

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox Lactating Cow Intramammary suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3 g intramammary syringe contains:

Active substance:

| | |
|--|--------|
| Amoxicillin (as amoxicillin trihydrate) | 200 mg |
| Clavulanic acid (as potassium clavulanate) | 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:

Staphylococci (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 cases of hypersensitivity to the active substance or to any of the excipients.

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

4.4 Special warnings for each target species

Do not use in cases associated with *Pseudomonas*.

4.5 Special precautions for use

- i) 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 β -lactam antibiotics and may decrease the effectiveness of treatment with β -lactam antibiotics, due to the potential for cross-resistance.

- 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 a 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.

Special precautions for the protection of the environment:

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

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 its local representative> or the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

No special precautions.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amount(s) to be administered and administration route

Intramammary use.

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 reactions 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 11th milking).

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for intramammary use, antibacterials and corticosteroids.

ATC Vet Code: QJ51RV01

5.1 Pharmacodynamic 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)

5.2 Pharmacokinetic particulars

Not known.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium Sodium Aluminosilicate (dried)

Mineral Oil (Formula A)

Formula A:

Emulsifying Wax

White Soft Paraffin

Liquid Paraffin Light

6.2 Major Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

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

Low density polyethylene intramammary syringes packed in cartons containing 3, 12, 24 or 300 syringes. Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste. 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 UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5105

9. DATE OF FIRST AUTHORISATION

11 December 1986

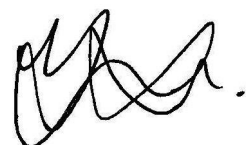
10. DATE OF REVISION OF THE TEXT

April 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

A handwritten signature in black ink, consisting of stylized, overlapping loops and strokes, positioned above the approval date.

Approved: 27 February 2024