# ANNEX III

# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**
**Cardboard box with 3, 15, 20 or 24 intramammary syringes and cleaning towels**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEFFECT LC, 75 mg, intramammary ointment for lactating cows (BE, BG, CZ, HU, IE, IT, LU, NL, PL, PT, RO, SI, SK, UK)
CEFAXXESS LC, 75 mg, intramammary ointment for lactating cows (AT, DE, FR)
CEFFECT Lactación 75 mg, pomada intramamaria (ES)
Cefquinome

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each prefilled intramammary syringe of 8 g contains:
Cefquinome (as sulfate) 75 mg

## 3. PHARMACEUTICAL FORM

Intramammary ointment

## 4. PACKAGE SIZE

3 intramammary syringes + 3 cleaning towels
15 intramammary syringes + 15 cleaning towels
20 intramammary syringes + 20 cleaning towels
24 intramammary syringes + 24 cleaning towels

## 5. TARGET SPECIES

Cattle (lactating cows)

## 6. INDICATIONS

Read the package leaflet before use.

## 7. METHOD AND ROUTE OF ADMINISTRATION

Intramammary use
Read the package leaflet before use.

The teat should be cleaned with a cleaning towel.
Do not touch the nozzle of the intramammary syringe with the fingers. Infuse the ointment gently.

## 8. WITHDRAWAL PERIODS

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

## 9. SPECIAL WARNINGS, IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions.
Read the package leaflet before use for full user warnings.

## 10. EXPIRY DATE

EXP *{month/year}*
Use immediately. Partly used intramammary syringes should be discarded.

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

## 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Emdoka bvba
John Lijsentraat 16
B-2321 Hoogstraten
Belgium

## 16. MARKETING AUTHORISATION NUMBER

Vm 34534/4006

## 17. MANUFACTURER'S BATCH NUMBER

<Batch> *{number}*

*[Optional:*
- *logo(s), name(s), address(es) and contact information of the Distributor(s) of the VMP in a Member State*
- *barcode, national code*
- *pictogram of target species]*
-

**MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING UNITS**
**Intramammary syringe containing 8 g of ointment**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEFFECT LC, 75 mg, intramammary ointment for lactating cows (BE, BG, CZ , HU, IE, IT, LU, NL, PL, PT, RO, SI, SK, UK)
CEFAXXESS LC, 75 mg, intramammary ointment for lactating cows (AT, DE, FR)
CEFFECT Lactación 75 mg, pomada intramamaria (ES)
Cefquinome

## 2. QUANTITY OF THE ACTIVE SUBSTANCE

Cefquinome (as sulfate) 75 mg

## 3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

intramammary syringe with 8 g of ointment.

## 4.. ROUTE OF ADMINISTRATION

Intramammary use.

## 5. WITHDRAWAL PERIODS

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

## 6. BATCH NUMBER

<Batch> *{number}*

## 7. EXPIRY DATE

EXP *{month/year}*

## 8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

# B. PACKAGE LEAFLET

**PACKAGE LEAFLET:**
**Ceffect LC, 75 mg,**
*intramammary ointment for lactating cows*

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT:

Marketing authorisation holder:
Emdoka bvba
John Lijsentraat 16
B-2321 Hoogstraten
Belgium

Manufacturer responsible for batch release:
Wirtschaftsgenossenschaft deutscher Tierärzte eG (WDT)
D-30827 Garbsen
Germany

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT:

CEFFECT LC, 75 mg, intramammary ointment for lactating cows (BE, BG, CZ, HU, IE, IT, LU, NL, PL, PT, RO, SI, SK, UK)
CEFAXXESS LC, 75 mg, intramammary ointment for lactating cows (AT, DE, FR)
CEFFECT Lactación 75 mg, pomada intramamaria (ES)
Cefquinome

## 3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS:

Each prefilled intramammary syringe of 8 g contains 75 mg of cefquinome (as sulfate).
White to slightly yellowish ointment.

## 4. INDICATIONS:

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*.

## 5. CONTRAINDICATIONS:

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

## 6. ADVERSE REACTIONS:

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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

## 7. TARGET SPECIES:

Cattle (lactating cows).

## 8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION:

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.

## 9. ADVICE ON CORRECT ADMINISTRATION:

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

## 10. WITHDRAWAL PERIODS:

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

## 11. SPECIAL STORAGE PRECAUTIONS:

Keep out of the sight and reach of children.
Do not store above 30°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after “EXP”. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: use immediately.

## 12. SPECIAL WARNINGS:

**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.

**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.

**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.

**Overdose (symptoms, emergency procedures, antidotes):**
No symptoms expected or emergency procedures required.

**Incompatibilities:** None known.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY:

Medicines should not be disposed of via wastewater or household waste. Any unused veterinary medicinal product or waste materials derived from such veterinary

medicinal product should be disposed of in accordance with local requirements. These measures should help to protect the environment.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED:

## 15. OTHER INFORMATION:

**Pack sizes**:
Cardboard box with 3, 15, 20 or 24 intramammary syringes.
Cleaning towels are added to the cartons.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
*[optional: name, address, contact information (tel., e-mail address) and logo of the local (national) representative].*

*[To be completed in accordance with national requirements]*

Approved: 15 July 2019