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 Lactating Cow Intramammary suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each syringe contains:Amoxicillin (as amoxicillin trihydrate)		200 mg
Clavulanic acid (as potassium clavulanate)	50 mg	
Prednisolone	10 mg	

3. PACKAGE SIZE

3 syringes
12 syringes
24 syringes
300 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

Do not store above 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

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland

14. MARKETING AUTHORISATION NUMBERS

Vm 60021/3038

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Polyethylene syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synulox Lactating Cow

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 Lactating Cow Intramammary suspension

2. Composition

Each 3 g intramammary syringe contains:

Active ingredients:

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

Pale cream/buff coloured 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 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 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

Vm 60021/3038

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

15. PID LINK (Do not print heading

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland

Manufacturer responsible for batch release:
Haupt Pharma Latina S.r.l.
Strada Statale 156 Dei Monti Lepini Km 47600
Latina
04100
Italy

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

To be completed nationally

Gavin Hall

Approved: 14 January 2025