1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cephaguard DC 150 mg intramammary ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3 g pre-filled syringe contains:

Active substance:
Cefquinome (as sulphate): 150.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Silica colloidal hydrophobic
Liquid paraffin

Homogeneous off-white oily intramammary ointment.

3. CLINICAL INFORMATION

3.1 Target species

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 dry period in the dairy cow caused by the following cefquinome susceptible organisms: *Streptococcus uberis*, *Streptococcus dysgalactiae*, *Streptococcus agalactiae*, *Staphylococcus aureus*, coagulase negative staphylococci.

3.3 Contraindications

Do not use in cases of hypersensitivity to cephalosporin antibiotics or other β-lactam antibiotics.
Do not use in cows with clinical mastitis (see 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 veterinary medicinal 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.

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.

The efficacy of the veterinary medicinal product is only established against the pathogens mentioned in section 3.2 “Indications for use”. Consequently, serious acute mastitis (potentially fatal) due to other pathogen species, mainly *Pseudomonas aeruginosa*, can occur after the drying off. Good hygienic practices should be thoroughly respected in order to reduce that risk; cows should be housed in a hygienic paddock far from the milking parlour and regularly checked several days after drying off.

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 veterinary medicinal 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 veterinary medicinal product with great care to avoid exposure. Personal protective equipment consisting of impervious gloves should be worn when handling the veterinary medicinal product. Wash exposed skin after use.

If you develop symptoms following exposure, such as skin rash, you should seek medical advice 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 veterinary medicinal product should avoid handling the product (and other cephalosporin and penicillin containing products) in future.

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (dry cows):

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

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:

There is no evidence of reproductive toxicity (incl. teratogenicity) in cattle. Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

The veterinary medicinal product is intended for use during pregnancy. In the clinical trials, no adverse effects on the foetus were observed.

Lactation:

Do not use during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

See section 4.2 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.

3.9 Administration routes and dosage

Intramammary use.

Single intramammary administration of 150 mg cefquinome.
The content of one 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. 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 instil the content of one syringe into each quarter. Disperse the product by gentle massage of the teat and udder.

The syringe must only be used once.

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

Not relevant.

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: 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ51DE90.

4.2 Pharmacodynamics

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 *Escherichia coli*, *Citrobacter* spp., *Klebsiella* spp., *Pasteurella* spp., *Proteus* spp., *Salmonella* spp., *Serratia marcescens*, *Arcanobacterium pyogenes*, *Corynebacterium* spp., *Staphylococcus aureus*, *coagulase negative Staphylococci, Streptococcus dysgalactiae, Streptococcus agalactiae, Streptococcus uberis, Streptococcus bovis.*
Following bacterial species: *Staphylococcus aureus*, *coagulase negative Staphylococci*, *Streptococcus uberis*, *Streptococcus dysgalactiae* and *Streptococcus agalactiae* isolated from a field study conducted between 2000 and 2002 in Germany, France, Belgium and the Netherlands proved to be susceptible to cefquinome with MIC values between ≤ 0.008 µg/ml and 2.0 µg/ml.
An overview of the MIC_{90} of each bacterial pathogen is presented in the table below:

Bacterial species isolated	**MIC_{90} (µg/ml)**
Staphylococcus aureus	0.5
coagulase negative Staphylococci	0.5
Streptococcus uberis	0.063
Streptococcus dysgalactiae	≤0.008
Streptococcus agalactiae	0.032

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.

4.3 Pharmacokinetics

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.

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

Pre-filled syringe consisting of:
- barrel made from high density polyethylene (HDPE)
- plunger made from low density polyethylene (LDPE)
- cap made from low density polyethylene (LDPE)

Box of 1 sachet of 4 applicators and 4 cleaning towels. Box of 5 sachets of 4 applicators and 20 cleaning towels. Box of 6 sachets of 4 applicators and 24 cleaning towels. Box of 15 sachets of 4 applicators and 60 cleaning towels. Box of 30 sachets of 4 applicators and 120 cleaning towels.

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 or household waste.

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

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

VPA10988/083/001

8. DATE OF FIRST AUTHORISATION

28/11/2008

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

25/09/2023

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*).