# SUMMARY OF PRODUCT CHARACTERISTICS

## 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

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Intramammary ointment
Homogeneous 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 susceptible organisms: *Streptococcus uberis, Streptococcus dysgalactiae, Streptococcus agalactiae, Staphylococcus aureus,* coagulase negative staphylococci.

### 4.3 Contraindications

Not to be administered to animals which are known to be hypersensitive to cephalosporin antibiotics or other β-lactam antibiotics.
Not to be administered to cows with clinical mastitis and (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.

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 product is only established against the pathogens mentioned in section 4.2 “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 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 and show the Doctor this warning. 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.

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)

In very rare cases hypersensitivity reactions can occur in animals after administration of cephalosporins.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

## 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.

The product is intended for use during pregnancy. In the clinical trials, no adverse effects on the foetus were observed.
Do not use during lactation.

## 4.8 Interaction with other medicinal products and other forms of interaction

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

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.

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

Not relevant.

### 4.11 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

## 5. PHARMACOLOGICAL PROPERTIES

Active ingredient: cefquinome.
Pharmacotherapeutic group:
- cephalosporins and related substances.
- ATCvet code: QJ51DE90.

Substance group: antibacterials for intramammary use.

### 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 *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.

### 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 colloidal hydrophobic,

Liquid paraffin

### 6.2 Major incompatibilities

None known.

### 6.3 Shelf life

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

### 6.4 Special precautions for storage

Do not store above 25 °C.

### 6.5 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

## 8. MARKETING AUTHORISATION NUMBER

Vm 05653/4163

## 9. DATE OF FIRST AUTHORISATION

08 February 2005

## 10. DATE OF REVISION OF THE TEXT

December 2021

Approved 10 December 2021