PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX – 4 SYRINGES
CARTON BOX – 10 SYRINGES

1.NAME OF THE VETERINARY MEDICINAL PRODUCT

Pathozone 250 mg Intramammary Suspension for Cattle
Cefoperazone

2.STATEMENT OF ACTIVE SUBSTANCES

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

3.PHARMACEUTICAL FORM

Intramammary suspension.

4.PACKAGE SIZE

4 x 12 ml syringes.
10 x 12 ml syringes.

5.TARGET SPECIES

Cattle (lactating dairy cows).

6.INDICATION(S)

7.METHOD AND ROUTE OF ADMINISTRATION

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

Read the package leaflet before use.

8.WITHDRAWAL PERIOD

Meat and offal:	2 days
Milk:	72 hours

9.SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use

Penicillins and cephalosporins may occasionally cause severe allergic reactions.

10. EXPIRY DATE

<EXP {month/year}>

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4095

17. MANUFACTURER'S 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 Intramammary Suspension for Cattle
Cefoperazone

2. QUANTITY OF THE ACTIVE SUBSTANCE

		mg/10 ml
Active substance:	Cefoperazone	250
(as the sodium salt)		258.9

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10ml/syringe.

4. ROUTE OF ADMINISTRATION

Intramammary use. Single administration.

5. WITHDRAWAL PERIOD

Meat and offal: 2 days
Milk: 72 hours

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

<EXP {month/year}>

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET
Pathozone 250 mg Intramammary Suspension for Cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

Manufacturer for the batch release:

Haupt Pharma Latina S.r.l a soclo unico
Sede Legale,
S.S. 156 Km 47,600,
04100 Borgo Michele,
Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pathozone 250 mg Intramammary Suspension for Cattle
Cefoperazone

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT(S)

		mg/10 ml
Active substance:		
Cefoperazone		250
(as the sodium salt)		258.9
Excipients:	all-rac-α-Tocopherol (E307)	4.6

White to off-white oily suspension

4. INDICATION(S)

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 case of hypersensitivity to cephalosporins or to any of the excipients or in case of severe disturbance of kidney function.

6. ADVERSE REACTIONS

Adverse reactions are very rare.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (lactating dairy cows).

8. DOSAGE FOR EACH SPECIES, ROUTE 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 PERIOD

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.
For single use only.
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 WARNINGS

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

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 for use
Use of the product should be based on susceptibility testing and should take into account official and local antimicrobial policies.

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.
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.

Incompatibilities
Cefoperazone is not physico-chemically compatible with drugs of the aminoglycoside group.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2017

15. OTHER INFORMATION

Carton containing 4 or 10 x 12 ml syringes (containing 10 ml intramammary suspension)

Not all pack sizes may be marketed

Approved: 08 February 2018