Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox Bolus 500 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active Substances
Amoxicillin Trihydrate 400 mg
Potassium Clavulanate 100 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

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

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, Synulox should not be administered orally to rabbits, guinea pigs, hamsters or gerbils.
Do not use in animals with known hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals
None.

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.

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 interactions

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 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.

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

Synulox Bolus 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(s)

Animals must not be slaughtered for human consumption until after 7 days following the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

In vitro, Synulox 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Major 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, 500 boli, which are pink biconvex film coated tablets packed in heat sealed aluminium foil.
Each bolus is individually heat sealed and contained in a strip of 10.
Not all pack sizes may be marketed.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/072/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1987
Date of last renewal: 30 September 2007

10 DATE OF REVISION OF THE TEXT

August 2017