Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Pathocef 25 mg/ml intramammary suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each syringe contains:

Active substance

Cefoperazone (as the Sodium salt)	250.0	mg

Excipients

All-rac-α-tocopherol	4.6	mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Intramammary suspension. A white to whitish oily suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

For intramammary administration to lactating cattle for the single dose treatment of clinical mastitis. The following pathogens may be treated with this product:

- *Streptococcus dysgalactiae*
- *Streptococcusuberis*
- *Streptococcus agalactiae*
- *Staphlococcus aureus* (including penicillinase producing strains)
- *Escherichia coli*
- *Arcanobacterium pyogenes*
- *Pseudomonas aeruginosa*
- *Micrococcus* spp.
- *Klebsiella* spp.

4.3 Contraindications

Do not use in animals which are known to have exhibited allergic reactions to cephalosporins or to have severe disturbance of kidney function. There is the rare possibility of cross reaction with other beta-lactam antibiotics.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precaution(s) for use in animals

None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash hands after use.

1. Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross sensitivity 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.

2. Handle this product with great care to avoid exposure, taking all recommended precautions.

3. 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 and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

None known.

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 interactions

Cefoperazone is not compatible with aminoglycoside antibiotics such as streptomycin, neomycin and gentamycin. The simultaneous administration of possibly nephrotoxic drugs may prolong the elimination of cefoperazone.

4.9 Amounts to be administered and administration route

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 are administered.

4.11 Withdrawal period(s)

Milk for human consumption must not be taken from a cow during treatment. With cows milked twice daily, milk for human consumption may only be taken from 72 hours (i.e. at the 6th milking), from the last treatment with this product. Where any other milking routine is followed, consult your veterinary surgeon.
Animals intended for human consumption should not be slaughtered until 2 days after last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for intramammary use, Cephalosporins and related substances
ATCvet code: QJ51DD12

5.1 Pharmacodynamic properties

Cefoperazone is a third generation, semi-synthetic cephalosporin antibiotic with a broad spectrum of bactericidal activity covering both Gram-positive and Gram-negative organisms. It acts by inhibition of bacterial cell wall synthesis. As a third generation cephalosporin, cefoperazone shows greater ability to withstand degradation by beta-lactamase enzymes than do members of the first and second generations whose activity in the presence of beta-lactamases is therefore less reliable.

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
For single use only.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

12 ml low density polyethylene syringe (containing 10 ml intramammary suspension) fitted with a protective cap of red low density polyethylene. Cartons of 4 syringes.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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 Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park, Loughlinstown
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8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/047/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1988
Date of last renewal: 30th September 2008

10 DATE OF REVISION OF THE TEXT

June 2020