

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Syringe Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefimam LC, 75 mg Intramammary Ointment for Lactating Cows
Cefquinome (as Sulfate)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Cefquinome (as sulfate): 75 mg

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

8g

4. ROUTE(S) OF ADMINISTRATION

Single intramammary administration.

5. WITHDRAWAL PERIOD

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

6. BATCH NUMBER

BN

7. EXPIRY DATE

<EXP {day/month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefimam LC, 75 mg Intramammary Ointment for Lactating Cows
Cefquinome (as Sulfate)

2. STATEMENT OF ACTIVE SUBSTANCES

Each pre-filled syringe of 8 g contains:

Active substance:

Cefquinome (as sulfate) 75 mg

3. PHARMACEUTICAL FORM

Intramammary ointment

4. PACKAGE SIZE

12 x 8g syringe
24 x 8g syringe
36 x 8g syringe

5. TARGET SPECIES

Cattle (Lactating cow)

6. INDICATION(S)

For the treatment of clinical mastitis in the lactating cow caused by bacteria susceptible to cefquinome, namely *Staphylococcus aureus*, *Streptococcus uberis*, *Streptococcus dysgalactiae*, *Escherichia coli*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Single intramammary administration.
The syringe must only be used once.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

<EXP {day/month/year}>

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

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
County Down
BT35 6JP
Northern Ireland

Tel. + 44 (0)28 30264435
Fax. + 44(0)28 30265060
e-mail enquiries@norbrook.co.uk

Distributed by:

Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4387

17. MANUFACTURER'S BATCH NUMBER

BN

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Cefquinome Norbrook LC, 75 mg Intramammary Ointment for Lactating Cows [IE]

Cefimam LC, 75 mg Intramammary Ointment for Lactating Cows [UK AT, BE, IT, PT]

Cefimam lactación, 75 mg Intramammary Ointment for Lactating Cows [ES]

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

Marketing Authorisation Holder: and

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

Manufacturer Responsible for Batch Release:

Norbrook Manufacturing Limited
Rossmore Industrial Estate,
Monaghan,
Ireland

Norbrook Laboratories Ltd,
Station Works,
Newry,
BT35 6JP
Co. Down,
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefimam LC, 75 mg Intramammary Ointment for Lactating Cows
Cefquinome (as Sulfate)

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

Each pre-filled syringe of 8 g contains:

Active substance:

Cefquinome 75 mg
(as cefquinome sulfate)

A homogeneous off-white oily ointment

4. INDICATION(S)

For the treatment of clinical mastitis in the lactating cow caused by bacteria susceptible to cefquinome, namely *Staphylococcus aureus*, *Streptococcus uberis*, *Streptococcus dysgalactiae*, *Escherichia coli*.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (Lactating cow)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

For intramammary administration. The syringe must only be used once.

Partly used syringes should be discarded.

Milk out the affected quarter(s). After thoroughly cleaning and disinfecting the teat and teat orifice, 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 PERIOD

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}.

12. SPECIAL WARNING(S)

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.

Do not use the cleaning towel on teats with lesions.

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

When infusing the product, protective gloves should always be worn in order 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.

The cleaning towels provided with the intramammary product contain isopropyl alcohol. 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.

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.

Overdose:

No symptoms expected or emergency procedures required.

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.

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 products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

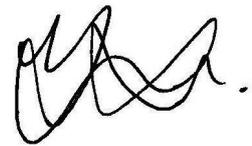
15. OTHER INFORMATION

Pre-filled 8 g Intramammary syringe consisting of white opaque low density polyethylene (LDPE) barrel with white opaque LDPE plunger and white opaque LDPE end-cap.

Cartons of 12, 24 and 36 syringes including 12, 24 and 36 individually wrapped teat cleaning towels.

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.

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 17 August 2020