ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton / Bucket}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cepritect 250 mg Intramammary Suspension for Dry Cows
Cefalonium

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Cefalonium (as Cefalonium Dihydrate) 250 mg/syringe

3. PHARMACEUTICAL FORM

Intramammary Suspension

4. PACKAGE SIZE

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

5. TARGET SPECIES

Dairy cattle (dry cow)

6. INDICATION(S)

To be included on product carton where permissible and when font size considerations permit
For the treatment of subclinical mastitis at drying-off and the prevention of new bacterial infections of the udder during the non-lactating period of cows caused by *Staphylococcus aureus, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus uberis, Trueperella pyogenes, Escherichia coli* and *Klebsiella spp*. susceptible to cefalonium.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

Withdrawal Period:
Meat and offal: 21 days

Milk: 96 hours after calving if the dry period is longer than 54 days
58 days following treatment if the dry period is less than or equal to 54 days or less.

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP dd/mm/yyyy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25^{o}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.

UK Only

POM-V

To be supplied only on veterinary prescription.

Vm: 02000/4423

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4423

17. MANUFACTURER'S BATCH NUMBER

BN

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Syringe}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cepritect 250 mg Intramammary Suspension for Dry Cows
Cefalonium

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Cefalonium 250 mg/syringe

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

3g

4. ROUTE(S) OF ADMINISTRATION

Single intramammary administration.

5. WITHDRAWAL PERIOD

Withdrawal Period:
Meat and offal: 21 days

Milk: 96 hours after calving if the dry period is longer than 54 days
58 days following treatment if the dry period is less than or equal to 54 days or less.

6. BATCH NUMBER

<Batch><Lot> {number}

7. EXPIRY DATE

EXP dd/mm/yyyy

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

ANNEX II

PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Cepritect 250 mg Intramammary Suspension 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 and manufacturer responsible for batch release:
Norbrook Laboratories Limited,
Station Works
Newry,
County Down, BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cepritect 250 mg Intramammary Suspension for Dry Cows
Cefalonium (as Cefalonium Dihydrate)

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

Each 3 g pre-filled syringe contains:

Active substance:
Cefalonium (as Cefalonium Dihydrate) 250 mg

Homogeneous white to beige coloured suspension.

4. INDICATION(S)

For the treatment of subclinical mastitis at drying-off and the prevention of new bacterial infections of the udder during the non-lactating period of cows caused by *Staphylococcus aureus, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus uberis, Trueperella pyogenes, Escherichia coli* and *Klebsiella spp.* susceptible to cefalonium.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to cephalosporins, other ß-lactam antibiotics or to any of the excipients.

6. ADVERSE REACTIONS

In very rare cases immediate hypersensitivity reactions were observed in some animals (restlessness, tremors, swelling of mammary gland, eyelids and lips). These reactions can lead to death.

The frequency of adverse reactions is defined using the following convention:

-very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, 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.

Alternatively you can report via your national reporting system.

7. TARGET SPECIES

Dairy cattle (dry cow).

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

For intramammary infusion.

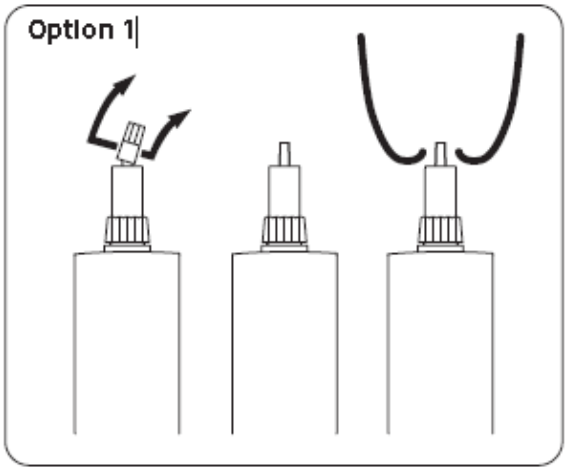
Single intramammary administration.
250 mg Cefalonium, i.e. the contents of one syringe should be infused into the teat canal of each quarter immediately after the last milking of the lactation.

