

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Folding carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox Bolus 500 mg Film-Coated Tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each bolus contains 100 mg clavulanic acid as Potassium clavulanate and 400 mg amoxicillin as Amoxicillin Trihydrate.

clavulanate-potentiated amoxicillin

3. PHARMACEUTICAL FORM

Film-Coated Tablets

4. PACKAGE SIZE

20 boluses

100 boluses ECONOMY PACK

5. TARGET SPECIES

Calves

6. INDICATION(S)

Uses: The clinical indications for Synulox boluses are in the treatment of enteritis and navel ill in calves.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Directions: See enclosed leaflet.

Administration: Synulox boluses should be administered by the oral route.

Dosage rate: 6.25 - 12.5 mg combined actives/kg bodyweight twice daily, e.g. a 40 kg calf will require half a bolus twice daily, but this may be doubled in cases of severe infection.

Treatment should be continued for up to 12 hours after the clinical signs have subsided, up to a maximum of 3 days of treatment.

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption for 9 days following the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

Contra-indications, warnings, etc.:

Operator warning: 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.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

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

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

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

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

For animal treatment only.

POM-V

To be supplied only on veterinary prescription.

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(S)

Vm 42058/4142

17. MANUFACTURER'S BATCH NUMBER

Batch No:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS {Foil strips}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox® 500 mg bolus

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis [logo]

3. EXPIRY DATE

Printed on line

4. BATCH NUMBER

Printed on line

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

PACKAGE LEAFLET FOR: Synulox Bolus 500 mg Film-Coated Tablet

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 Bolus 500 mg Film-Coated Tablet

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

Synulox boluses are presented as large, pink, film-coated, bolus-shaped tablets with a break line on one face and 'SYNULOX' engraved on the other. Each bolus contains 100 mg clavulanic acid as Potassium clavulanate and 400 mg amoxicillin as Amoxicillin Trihydrate.

4. INDICATION(S)

The clinical indications for Synulox boluses are in the treatment of enteritis and navel ill in calves.

Synulox boluses have a notably broad spectrum of bactericidal activity against bacteria commonly found in calves.

Mode of Action

Resistance to many antibiotics is caused by β -lactamase enzymes which destroy the antibiotic before they can act on the bacteria themselves. The clavulanate in Synulox counteracts this defence mechanism by inactivating the β -lactamases, thus rendering the organisms sensitive to amoxicillin's rapid bactericidal effect.

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

Gram-positive: Staphylococci (including β -lactamase producing strains)
Streptococci
Corynbacteria

Clostridia

Actinomyces bovis

Gram-negative: *Escherichia coli* (including most β -lactamase producing strains)

Salmonellae (including most β -lactamase producing strains)

Klebsiellae

Proteus spp.

Pasteurellae

Fusobacterium spp.

Haemophilus spp.

5. CONTRAINDICATIONS

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6. ADVERSE REACTIONS

■

7. TARGET SPECIES

Calves

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

By the oral route.

6.25 - 12.5 mg combined actives/kg bodyweight twice daily, e.g. A 40 kg calf will require half a bolus twice daily, but this may be doubled in cases of severe infections.

9. ADVICE ON CORRECT ADMINISTRATION

Treatment should be continued for up to 12 hours after the clinical signs have subsided, up to a maximum of 3 days of treatment.

10. WITHDRAWAL PERIOD(S)

Animals should not be slaughtered for human consumption for nine days following the last treatment.

11. SPECIAL STORAGE PRECAUTIONS

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

12. SPECIAL WARNING(S)

Operator Warning

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 animal treatment only.

Keep out of the sight and reach of children.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

AVAILABILITY

Synulox boluses are supplied foil wrapped in packs containing 20 and 100 boluses.

POM-V

To be supplied only on veterinary prescription.

Vm 42058/4142

PRODUCT SUMMARY

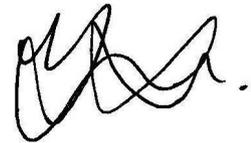
- **Unique Formulation** - dual action of clavulanate - potentiated amoxicillin
- **Extended Spectrum of Activity** - clavulanate extends the spectrum of amoxicillin

by making it active against resistant (β -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.
- **Simple Twice Daily Dosage** - easy to remember.
- **Convenient Foil Packaging** - easy to dispense.
- **Highly Effective** - the novel formulation of Synulox increases the high cure rates achieved with amoxicillin alone.

FURTHER INFORMATION

- Synulox is a novel concept in antibiotic therapy.
- Synulox is effective against *Klebsiella* infections found in veterinary practice but is not indicated for cases involving *Pseudomonas* species.



Approved: 27 August 2020