Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefimam DC, 150 mg Intramammary Ointment for Dry Cows

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3 g intramammary syringe contains:
Active substance:
Cefquinome: (as Cefquinome Sulfate) 150 mg

Excipients:
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary ointment.
Homogenous off-white oily ointment.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (Dry cows).

4.2 Indications for use, specifying the target species

For the treatment of subclinical mastitis at drying off and the prevention of new bacterial infections of the udder during the dry period in the dairy cow caused by the following cefquinome sensitive organisms: *Streptococcus uberis, Streptococcus dysgalactiae, Streptococcus agalactiae, Staphylococcus aureus,* coagulase negative staphylococci.

4.3 Contraindications

Do not use in cows with clinical mastitis.
Do not use in cases of known hypersensitivity to cephalosporin antibiotics or other β-lactam antibiotics, or to any of the excipients.
See section 4.7.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If it is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria. The product should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials or narrow spectrum β-lactam antimicrobials.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to cefquinome and may decrease the effectiveness of treatment with cephalosporins, due to the potential for cross resistance.
Do not use the cleaning towel on teats with lesions.
In case of erroneous use during lactation, the milk should be discarded for 35 days.
Official, national and regional antimicrobial policies should be taken into account when the product is used.

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 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 to penicillins or cephalosporins, or if you have been advised not to work with such preparations.
Handle this product with great care to avoid exposure. Use impervious gloves when handling and administering the product. Wash exposed skin after use.
If you develop symptoms following exposure, such as skin rash, you should seek medical advice immediately and show the package leaflet or the label to the physician.
Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention. Persons developing a reaction after contact with the product should avoid handling the product (and other cephalosporin and penicillin containing products) in future.
The cleaning towels provided with the intramammary product contain isopropyl alcohol. Wash hands after using the towels and 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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

There is no evidence of reproductive toxicity (incl. teratogenicity) in cattle.
Laboratory studies in rats and rabbits have not shown any teratogenic, foetotoxic or maternotoxic effects.
Can be used during pregnancy.
Do not use during lactation.

4.8 Interaction with other medicinal products and other forms of interactions

See point 5.1 with regard to cross-resistance in the cephalosporin group.
The neutralizing effect of bacteriostatic acting pharmaceuticals (macrolides, sulfonamides and tetracyclines) on bactericidal effect of cefquinome has not been evaluated yet. Therefore there is no information about the safety and efficacy of this kind of association**.**

4.9 Amounts to be administered and administration route

Intramammary use.
Single intramammary administration.
150 mg cefquinome, i.e. the content of one intramammary syringe should be instilled gently into the teat of each quarter, immediately after the last milking.
Before instillation, the udder should be milked out completely and the teat and its orifice should be thoroughly cleaned and disinfected with the cleaning towel provided. Care should be taken to avoid contamination of the injector nozzle.
Gently insert either about 5mm or the total length of the nozzle and instill the content of one syringe into each quarter.
Disperse the product by gentle massage of the teat and udder.
The intramammary syringe must only be used once.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No symptoms expected or emergency proceduresrequired.

4.11 Withdrawal period(s)

Meat and offal: 2 days
Milk: 1 day after calving when dry period is more than 5 weeks
36 days after treatment when dry period is 5 weeks or less

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for intramammary use, fourth-generation cephalosporins
ATCvet code: QJ51DE90

5.1 Pharmacodynamic properties

The antibacterial drug cefquinome is a broad spectrum cephalosporin of the fourth generation which acts by inhibition of cell wall synthesis. It is bactericidal and is characterised by its broad therapeutic spectrum of activity and a high stability against penicillinases and beta-lactamases.
In vitro activity has been demonstrated against common Gram positive and Gram negative bacteria including *Staphylococcus aureus, Streptococcus dysgalactiae, Streptococcus agalactiae, Streptococcus uberis, coagulase negative Staphylococci, Streptococcus bovis, Escherichia coli, Citrobacter spp., Klebsiella spp., Pasteurella spp., Proteus spp., Salmonella spp., Serratia marcescens, Arcanobacterium pyogenes, Corynebacterium spp.*.

The following bacterial species: *Streptococcus uberis, Streptococcus dysgalactiae, Streptococcus agalactiae, Staphylococcus aureus, and coagulase negative staphylococci* isolated from a field study conducted between 2000 and 2002 in Germany, France, Belgium and the Netherlands and field studies conducted between 2011 and 2017 in France, Italy and Austria, proved to be susceptible to cefquinome with MIC values between ≤0.008 microgram/ml and 1.0 microgram/ml.

An overview of the MIC90 of each bacterial pathogen is presented in the table below:

Bacterial Species Isolated	**MIC_{90} (µg/ml)**
Streptococcus uberis	0.25
Streptococcus dysgalactiae	≤0.008
Streptococcus agalactiae	0.032
Staphylococcus aureus	0.24-0.50
Coagulase negative Staphylococci	1.0

Cefquinome as a fourth generation cephalosporin combines high cellular penetration and β-lactamase stability. In contrast to cephalosporins of previous generations, cefquinome is not hydrolysed by chromosomally–encoded cephalosporinases of the Amp-C type or by plasmid mediated cephalosporinases of some enterobacterial species.
However, some extended spectrum beta-lactamases (ESBL) can hydrolyse cefquinome and cephalosporins of other generations.
The potential for resistance development against cefquinome is rather low. High-level resistance to cefquinome would require the coincidence of two genetic modifications, i.e. hyperproduction of specific β-lactamases as well as decreased membrane permeability.
No cross-resistance has been described for the mechanism of alteration of penicillin binding protein encountered in Gram positive bacteria. Resistance due to changes in membrane permeability might result in cross-resistance.

5.2 Pharmacokinetic particulars

Resorption of cefquinome from the udder to the systemic circulation is insignificant. The cefquinome concentrations reach a peak in the dry udder secretions after 7 to 14 days and slowly decrease during the dry period.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Silica, hydrophobic colloidal
Paraffin, liquid

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal productas packaged for sale: 2 years

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Pre-filled 4.5 ml intramammary syringe consisting of white opaque high density polyethylene (HDPE) barrels with white opaque low density polyethylene (LDPE) plungers and white opaque (LDPE) dual end cap.
Cartons of 20, 24 and 60 intramammary syringes or container of 120 intramammary syringes (in aluminium foil sachets containing 4 intramammary syringes) including 20, 24, 60 or 120 individually wrapped teat cleaning towels.
Not all pack sizes may be marketed.

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 product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/123/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 September 2014
Date of last renewal: 19 August 2019

10 DATE OF REVISION OF THE TEXT

August 2019