SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ceffect LC, 75 mg, intramammary ointment for lactating cows

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each prefilled intramammary syringe of 8 g contains:

Active substance:

Cefquinome 75 mg
(Equivalent to Cefquinome sulfate 88.92 mg)

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Intramammary ointment.
White to slightly yellowish ointment.

4. CLINICAL PARTICULARS

4.1. Target species

Cattle (lactating cows).

4.2. Indications for use, specifying the target species

For the treatment of clinical mastitis in the lactating dairy cow caused by the following cefquinome-susceptible microorganisms: *Streptococcus uberis, Streptococcus dysgalactiae, Staphylococcus aureus* and *Escherichia coli*.

4.3 Contraindications

Do not use in cases of hypersensitivity to cephalosporin antibiotics, other ß-lactam antibiotics or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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 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.
Official, national and regional antimicrobial policies should be taken into account when the product is used.
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.
The feeding to calves of milk containing residues of cefquinome (i.e. milked during treatment) should be avoided due to selection for antimicrobial-resistant bacteria.
Do not use the cleaning towel if lesions are present on the teat.

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

When infusing the product, protective gloves should be worn to avoid skin contact.

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.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure, taking all recommended precautions.
3. 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.
4. Care should be taken to avoid contact with skin.

Wash hands after using the cleaning towels and wear protective gloves if skin irritation due to isopropyl alcohol is known or suspected.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases anaphylactic reactions have been noted in animals after administration of the product.
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 and lactation

The product is intended for use during lactation. There is no available information indicating reproductive toxicity (inc. teratogenicity) in cattle. In reproductive toxicity studies in laboratory animals cefquinome did not reveal any effect on reproduction or teratogenic potential.

4.8 Interaction with other medicinal products and other forms of interaction

It is known that a cross sensitivity to cephalosporin exists for bacteria sensitive to the cephalosporin group.

4.9 Amounts to be administered and administration route

For intramammary use.

The content of one intramammary syringe should be infused gently into the teat of the infected quarter every 12 hours after each of three successive milkings.

Milk out the affected quarter(s). After thoroughly cleaning and disinfecting the teat and teat orifice with the cleaning towel provided remove the cap from the nozzle without touching the nozzle with the fingers.
Gently infuse the contents of one intramammary syringe into each affected quarter. Disperse the product by gentle massage of the teat and udder of the affected animal.

The intramammary syringe must only be used once. Partly used intramammary syringes should be discarded.

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

No symptoms expected or emergency procedures required.

4.11 Withdrawal periods

Meat and offal: 4 days
Milk: 5 days (120 hours).

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for intramammary use, fourth generation cephalosporins.
ATCVet code: QJ51DE90

5.1 Pharmacodynamic properties

Cefquinome is an antibacterial drug of the cephalosporin group which acts by inhibition of cell wall synthesis. It is characterised by its broad therapeutic spectrum of activity and a high stability against beta-lactamases.

In vitro, Cefquinome has antibacterial activity against common Gram negative and Gram positive bacteria including *Escherichia coli, Staphylococcus aureus, Streptococcus dysgalactiae, Streptococcus agalactiae* and *Streptococcus uberis*. The highest MIC_{90} value was found for *Staphylococcus aureus*. This pathogen has a MIC_{90} of ≤ 1 µg/ml. *E.coli* isolates have variable susceptibility.
As a fourth generation cephalosporin, cefquinome combines high cellular penetration and a high beta-lactamases stability. In contrast to cephalosporins of previous generations, cefquinome is not hydrolysed by chromosomally–encoded cephalosporinases of the AmpC type or by plasmid mediated cephalosporinases of some enterobacterial species. Bacteria that produce ESBL and methicillin-resistant Staphylococcus species are resistant. Resistance mechanism in Gram negative organisms due to extended spectrum beta-lactamases (ESBL) and in Gram-positive organisms due to alteration of penicillin binding proteins (PBPs) may lead to cross-resistance with other beta-lactams.

5.2 Pharmacokinetic particulars

After intramammary administration, a mean concentration of 19 µg/ml in milk is observed 12 hours post last infusion.
At the second milking following the last infusion the mean concentration is still approximately 2.5 µg/ml and then falls to 0.75 µg/ml at the third milking post last infusion.

Resorption of cefquinome from the udder is insignificant.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin
Liquid paraffin

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 32 months.
Shelf life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and composition of immediate packaging

White, low-density polyethylene intramammary syringes with a dual push-fit nozzle cap containing 8 grams of ointment.
Cardboard box with 3, 15, 20 or 24 intrarmammary syringes and respectively 3, 15, 20 or 24 cleaning towels individually packed in a laminate sachet with copolymer inner layer. The paper cleaning towels contain 70% isopropanol.

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

Emdoka bvba
John Lijsenstraat 16
B-2321 Hoogstraten
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 34534/4006

9. DATE OF FIRST AUTHORISATION

08 May 2014

10. DATE OF REVISION OF THE TEXT

July 2019

Approved: 15 July 2019

D. Austin