17. MANUFACTURER’S BATCH NUMBER

Batch No:

PACKAGE LEAFLET FOR: Synulox Palatable Drops Powder for Oral Suspension

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Batch release site not stated

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox Palatable Drops Powder for Oral Suspension

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Powder for oral suspension containing 193mg Potassium Clavulanate (equivalent to 162mg clavulanic acid) and 743.8mg Amoxicillin Trihydrate (equivalent to 648mg amoxicillin). Upon reconstitution with 15ml water, the product provides 10mg/ml clavulanic acid and 40mg/ml amoxicillin.

4. INDICATION(S)

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

Mode of action
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-lactamase, thus rendering the organisms sensitive to amoxicillin's rapid bactericidal effect at concentrations readily attainable in the body.

(i) *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.

(ii) 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 (e.g. gingivitis)
- Urinary tract infections
- Respiratory disease (involving upper and lower respiratory tract)
- Enteritis

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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).

7. TARGET SPECIES

Dogs and cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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. 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 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 (i.e. 0.5 ml of reconstituted product per 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 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

9. ADVICE ON CORRECT ADMINISTRATION

Administration: For oral administration only. Reconstitute the product with 15ml clean tap water and shake well.

10. WITHDRAWAL PERIOD(S)

-

11. SPECIAL STORAGE PRECAUTIONS

Powder: Do not store above 25°C.

Suspension: store in a refrigerator (2°C - 8°C).

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle.

The expiry date refers to the last day of that month.

Shelf life after reconstitution: 7 days

Shake the reconstituted product before use.

12. SPECIAL WARNING(S)

For animal treatment only.

Keep out of the sight and reach of children.

Operator Warnings
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.

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 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.

4. Wash hands after use.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2022

15. OTHER INFORMATION

Synulox Palatable Drops are supplied in bottles containing the equivalent of 750 mg of clavulanate-potentiated amoxicillin. A dropper with graduations of 0.25 ml, up to 1 ml, is included in each pack to ensure accurate, convenient dosing.

POM-V

To be supplied only on veterinary prescription.

Vm 42058/4144

PRODUCT SUMMARY

• **Extended Spectrum of Activity** - clavulanate extends the spectrum of amoxicillin by making it active against resistant (ß-lactamase producing) strains of Staphylococci, E. coli and Salmonellae, as well as adding Klebsiella species to the list of susceptible organisms.

• **Kills Bacteria Rapidly** - increases the likelihood of a rapid clinical cure.

• **Excellent Absorption and Penetration** - ensures sufficiently high levels of Synulox at the common infection sites to achieve clinical success.

• **Easy to Administer** - exceptional palatability makes the drops readily acceptable to dogs and cats.

• **Simple Twice Daily Dosage** - easy to remember.

• **Convenient Dropper-Bottle Presentation** - easy to dispense with graduated dropper.

• **Highly Effective** - the unique formulation of Synulox increases the high cure rates achieved with amoxycillin alone.

Further information

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

Approved 04 March 2022