

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pathocef 250 mg Intramammary Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	mg/10 ml
Cefoperazone	250
(as the Sodium salt)	258.9
Excipients	
Tocopherol	4.6

For the full list of all other excipients see section 6.1

3. PHARMACEUTICAL FORM

Intramammary Suspension.
White to off-white oily suspension

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

PATHOCEF Intramammary Suspension 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*
- *Arcanobacterium (Actinomyces) pyogenes*
- *Pseudomonas aeruginosa*
- *Micrococcus* spp.
- *Klebsiella* spp.

The single dose treatment with PATHOCEF Intramammary Suspension has been shown to provide a high response rate in mastitis caused by major pathogens.

4.3 Contraindications

The product is contraindicated in animals which are known to have exhibited allergic reactions to cephalosporins or to have severe disturbance of kidney function.

There is a 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

- (i) Special precautions for use in animals

None

- (ii) 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)

None.

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 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 have been administered.

4.11 Withdrawal periods

Meat: 2 days
Milk: 72 hours

5. PHARMACOLOGICAL 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.

ATC Vet Code: QJ51DD12

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tocopherol
Glycerol monostearate
Sorbitan monostearate
Arachis oil

6.2 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 syringes.

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

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
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4094

9. DATE OF THE FIRST AUTHORISATION

05 June 1985

10. DATE OF REVISION OF THE TEXT

September 2020

Revised: September 2020
Amended ATCVet code



Approved: 04 September 2020

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