## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox Bolus 500 mg film-coated tablet

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

**Active substances:**
Amoxicillin Trihydrate 400 mg
Potassium Clavulanate 100 mg

**Excipients:**

| **Qualitative composition of excipients and other constituents** |
|---|
| Magnesium Stearate |
| Sodium Starch Glycollate |
| Silicon Dioxide |
| Microcrystalline Cellulose |
| Titanium Dioxide |
| Hypromellose E5 |
| Hypromellose E15 |
| Polyethylene Glycol 4000 |
| Polyethylene Glycol 6000 |
| Ponceau 4R Aluminium lake |
| Carmosine Aluminium lake |
| Sunset Yellow Aluminium lake |
| Indigo Carmine Aluminium lake |

Pink, biconvex, film-coated bolus shaped tablet. The tablet has a break line on one side and is embossed 'Synulox' on the other.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle (calves).

### 3.2 Indications for use for each target species

For the treatment of enteritis and navel ill in calves.

### 3.3 Contraindications

In common with other penicillins, the veterinary medicinal product should not be administered orally to rabbits, guinea pigs, hamsters or gerbils.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

### 3.4 Special warnings

None.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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.

People with known hypersensitivity to penicillins and cephalosporins should avoid contact with the veterinary medicinal product. 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.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Not applicable.

### 3.8 Interaction with other medicinal products and other forms of interaction

None known.

### 3.9 Administration routes and dosage

Oral use.

6.25 - 12.5 mg/kg bodyweight twice daily.

For example a 40 kg calf will require ½ 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.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

### 3.12 Withdrawal periods

Meat and offal: 7 days.

## 4. IMMUNOLOGICAL INFORMATION

### 4.1 ATCvet code : QJ01CR02

*In vitro*, the veterinary medicinal product is effective against a wide range of clinically important bacteria including:

Gram-positive:
Staphylococci (including ß-lactamase producing strains)
Streptococci
Corynebacteria
Clostridia
*Actinomyces bovis*

Gram-negative:
*Escherichia coli* (including most ß-lactamase producing strains)
Salmonellae (including β-
lactamase producing strains)
Klebsiellae
*Proteus* spp.
Pasteurellae
*Fusiformis* spp.
*Haemophilus* spp.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

None known.

### 5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

### 5.3 Special precautions for storage

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

### 5.4 Nature and composition of immediate packaging

Pink biconvex film coated tablets packed in heat sealed aluminium foil. Each bolus is individually heat sealed and contained in a strip of 10.

Cardboard box contains: 20, 100 or 500 boli.

Not all pack sizes may be marketed.

### 5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA10387/072/001

## 8. DATE OF FIRST AUTHORISATION

15/08/2014

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

11/07/2025

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).