SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cepritect 250 mg Intramammary Suspension for Dry Cows

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Each intramammary syringe of 3 g contains:

Cefalonium (as Cefalonium Dihydrate) 250 mg

Excipients:

Qualitative composition of excipients and other constituents
Aluminium distearate
Liquid paraffin

Homogeneous white to beige coloured suspension.

3. CLINICAL INFORMATION

3.1 Target Species

Dairy cattle (dry cows).

3.2 Indications for use for each target species

For the treatment of subclinical mastitis at drying-off and the prevention of new bacterial infections of the udder during the non-lactating period of cows caused by *Staphylococcus aureus, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus uberis, Trueperella pyogenes, Escherichia coli* and *Klebsiella* spp. susceptible to cefalonium.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, other β-lactam antibiotics or to any of the excipients.

Please refer to section 3.7.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to cefalonium and may decrease the effectiveness of treatment with other beta lactams.

The efficacy of the product is only established against the pathogens mentioned in section 3.2 of the SPC. 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.

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

Wash hands after use.
Penicillin and cephalosporins may cause sensitisation (allergy) following injection, inhalation, ingestion or skin contact. Sensitivity to penicillin may lead to cross-sensitivity to cephalosporin 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.
Handle this product with great care to avoid exposure, taking all recommended precautions.
If you develop symptoms following exposure such as a skin rash you should seek medical advice and show the doctor this warning. Swellings of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.
The cleaning towels provided with the intramammary product contain isopropyl alcohol. Wear protective gloves if skin irritation due to isopropyl alcohol is known or suspected. Avoid contact with eyes because isopropyl alcohol can cause eye irritation.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[1] (Swollen lip Restlessness, Tremor, Mammary gland oedema Eyelid oedema)[1]

[1] Can lead to death.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national

competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Intended for use during the last trimester of pregnancy once the lactating cow has been dried off. There is no adverse treatment effect on the foetus.

Lactation:
Do not use in lactating cows.

3.8 Interaction with other medicinal products and other forms of interactions

Cephalosporins should not be administered concurrently with bacteriostatic antimicrobials. Concomitant use of cephalosporins and nephrotoxic drugs may increase renal toxicity.

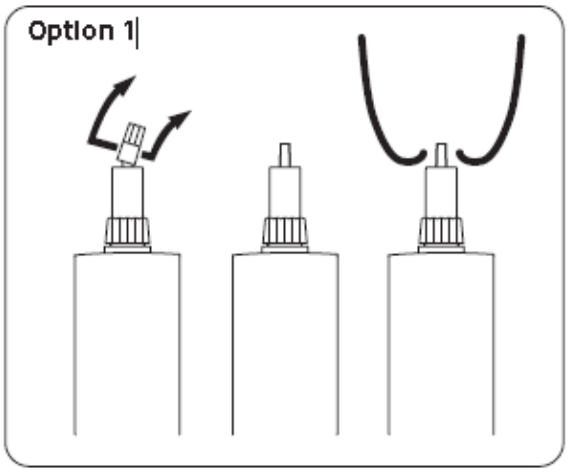
3.9 Administration routes and dosage

Intramammary use.

The contents of one syringe should be infused into the teat canal of each quarter immediately after the last milking of the lactation. Avoid contamination of the nozzle after removing the cap. Before infusion, thoroughly clean and disinfect the end of the teat with the cleaning towel provided.

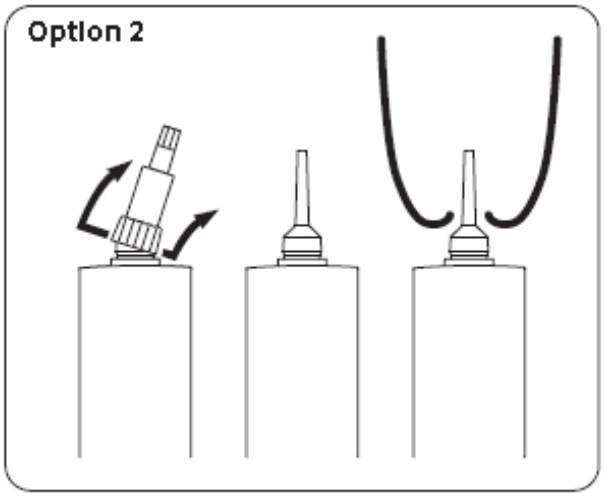
Option 1: For short nozzle intramammary administration hold the barrel of the syringe and the base of the cap in one hand and twist off the small upper part of the cap above the indent mark (the base portion of the cap remains on the syringe). Take care not to contaminate the short exposed part of the nozzle.

Option 1: For short nozzle intramammary administration.



Option 2: For full nozzle intramammary administration remove the cap fully by holding the barrel of the syringe firmly in one hand and with the thumb push up and along the length of the cap until the cap clicks off. Take care not to contaminate the nozzle.

Option 2: For full nozzle intramammary administration.



Insert the nozzle into the teat canal and apply steady pressure on the syringe plunger until the full dose has been delivered. Holding the end of the teat with one hand, gently massage upwards with the other to aid dispersion of the antibiotic into the quarter.

After infusion it is advisable to dip the teats in an antiseptic preparation specifically designed for this purpose.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes),

Repeated doses in cattle on three consecutive days did not demonstrate or produce any adverse effects.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 21 days.

Milk:
96 hours after calving if the dry period is longer than 54 days.
58 days following treatment if the dry period is less than or equal to 54 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ51DB90.

4.2 Pharmacodynamics

Cefalonium is an antibacterial drug of the first generation cephalosporin group which acts by inhibition of cell wall synthesis (bactericidal mode of action). The antibacterial activity is not impaired in the presence of milk.
Three mechanisms of resistance to cephalosporin are known: reduced permeability of the cell wall, enzymatic inactivation and absence of specific penicillin binding sites. In Gram-positive bacteria and particularly staphylococci, the main cephalosporin resistance mechanism is through alteration of penicillin binding proteins. In Gram-negative bacteria resistance may consist in the production of β-lactamases, especially extended-spectrum β-lactamases.
Cefalonium is active against: *Staphylococcus aureus, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus uberis, Trueperella pyogenes, Escherichia coli* and *Klebsiella* spp.

4.3 Pharmacokinetics

Cefalonium is extensively but slowly absorbed from the udder and excreted primarily in the urine. Between 7 and 13 % of the active substance is eliminated in urine on each of the first three days post dosing whilst daily excretion in faeces is < 1 % over the same period.

Mean blood concentration remains fairly constant during approximately 10 days after dosing which is consistent with slow but prolonged absorption of cefalonium from the udder.

The long term persistence of cefalonium in the dry udder was examined over a time span of 10 weeks after infusion. Effective levels of Cefalonium in udder secreta remain up to 10 weeks after infusion.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

Single dose 3 g white LDPE syringes with a white LDPE dual push-fit cap.
Cartons of 24 and 60 syringes or buckets of 120 syringes including 24, 60 or 120 individually wrapped teat cleaning towels containing isopropyl alcohol.

Not all pack sizes may be marketed.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER

Vm 02000/4423

8. DATE OF FIRST AUTHORISATION

23 November 2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

November 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

Gavin Hall

Approved 27 February 2025