ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox LC Plus Intramammary suspension (DE)

Synulox LC Intramammary suspension (BE/LU)

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
Emulsifying wax
White soft paraffin
Light liquid paraffin

White to off-white 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 also section 16 of the 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 intramammary 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

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 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 *T. pyogenes*)
Escherichia coli (including β-lactamase producing strains).

4.3 Pharmacokinetics

No information.

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 intramammary syringes.
Not all pack sizes may be marketed.

5.5 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.
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 after conclusion of the procedure.

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox LC Plus Intramammary suspension.(DE)
Synulox LC Intramammary suspension(BE/LU)

2. STATEMENT OF ACTIVE SUBSTANCES

Each 3 g intramammary syringe contains:

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

3. PACKAGE SIZE

3 intramammary syringes
12 intramammary syringes
24 intramammary syringes
300 intramammary syringes

4. TARGET SPECIES

Cattle (lactating cows).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramammary use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 7 days.
Milk: 84 hours, i.e. 7 milking times with 2 times a day milking or 11 milking times with 3 times a day milking.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.
Store in a dry place.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Polyethylene intramammary syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox LC Plus (DE)
Synulox LC (BE/LU)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each syringe contains:

Amoxicillin	200 mg
Clavulanic acid	50 mg
Prednisolone	10 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Synulox LC Plus Intramammary suspension (DE)

Synulox LC Intramammary suspension (BE/LU)

2. 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

White to off-white oily intramammary suspension.

3. Target species

Cattle (lactating cows).

4. Indications for use

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).

5. 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.

6. Special warnings

Special warnings:
Do not use in cases associated with *Pseudomonas.*

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.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

None known.

7. Adverse events

Cattle (lactating cows)
None known.
Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: *{national system details}*.

8. Dosage for each species, routes and method of administration

Intramammary use.
The contents of one intramammary 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.

9. Advice on correct administration

Before the infusion is made, the teat end should be cleaned and disinfected.

10. Withdrawal periods

Meat and offal: 7 days.
Milk: 84 hours, i.e. 7 milking times with 2 times a day milking or 11 milking times with 3 times a day milking.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

To be completed nationally

Pack sizes:
Carton containing 3, 12, 24 or 300 intramammary syringes.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}
To be completed nationally

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
To be completed nationally

Manufacturer responsible for batch release:
Haupt Pharma Latina S.r.l.

Strada Statale 156 Dei Monti Lepini Km 47600
Latina
04100
Italy

Local representative and contact details to report suspected adverse reactions:
To be completed nationally

17. Other information

To be supplied by a surgeon or under their direct responsibility.

To be completed nationally