9. ADVICE ON CORRECT ADMINISTRATION

The contents of one syringe should be infused into the teat canal of each quarter immediately after the last milking of the lactation. Avoid contamination of the nozzle after removing the cap. Before infusion, thoroughly clean and disinfect the end of the teat with the cleaning towel provided.

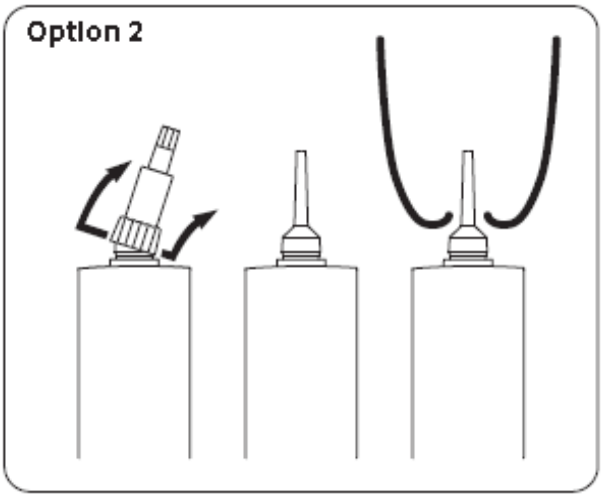
Option 1: For short nozzle intramammary administration hold the barrel of the syringe and the base of the cap in one hand and twist off the small upper part of the cap above the indent mark (the base portion of the cap remains on the syringe). Take care not to contaminate the short exposed part of the nozzle.

Option1: For short nozzle intramammary administration.



Option 2: For full nozzle intramammary administration remove the cap fully by holding the barrel of the syringe firmly in one hand and with the thumb push up and along the length of the cap until the cap clicks off. Take care not to contaminate the nozzle.

Option2: For full nozzle intramammary administration



Insert the nozzle into the teat canal and apply steady pressure on the syringe plunger until the full dose has been delivered. Holding the end of the teat with one hand, gently massage upwards with the other to aid dispersion of the antibiotic into the quarter.
After infusion it is advisable to dip the teats in an antiseptic preparation specifically designed for this purpose.

10. WITHDRAWAL PERIOD

Withdrawal Period:
Meat and offal: 21 days

Milk: 96 hours after calving if the dry period is longer than 54 days
58 days following treatment if the dry period is less than or equal to 54 days or less.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25^{o}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
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Use of the product deviating from the instructions given in this package leaflet may increase the prevalence of bacteria resistant to cefalonium and may decrease the effectiveness of treatment with other beta lactams.

The efficacy of the product is only established against the pathogens mentioned in the indications section of this package leaflet. Consequently, serious acute mastitis (potentially fatal) due to other pathogen species, particularly *Pseudomonas aeruginosa*, can occur after drying off. Good hygienic practices should be thoroughly respected in order to reduce this risk.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after use.
Penicillin and cephalosporins may cause sensitisation (allergy) following injection, inhalation, ingestion or skin contact. Sensitivity to penicillin 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 a skin rash you should seek medical advice and show the doctor this warning. Swellings of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.
The cleaning towels provided with the intramammary product contain isopropyl alcohol. 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:
Intended for use during the last trimester of pregnancy once the lactating cow has been dried off. There is no adverse treatment effect on the foetus.

Lactation:
Not to be used in cows that are lactating

Interaction with other medicinal products and other forms of interaction:
Cephalosporins should not be administered concurrently with bacteriostatic antimicrobials. Concomitant use of cephalosporins and nephrotoxic drugs may increase renal toxicity.

Overdose (symptoms, emergency procedures, antidotes):
Repeated doses in cattle on three consecutive days did not demonstrate or produce any adverse effects.

Incompatibilities:
There are no known incompatibilities

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

July 2019

15. OTHER INFORMATION

DISTRIBUTED BY:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

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

Not all pack sizes may be marketed.

Approved 28 October 2022