1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox LC Intramammary suspension (BG, CY, CZ, ES, EL, HU, LT, LV, PL, PT, RO, SI, SK)

Synulox Intramammary suspension (FR, IT)

Synulox Lactating Cow Intramammary suspension (IE/UK(NI))

Synulox Comp. Intramammary suspension (AT)

Synulox Comp. Vet. Intramammary suspension (NO)

Avuloxil Intramammary suspension (NL)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3 g intramammary syringe contains:

Active substances:

Amoxicillin (as amoxicillin trihydrate)	200 mg
Clavulanic acid (as potassium clavulanate)	50 mg
Prednisolone	10 mg

Excipients:

Qualitative composition of excipients and other constituents
Calcium Sodium Aluminosilicate (dried)
Emulsifying Wax
White Soft Paraffin
Light Liquid Paraffin

Pale cream/buff coloured oily intramammary suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (lactating cows).

3.2 Indications for use for each 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)

3.3 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.

3.4 Special warnings

Do not use in cases associated with *Pseudomonas*.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 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.

3.6 Adverse events

Cattle (lactating cows)
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 package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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.

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

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

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

To be completed in accordance with national requirements.

3.12 Withdrawal periods

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).

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ51RV01

4.2 Pharmacodynamics

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)

4.3 Pharmacokinetics

None known.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

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

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

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

To be completed nationally

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

8. DATE OF FIRST AUTHORISATION

To be completed nationally

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

To be completed nationally

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).