SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pathozone 250 mg Intramammary Suspension for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Intramammary Suspension.
White to off-white oily suspension

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (lactating dairy cows).

4.2 Indications for use, specifying the target species

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 aureu*s (including penicillinase producing strains)
- *Escherichia coli*
- *Trueperella pyogenes*
- *Pseudomonas aeruginosa*
- *Micrococcus* spp.
- *Klebsiella* spp.

4.3 Contraindications

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

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals

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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

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.

4.8 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.

4.9 Amounts to be administered and administration route

For intramammary use. Single administration. The contents of one syringe should be injected into the infected quarter immediately after milking. Before injection the teat should be thoroughly cleaned and disinfected.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Meat and offal: 2 days
Milk: 72 hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial for intramammary use, cephalosporins and related substances
ATCvet code: QJ51DA32

5.1 Pharmacodynamic properties

Cefoperazone is a third generation, semi-synthetic cephalosporin antibiotic with a broad spectrum of bactericidal activity covering the following Gram-positive and Gram-negative organisms:
- *Streptococcus dysgalactiae*
- *Streptococcus uberis*
- *Streptococcus agalactiae*
- *Staphylococcus aureu*s (including penicillinase producing strains)
- *Escherichia coli*
- *Trueperella pyogenes*
- *Pseudomonas aeruginosa*
- *Micrococcus* spp.
- *Klebsiella* spp

Cefoperazone acts by inhibition of bacterial cell wall synthesis.

5.2 Pharmacokinetic particulars

Systemic drug absorption of cefaperazone has been found to be negligible in healthy animals, whereas it tends to be higher in infected animals, probably due to the damage to epithelial cell junctions caused by subclinical infections.

The detected urine concentrations indicate that cefoperazone is absorbed from the udder and is at least partly excreted by the kidneys. In tissue residue studies, no residues were detected in samples of muscle, liver, kidney, fat, heart or supramammary lymph node.

The highest concentrations of cefoperazone in milk are detected at the first milking (12 hours) after administration. From five days after administration, cefoperazone is not detectable in the milk. Milk yield does not influence the percentage of cefoperazone excreted in the milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

all-rac-α-Tocopherol (E307)
Glycerol monostearate
Sorbitan stearate
Arachis oil, Refined

6.2 Major incompatibilities

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

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25°C.
For single use only.

6.5 Nature and composition of immediate packaging

12 ml white opaque low density polyethylene syringe (containing 10 ml intramammary suspension) fitted with a protective cap of red low density polyethylene. Cartons contain four or ten syringes.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4095

9. DATE OF FIRST AUTHORISATION

14 December 2012

10. DATE OF REVISION OF THE TEXT

February 2018

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

Approved: 08 February 2018