Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox Lactating Cow Intramammary suspension.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances
One syringe (3g) contains:

Amoxicillin trihydrate equivalent to amoxicillin	200 mg
Potassium clavulanate equivalent to clavulanic acid	50 mg
Prednisolone	10 mg

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Intramammary suspension. Pale cream/buff coloured oily suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (lactating cows).

4.2 Indications for use, specifying the target species

For use in clinical cases of mastitis including cases associated with infections with the following pathogens:
Straphylococci (including β-lactamase producing strains)
Streptococci (including *S. agalactiae, S. dysgalactiae* and *S. uberis*)
Escherichia coli (including β-lactamase producing strains)

4.3 Contraindications

Do not use in animals which are known to be hypersensitive to ß-lactamase antibiotics.

4.4 Special warnings for each target species

Do not use in cases associated with *Pseudomonas*.

4.5 Special precautions for use

Special precautions for use in animals
Swab teat end with appropriate disinfectant before treatment.

Recommendations for prudent use
The product should be used for treatment of clinical mastitis only.

Use of the product should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria and take into account official and local antimicrobial policies.
The use of the product should preferably be based on susceptibility tests.

Avoid use of the product in herds where no β-lactamase producing *Staphylococci* strains have been isolated. Veterinarians should strive to use narrow spectrum antibiotics if possible. Inappropriate use of the product may increase the prevalence of

bacteria resistant to ß-lactam antibiotics and may decrease the effectiveness of treatment with ß-lactam antibiotics, due to the potential for cross-resistance.

Special precautions to be taken by the person administering the veterinarymedicinal product to animals
Penicillins and cephalosporins may cause hypersentitivity (allergy) following injection inhalation, ingestion or skin contact. Hypersentitivity to penicillins may lead to cross reactions to cepahalosporins 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 a skin rash, you should seek medical advice and show the doctor this warning. Swelling for 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

No special precautions.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Before the infusion is made, the teat end should be cleaned and disinfected.
The contents of one syringe should be infused into each affected quarter via the teat canal, immediately after milking, at 12 hour intervals for three consecutive milkings.
In cases of infections caused by *Staphylococcus aureus*, a longer course of antibacterial therapy may be required. Therefore overall treatment length must be at the veterinarian's discretion but should be long enough to ensure complete resolution of intramammary infection.

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

No adverse effects are to be expected from an accidental overdose.

4.11 Withdrawal period(s)

Meat and offal: 7 days.
Milk: 84 hours. With cows milked twice daily, milk for human consumption may only be taken from the 7th milking after the last treatment. Where any other milking routine is followed, milk may be taken for human consumption only after the same period from the last treatment (e.g. with 3 times a day milking, milk may be taken for human consumption at the 11thmilking).

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Amoxicillin is a broad spectrum bactericidal β-lactam antibiotic. Clavulanic acid inactivates β-lactamases. This combination is effective against β-lactamase producing organisms.
Prednisolone is an anti-inflammatory corticosteroid.
In vitro, clavulanic acid and amoxicillin in combination are active against a wide range of clinically important bacteria including the following organisms which are commonly associated with bovine mastitis:
Staphylococci (including β-lactamase producing strains)

Streptococci (including *S. agalactiae, S. dysgalactiae* and *S. uberis*)
Arcanobacteria (including *A. pyogenes*)
Escherichia coli (including β-lactamase producing strains)

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium sodium aluminosilicate, dried
Emulsifying Wax
White Soft Paraffin
Light Liquid Paraffin

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of veterinary medicinal product as packaged for sale: 18 months
The product is for single use only.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Low density polyethylene syringes packed in cartons containing 3, 12 or 24 or 300 syringes.
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

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
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8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/073/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 01 October 2007

10 DATE OF REVISION OF THE TEXT

September 2017