SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rilexine DC 375 mg intramammary suspension for dry cows

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each 8 g intramammary syringe contains:
Cefalexin 375 mg (equivalent to 500 mg of cefalexin benzathine)

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Intramammary suspension.
White to yellowish oily suspension.

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 dry-off and prevention of new intramammary infections occurring during the dry period, caused by *Staphylococcus aureus, Streptococcus dysgalactiae* and *Streptococcus uberis* .

4.3 Contraindications

Do not use in animals with known hypersensitivity to cephalosporins, other ß-lactam antibiotics or to any of the excipients.

4.4 Special warnings for each target species

Cross resistance occurs with other β-lactams.

4.5 Special precautions for use

Special precautions for use in animals

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target bacteria at farm level, or at local/regional level .
Use of the product should be in accordance with official, national and regional antimicrobial policies.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to cefalexin and may decrease the effectiveness of treatment with other beta lactam antibiotics due to the potential for cross-resistance.

The rules of asepsis must be scrupulously followed during the administration of the product. The efficacy of the product has only been established against the pathogen s mentioned in section 4.2. Consequently, serious acute mastitis (potentially fatal) due to other pathogen species, mainly *Pseudomonas aeruginosa*, can occur after the drying off.
Appropriate veterinary and husbandry measures including good hygienic practices should be taken to reduce that risk. Cows should be housed in a hygienic paddock located apart from the milking parlour. Cows should be regularly checked several days after drying off.
The feeding of waste milk containing residues of cefalexin to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

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-reactions to cephalosporins and vice versa. Allergic reaction to these substances may occasionally be serious.

People with known hypersensitivity to penicillins or cephalosporins, or who have been advised not to work with penicillin or cephalosporin preparations, should avoid contact with the veterinary medicinal product.

Handle this product with great care to avoid exposure. Wear gloves during administration of the product and wash hands after use.

In case of accidental contact with skin or eyes, wash immediately with clean water.

If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Those 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 supplied with the product contain isopropyl alcohol, which may cause skin or eye irritation in some people. The wearing of gloves is recommended during the administration of the product and when handling the cleaning towels.

4.6 Adverse reactions (frequency and seriousness)

Immediate allergic reactions (agitation, trembling, edema of the udders, eyelids and lips), which can lead to death in certain animals, were rarely observed from spontaneous pharmacovigilance reports.

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

Pregnancy:
The product is intended for use during pregnancy. The safety of the veterinary medicinal product has not been established during pregnancy in specific target animal safety studies. However, no adverse effects on the foetus were observed in the clinical trial. Moreover, as the quantities of cephalexin absorbed by the intramammary route are low, the use of this medication during pregnancy does not present any particular problem.

Lactation:
Do not use during lactation of lactating dairy cows.

4.8 Interaction with other medicinal products and other forms of interaction

The safety of concomitant use of the medicinal product and other intramammary products has not been established, simultaneous use is discouraged.

Do not use simultaneously with bacteriostatic antibiotics.

4.9 Amounts to be administered and administration route

For single intramammary use.
375 mg of cefalexin (equivalent to 500 mg of cefalexin benzathine) i.e. the content of one syringe should be infused one into each quarter via the teat canal immediately after the last milking of the lactation.
Milk out thoroughly before starting administration. Before administering the medicinal product, the teats should be thoroughly cleaned and disinfected using the provided cleaning towel, and care should be taken to avoid contamination of the syringe nozzle. Administer the full content of a syringe in each quarter. Massage after administration. After administration it is recommended to immerse the teat in an approved disinfectant bath. Do not milk after treatment.

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

See section 4.6.

4.11 Withdrawal period(s)

Meat and offal: 4 days
Milk:

- 12 hours after calving when dry period is more than 42 days
- 42.5 days after treatment when dry period is 42 days or less

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: other beta-lactam antibacterials for intramammary use, First-generation cephalosporins, cefalexin.
ATC vet code: QJ51DB01

5.1 Pharmacodynamic properties

Cefalexin is an antibacterial belonging to the group of β-lactam antibiotics , and is structurally analogous to and has similar mode of action to penicillins. It belongs to the first generation of cephalosporins.

The β-lactam antibiotics prevent the synthesis of the bacterial cell wall by inhibition of transpeptide and carboxypeptide enzymes, causing an osmotic imbalance that destroys growing bacteria. Cefalexin is active against gram-positive bacteria such as *Staphylococcus aureus* (including betalactamase-producing strains), other staphylococci which do or do not produce penicillinases, and *Streptococcus* spp., including *S. uberis* and *S. dysgalactiae* .

Critical concentrations (cutting points or breakpoints) sensitivity (S) and resistance (R), in µg/ml, for first generation cephalosporins (CLSI, 2013): Susceptible: ≤8, Intermediate:16 and Resistant: ≥ 32. The main mechanisms of resistance against beta-lactams are the production of enzymes (beta-lactamases) that inactivate the drug, the alteration of penicillin-fixing proteins and the alteration of the permeability of the bacterial outer membrane. Cephalosporins are generally not sensitive to the action of beta-lactamases.

There is a cross-resistance (involving the same resistance mechanism) between antibiotics of the beta-lactam group due to structural similarities. It occurs with beta-lactamase enzymes, structural changes in porins, or changes in efflux pumps. Co-resistance (involving different resistance mechanisms) has been described in *E.coli* due to the fact that a plasmid carries various genes encoding resistance.

5.2 Pharmacokinetic particulars

Cefalexin has excellent tissue diffusion and its tissular half-life is considerably longer than its plasma half-life. The elimination of cefalexin occurs mainly (85%)

through the urine in its active form. The urinary concentration peaks are much higher than the plasma concentration peaks.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium stearate
Paraffin, white soft
Paraffin, light liquid

6.2 Major incompatibilities

Not applicable .

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and composition of immediate packaging

Low-density p olyethylene intramammary syringe.

Box of 12 x 8g intramammary syringes and 12 cleaning towels.
Box of 24 x 8g intramammary syringes and 24 cleaning towels.
Box of 60 x 8g intramammary syringes and 60 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 product 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

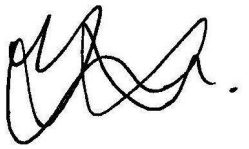
Vm 05653/3000

9. DATE OF FIRST AUTHORISATION

29 June 2022

10. DATE OF REVISION OF THE TEXT

June 2022



Approved: 29 June 2022