ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Pack of 3 syringes and 3 cleaning towels
Pack of 15 syringes and 15 cleaning towels
Pack of 20 syringes and 20 cleaning towels
Pack of 24 syringes and 24 cleaning towels
Pack of 60 syringes and 60 cleaning towels

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Plenix LC 75 mg, intramammary ointment for lactating cows

Cefquinome (as sulfate)

2. STATEMENT OF ACTIVE SUBSTANCES

1 syringe of 8 g contains 75 mg of cefquinome (as sulfate)

3. PHARMACEUTICAL FORM

Intramammary ointment

4. PACKAGE SIZE

3 syringes + 3 cleaning towels
15 syringes + 15 cleaning towels
20 syringes + 20 cleaning towels
24 syringes + 24 cleaning towels
60 syringes + 60 cleaning towels

5. TARGET SPECIES

Cattle (lactating cows)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramammary use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

User Warnings: Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet for full user warnings.

10. EXPIRY DATE

EXP:
Once opened, use immediately. Partly emptied syringes due to the unsuccessful use 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

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/4129

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Syringe of 8 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Plenix LC 75 mg, intramammary ointment for lactating cows

Cefquinome (as sulfate)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 syringe of 8 g contains 75 mg of cefquinome (as sulfate)

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

8 g

4. ROUTE(S) OF ADMINISTRATION

Intramammary use

5. WITHDRAWAL PERIOD(S)

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

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Plenix 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:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:
Lohmann Pharma Herstellung GmbH
Heinz-Lohmann-Strasse 5
Cuxhaven – Niedersachsen- 27472
Germany

Ceva Santé Animale
10, avenue de La Ballastière
33500 Libourne
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Plenix LC 75 mg, intramammary ointment for lactating cows

Cefquinome (as sulfate)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each prefilled syringe of 8 g contains 75 mg of cefquinome (as sulfate).
White to slightly yellow, oily, viscous homogeneous ointment.

4. INDICATION(S)

Lactating cows: For the treatment of clinical mastitis caused by the following cefquinome-sensitive microorganisms: *Streptococcus uberis, Streptococcus dysgalactiae, Staphylococcus aureus* and *Escherichia coli*.

5. CONTRAINDICATIONS

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

Do not use the cleaning towel if lesions are present on the teat.

6. ADVERSE REACTIONS

In very rare cases (less than 1 animal in 10,000 animals treated, including isolated reports) anaphylactic reactions have been noted in animals after administration of cefquinome containing intramammary products.

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(S) AND METHOD OF ADMINISTRATION

For intramammary administration.
The syringe must only be used once. Partly emptied syringes due to the unsuccessful use should be discarded.
The content of one syringe should be infused gently into the teat of the infected quarter every 12 hours after each of three successive milkings.

9. ADVICE ON CORRECT ADMINISTRATION

Milk out the affected quarter(s). After thoroughly cleaning and disinfecting the teat and teat orifice with the cleaning towel provided, gently infuse the contents of one syringe into each affected quarter. Disperse the product by gentle massage of the teat and udder of the affected animal.

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 carton and syringe after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species
None.

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 section "*Special precautions to be taken by the person administering the veterinary medicinal product to animals*" 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.

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.
Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
Handle this product with great care to avoid exposure, taking all recommended precautions.
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.
The cleaning towels provided with this product contain isopropyl alcohol, which may cause skin irritation in some people. It is recommended to wear protective gloves when using the towels.

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 cephalosporins 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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

Packsize:
Pack of 3 syringes and 3 cleaning towels
Pack of 15 syringes and 15 cleaning towels
Pack of 20 syringes and 20 cleaning towels
Pack of 24 syringes and 24 cleaning towels
Pack of 60 syringes and 60 cleaning towels
Cleaning towel (30% viscose / 70% polyester, alcohol impregnated) in a paper aluminium copolymer laminate sachet.
Not all pack sizes may be marketed.

Approved 14 October 2022