

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SYNULOX Bolus 500 mg Film-Coated Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<i>Active substances:</i>	mg/bolus
Amoxicillin as (Amoxicillin trihydrate)	400.00
Clavulanic Acid as (Potassium Clavulanate)	100.00

<i>Excipients:</i>	
Titanium Dioxide (E171)	26.58
Ponceau 4R Lake (E124)	0.546
Carmoisine Lake (E122)	0.399
Sunset Yellow Lake (E110)	0.357
Indigo Carmine Lake (E132)	0.119

For the full list of all other excipients see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

4. CLINICAL PARTICULARS

4.1 Target species

Calves.

4.2 Indications for use, specifying the target species

For the treatment of enteritis and navel ill in calves.

4.3 Contraindications

In common with other penicillins, the product should not be administered orally to rabbits, guinea pigs, hamsters or gerbils.
Do not use in animals with known sensitivity to the active ingredients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

- i) Special precautions for use in animals

None.

- ii) 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 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.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Orally. 6.25-12.5 mg/kg bodyweight twice daily. For example a 40 kg calf will require $\frac{1}{2}$ 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The combination is of a low order of toxicity and is well tolerated by the oral route. Limited overdose normally produces no adverse effect.

4.11 Withdrawal period

Meat: 9 Days.

5. PHARMACOLOGICAL PROPERTIES

In vitro, the combination is effective against a wide range of clinically important bacteria including:

Gram-positive

Staphylococci (including β -lactamase producing strains)
Streptococci
Corynebacteria
Clostridia
Actinomyces bovis

Gram-negative

Escherichia coli (including most β -lactamase producing strains)
Salmonellae (including β -lactamase producing strains)
Klebsiellae
Proteus spp.
Pasteurellae
Fusiformis spp.
Haemophilus spp.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Stearate
Sodium Starch Glycollate Type A, dried
Silicon Dioxide
Microcrystalline Cellulose, dried

Film coating:

Ponceau 4R Lake (E124)
Carmoisine Lake (E122)
Sunset Yellow Lake (E110)
Indigo Carmine Lake (E132)
Titanium Dioxide E171
Hypromellose 5 mPa s
Hypromellose 15 mPa s
Polyethylene Glycol 4000
Polyethylene Glycol 6000

6.2 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

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

6.5 Nature and composition of immediate packaging

Packs contain 20, 100 or 500 boli, which are pink biconvex film coated tablets packed in heat sealed aluminium foil.

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

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

7. MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 60021/3024

9. DATE OF FIRST AUTHORISATION

01 November 1990

10. DATE OF REVISION OF THE TEXT

January 2025

Gavin Hall
Approved: 14 January 2025