

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pathocef™ 250 mg Intramammary Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each syringe contains 250 mg cefoperazone (as the sodium salt).

3. PHARMACEUTICAL FORM

Intramammary Suspension

4. PACKAGE SIZE

Contents: 4 x 10 ml syringes

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Recommended for the single dose treatment of clinical mastitis in the lactating cow caused by a wide range of Gram-positive and Gram-negative organisms.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Use as recommended in the package leaflet. A teat wipe is supplied with each syringe. For single use only.

8. WITHDRAWAL PERIOD

Cattle: Milk – 72 hours.

Meat – 2 days.

9. SPECIAL WARNING(S), IF NECESSARY

IMPORTANT NOTE

As with conventional intramammaries, clinical improvement will take a few days before becoming apparent.

PATHOCEF will persist in the udder for several days and emptying the udder after treatment will not affect its effectiveness.

Give PATHOCEF enough time to become effective before seeking further treatment or veterinary advice.

Operator Warnings:

Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet for full user warnings.

10. EXPIRY DATE

EXP.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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

Dispose of any unused product and empty syringes in accordance with guidance from your local waste regulations authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only

POM-V

To be supplied only on veterinary prescription

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4094

17. MANUFACTURER’S BATCH NUMBER

LOT

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Syringe Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pathocef™ 250 mg Intramammary Suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Contains 250 mg Cefoperazone (as the sodium salt)

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

10 ml

4. ROUTE(S) OF ADMINISTRATION

Shake well before use. For single use only.

See package leaflet for instructions for use and full user warnings.

5. WITHDRAWAL PERIOD

Withdrawal periods: Milk – 72 hours. Meat – 2 days.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

Keep out of the sight and reach of children.

Do not store above 25°C.

Vm 42058/4094

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MA Holder:
Zoetis UK Limited
1st Floor, Birchwood Building
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Surrey
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PACKAGE LEAFLET FOR: Pathocef™ 250 mg Intramammary Suspension

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

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

Batch release site not listed

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pathocef™ 250 mg Intramammary Suspension

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

Pathocef 250 mg Intramammary Suspension is a sterile white to off-white vegetable oil based suspension containing 250 mg cefoperazone (as the sodium salt) in each 10 ml syringe.

4. INDICATIONS

Pathocef 250 mg Intramammary Suspension is indicated for the single dose 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 250 mg Intramammary Suspension has been shown to provide a high response rate in mastitis caused by major pathogens.

5. 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.

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.

6. ADVERSE REACTIONS

■

7. TARGET SPECIES

■

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF 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

Milk for human consumption must not be taken from cows during treatment. Milk must not be taken for human consumption until 72 hours after the last treatment.

Animals intended for human consumption must not be slaughtered until 2 days after the last treatment.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Shake well before use.

For single use only.

Keep out of the sight and reach of children.

12. SPECIAL WARNINGS

Operator Warnings

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 following exposure, such as skin rash, you should seek medical advice and show the doctor this warning.

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.

For animal treatment only.

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

Dispose of any unused product and empty syringes in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

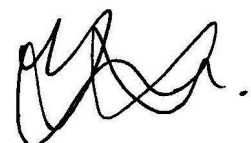
15. OTHER INFORMATION

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

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Approved: 27 August 2020