PARTICULARS TO APPEAR ON THE OUTER PACKAGE: CARDBOARD BOX AND PLASTIC BUCKET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CepraShort 300 mg Intramammary Suspension for dairy cows at drying-off

2. STATEMENT OF ACTIVE SUBSTANCES

Cefapirin 300 mg (equivalent to 383.3 mg cefapirin benzathine)/10 ml intramammary syringe

3. PACKAGE SIZE

20 intramammary syringes
144 intramammary syringes

4. TARGET SPECIES

Cattle (Dairy cow at drying-off).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramammary use.

7. WITHDRAWAL PERIODS

Withdrawal period(s):
Milk: 24 hours after calving if the interval between treatment and calving is 32 days or longer.
33 days after treatment if the interval between treatment and calving is less than 32 days.
Meat and offal: 14 days

The udder of treated cows must not be used for human consumption during the dry period and the following lactation period.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C. Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

Penicillins and cephalosporins may occasionally cause severe allergic reactions.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/3029
Vm 06376/5028

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS INTRAMAMMARY SYRINGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CepraShort

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Cefapirin 300 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

CepraShort 300 mg Intramammary Suspension for dairy cows at drying-off

2. Composition

Each 10 ml intramammary syringe contains:

Active substance:
Cefapirin 300 mg
(equivalent to 383.3 mg cefapirin benzathine)
Creamy, oily suspension

3. Target species

Cattle (Dairy cow at drying-off)

4. Indications for use

For the treatment of subclinical mastitis at drying-off caused by *Staphylococcus aureus,* coagulase-negative staphylococci*, Streptococcus agalactiae, Streptococcus dysgalactiae* and *Streptococcus uberis* susceptible to cefapirin.

5. Contraindications

Do not administer to animals which are known to be hypersensitive to cephalosporins, other beta-lactam antibiotics or to any of the excipients.
Do not use in animals suffering from severe renal disease.
Do not use in cows with clinical mastitis.
Please refer also to section “Special warnings”.

6. Special warnings

Special precautions for safe use in the target species:
In animals suffering from renal impairment use only following a benefit/risk assessment performed by the responsible veterinarian.
Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated form the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of target bacteria. Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to cefapirin and may

decrease the effectiveness of treatment. Official, national and regional antimicrobial policies should be taken into account when the product is used.
The efficacy of the veterinary medicinal product is only established against the pathogens mentioned in Section “Indications for use”. Consequently, serious acute mastitis (potentially fatal) due to other pathogen species, particularly *Pseudomonas aeruginosa*, can occur after drying off. Good hygienic practices should be thoroughly respected in order to reduce this risk.

Do not use the cleaning towel if lesions are present on the teat.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Penicillins and cephalosporins may cause allergy (hypersensitivity) following injection, inhalation, ingestion or skin contact. These reactions are occasionally serious. Hypersensitivity to penicillin may lead to cross sensitivity to cephalosporins and vice versa. People with known hypersensitivity to penicillins or cephalosporins should avoid contact with the veterinary medicinal product.
If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.

Wash hands after using the cleaning towels. People with known hypersensitivity to isopropyl alcohol should avoid direct contact with the cleaning towels. Avoid eye contact since Isopropyl alcohol may cause eye irritation.

Lactation:
Do not use during lactation.

Interaction with other medicinal products and other forms of interaction:
Simultaneous parenteral administration of nephrotoxic substances (e.g. aminoglycoside and polypeptide antibiotics) may prolong excretion of cefapirin. Concomitant use of cephalosporins and nephrotoxic drugs may increase renal toxicity. Cephalosporins should not be administered concurrently with bacteriostatic antimicrobials.

7. Adverse events

Cattle (Dairy cow at drying-off):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Allergic reaction

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first

instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Intramammary use.
For single use only.
Administer 300 mg of cefapirin (the contents of one syringe) into each quarter, via the intra-mammary route.

9. Advice on correct administration

The contents of one syringe should be infused into the teat canal of each quarter immediately after the last milking of the lactation. Before infusion, the teat should be thoroughly cleaned and disinfected with the cleaning towel provided. Remove the cap fully by holding the barrel of the syringe firmly in one hand and push up the cap with the thumb along the length of the cap until the cap clicks off. Take care not to contaminate the nozzle. Do not bend the nozzle.
Insert the nozzle into the teat canal and infuse the contents of one syringe.

Holding the end of the teat with one hand, gently massage upwards with the other hand to aid dispersion of the antibiotic into the quarter.
The intramammary syringe must only be used once.

After treatment, it is recommended to dip the teats in an appropriate disinfectant solution.

10. Withdrawal periods

Milk: 24 hours after calving if the interval between treatment and calving is 32 days or longer.
33 days after treatment if the interval between treatment and calving is less than 32 days.
Meat and offal: 14 days

The udder of treated cows must not be used for human consumption during the dry period and the following lactation period.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 °C. Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton or bucket after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 06376/3029
Vm 06376/5028

Pre-filled polyethylene syringe consisting of white low density polyethylene (LDPE) barrel with white LDPE plunger and light blue LDPE protective cap with 10 ml suspension for intramammary use and cleaning towels in a sachet consisting of paper/PE/Alu/sealing layer.

Box of 20 syringes and 20 cleaning towels.
Bucket of 144 syringes and 144 cleaning towels.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Contact details to report suspected adverse reactions:
UK(GB)
MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

UK(NI)
Intervet Ireland Ltd.
Tel.: +353 (0)1 2970220

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Approved 04 February 2025
Gavin Hall