ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX OF 4 OR 10 SYRINGES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pathozone 250 mg Intramammary Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Cefoperazone	250 mg/syringe
(as the sodium salt)	258.9 mg/syringe

3. PACKAGE SIZE

4 x 10 ml syringes.
10 x 10 ml syringes.

4. TARGET SPECIES

Cattle (lactating dairy cows).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For intramammary use. Single administration. The contents of one syringe should be injected into the infected quarter immediately after milking.

7. WITHDRAWAL PERIODS

Meat and offal:	2 days.
Milk:	72 hours.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

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

{Name or company name or logo name of the marketing authorisation holder}
To be completed nationally

14. MARKETING AUTHORISATION NUMBERS

Number allocated by the Member State.
To be completed nationally

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

12 ML SYRINGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pathozone 250 mg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Cefoperazone	250 mg/syringe
(as the sodium salt)	258.9 mg/syringe

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Pathozone 250 mg Intramammary Suspension for Cattle

2. Composition

Each 10 ml dose contains:

Active substance:

Cefoperazone	250
(as the sodium salt)	258.9

Excipient:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
all-rac-α-Tocopherol (E307)	4.6 mg

White to off-white oily intramammary suspension.

3. Target species

Cattle (lactating dairy cows).

4. Indications for use

The product is indicated for the treatment of clinical mastitis in lactating cows.

Clinical mastitis caused by a wide range of organisms including the following pathogens have been shown to respond to treatment with cefoperazone.

- *Streptococcus dysgalactiae*
- *Streptococcus uberis*
- *Streptococcus agalactiae*
- *Staphylococcus aureus* (including penicillinase producing strains)
- *Escherichia coli*
- *Trueperella pyogenes*
- *Pseudomonas aeruginosa*
- *Micrococcus* spp.
- *Klebsiella* spp.

5. Contraindications

Do not use in cases of hypersensitivity to cephalosporins or to any of the excipients or in case of severe disturbance of kidney function.

6. Special warnings

Special warnings:
It is not envisaged for this product to be administrated to species other than lactating cattle.

Special precautions for safe use in the target species:
Use of the product should be based on susceptibility testing of bacteria isolated from the affected quarter(s). If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about the susceptibility of target bacteria. Official, national, and regional antimicrobial policies should be taken into account when the product is used. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to cefoperazone, and may decrease the effectiveness of treatment with other cephalosporins, 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 reaction 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, such as a skin rash, you should seek medical advice and show the doctor this warning or the package leaflet. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and may require urgent medical attention. Wash hands after use.

Pregnancy and lactation:
By definition the product has been developed for use in lactating cows and has been shown to be safe in that regard.
In reproductive studies no adverse findings have been seen which might make the product unsafe in pregnant animals.

Interaction with other medicinal products and other forms of interaction:
Cefoperazone is not compatible with aminoglycoside antibiotic such as streptomycin, neomycin and gentamicin. The simultaneous administration of possibly nephrotoxic drugs may prolong the elimination of cefoperazone.
There is a rare possibility of cross reaction with other beta-lactam antibiotics.

Overdose:
Overdosing is unlikely to be a problem as the contents of a full syringe have been administered.

Major incompatibilities:
Cefoperazone is not physico-chemically compatible with drugs of the aminoglycoside group.

7. Adverse events

Cattle (lactating dairy cows):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Unclassified adverse event

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

For intramammary use. Single administration. The contents of one syringe should be injected into the infected quarter immediately after milking.

9. Advice on correct administration

Before injection the teat should be thoroughly cleaned and disinfected.

10. Withdrawal periods

Meat and offal: 2 days.
Milk: 72 hours.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

Do not use this veterinary medicinal product after the expiry date which is state 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

To be completed nationally.

Carton containing 4 or 10 x 10 ml syringes.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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 47,600
Latina
04100
Italy

<Local representatives <and contact details to report suspected adverse reactions*>:>

To be completed nationally (if needed)*