ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton / Bucket}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefimam DC, 150 mg Intramammary Ointment for Dry Cows
Cefquinome (as Cefquinome Sulfate)

2. STATEMENT OF ACTIVE SUBSTANCES

Each 3 g intramammary syringe contains:
Active substance:
Cefquinome: 150 mg
(as Cefquinome sulfate)

3. PHARMACEUTICAL FORM

Intramammary ointment

4. PACKAGE SIZE

20 x 3 g syringes
24 x 3 g syringes
60 x 3 g syringes
120 x 3 g syringes

5. TARGET SPECIES

Cattle (dry cows)

6. INDICATION(S)

For the treatment of subclinical mastitis at drying off and the prevention of new bacterial infections of the udder during the dry period in the dairy cow caused by the following cefquinome sensitive organisms: *Streptococcus uberis, Streptococcus dysgalactiae, Streptococcus agalactiae, Staphylococcus aureus,* coagulase negative staphylococci.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramammary use
Single intramammary administration.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Meat and offal: 2 days
Milk: 1 day after calving when dry period is more than 5 weeks
36 days after treatment when dry period is 5 weeks or less

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {day/month/year}

11. SPECIAL STORAGE CONDITIONS

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
Co. Down
BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4393

17. MANUFACTURER'S BATCH NUMBER

<Batch>{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefimam DC, 150 mg Intramammary Ointment for Dry Cows
Cefquinome (as Cefquinome Sulfate)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 3 g intramammary syringe contains:
Active substance:
Cefquinome: 150 mg
(as Cefquinome sulfate)

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

Sachet of 4 intramammary syringes

4. ROUTE(S) OF ADMINISTRATION

Intramammary use
Single intramammary administration.

5. WITHDRAWAL PERIOD

Withdrawal periods:
Meat and offal: 2 days
Milk: 1 day after calving when dry period is more than 5 weeks
36 days after treatment when dry period is 5 weeks or less

6. BATCH NUMBER

<Batch>{number}

7. EXPIRY DATE

EXP {day/month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefimam DC, 150 mg Intramammary Ointment for Dry Cows
Cefquinome (as Cefquinome Sulfate)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Cefquinome: 150 mg
(as Cefquinome sulfate)

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

3 g

4. ROUTE(S) OF ADMINISTRATION

Intramammary use
Single intramammary administration.

5. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Meat and offal: 2 days
Milk: 1 day after calving when dry period is more than 5 weeks
36 days after treatment when dry period is 5 weeks or less

6. BATCH NUMBER

<Batch>{number}

7. EXPIRY DATE

EXP {day/month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Cefimam DC, 150 mg Intramammary Ointment for Dry 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:
EU: Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

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

Manufacturer Responsible for Batch Release:
Norbrook Laboratories Limited,
Newry,
County Down,
Northern Ireland
BT35 6JP

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefimam DC, 150 mg Intramammary Ointment for Dry Cows.
Cefquinome (as Cefquinome sulfate)

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

Each 3 g intramammary syringe contains:
Active substance:
Cefquinome: 150 mg
(as cefquinome sulfate)

An off-white oily ointment.

4. INDICATION(S)

For the treatment of subclinical mastitis at drying off and the prevention of new bacterial infections of the udder during the dry period in the dairy cow caused by the following cefquinome sensitive organisms: *Streptococcus uberis, Streptococcus dysgalactiae, Streptococcus agalactiae, Staphylococcus aureus,* coagulase negative staphylococci.

5. CONTRAINDICATIONS

Do not use in cows with clinical mastitis.
Do not use in cases of known hypersensitivity to cephalosporin antibiotics or other β-lactam antibiotics, or to any of the excipients.
Please refer to the “Special Warnings” section of this leaflet for information on pregnancy and lactation.

6. ADVERSE REACTIONS

None known.

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 (dry cows)

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

Intramammary use
Single intramammary administration.
150 mg cefquinome, i.e. the content of one intramammary syringe should be instilled gently into the teat of each quarter, immediately after the last milking.

9. ADVICE ON CORRECT ADMINISTRATION

Before instillation, the udder should be milked out completely and the teat and its orifice should be thoroughly cleaned and disinfected with the cleaning towel provided.
Care should be taken to avoid contamination of the injector nozzle.
Gently insert either about 5mm or the total length of the nozzle and instill the content of one intramammary syringe into each quarter. Disperse the product by gentle massage of the teat and udder.
The intramammary syringe must only be used once.

10. WITHDRAWAL PERIOD

Meat and offal: 2 days
Milk: 1 day after calving when dry period is more than 5 weeks
36 days after treatment when dry period is 5 weeks or less

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.

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 warnings for each target species:
None.

Special precautions for use in animals:
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. 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 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 towels on teats with lesions.
In case of erroneous use during lactation the milk should be discarded for 35 days.

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 sensitivity to cephalosporin and vice versa. Allergic reactions to these substances may occasionally be serious.
Do not handle this product is you know you are sensitised to penicillins or cephalosporins, or if you have been advised not to work with such preparations.
Handle this product with great care to avoid exposure. Use impervious gloves when handling and administering the product. Wash exposed skin after use.
If you develop symptoms following exposure, such as a skin rash, you should seek medical advice
immediately and show the package leaflet or the label to the physician.
Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention. Persons 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 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:
There is no evidence of reproductive toxicity (incl. teratogenicity) in cattle.
Laboratory studies in rats and rabbits have not shown any teratogenic, foetotoxic or maternotoxic effects.
Can be used during pregnancy.

Lactation:
Do not use during lactation.

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

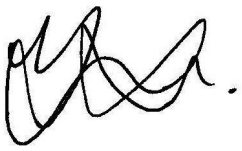
13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

15. OTHER INFORMATION

4.5 ml intramammary syringe consisting of white opaque high density polyethylene (HDPE) barrel with white opaque low density polyethylene (LDPE) plunger and white opaque (LDPE) dual end cap.
Cartons of 20, 24 and 60 syringes or containers of 120 intramammary syringes (in aluminium foil sachets containing 4 syringes) including 20, 24, 60 or 120 individually wrapped teat cleaning towels.
Not all pack sizes may be marketed.



Approved: 06 September 2019