LABELLING

N.B.: The label sachet of 4 syringes has been reduced because of the lack of space. All the deleted mentions of the label sachet appears ever on the carton box.
All the mentions which must appear on the immediate package units have been kept and also the following supplementary mentions:

- package size
- target species
- the words “keep out of the sight and reach of children”
- name of the marketing holder
- marketing authorisation number

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
(Carton box of X* sachet(s) of 4 syringes and 4xX cleaning towels)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cephaguard DC 150 mg intramammary ointment

Cefquinome sulphate

2. STATEMENT OF THE ACTIVE SUBSTANCE

Each 3 g pre-filled syringe of Cephaguard DC 150 mg contains:

Active substance

Cefquinome (as sulphate): 150.0 mg

3. PHARMACEUTICAL FORM

Intramammary ointment
Homogenous off-white oily ointment

4. PACKAGE SIZE

Box of 1 sachet with 4 applicators and 4 cleaning towels.
Box of 5 sachets with 4 applicators and 20 cleaning towels
Box of 6 sachets with 4 applicators and 24 cleaning towels.
Box of 15 sachets with 4 applicators and 60 cleaning towels.
Box of 30 sachets with 4 applicators and 120 cleaning towels.

Not all pack sizes may be marketed.

5. TARGET SPECIES

Cattle (dry cows)

6. INDICATIONS

* X=1 or 5 or 15

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

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

8. 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

9. SPECIAL WARNING(S)

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}.
Do not use after the date shown after EXP on the sachet, syringe or box.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER

Vm 05653/5047

17. MANUFACTURER’S BATCH NUMBER

<Batch> <Lot> <BN> {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

(Sachet / Label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cephaguard DC 150 mg intramammary ointment

Cefquinome sulphate

2. STATEMENT OF THE ACTIVE SUBSTANCE

Each 3 g pre-filled syringe of Cephaguard DC 150 mg contains:

Active substance

Cefquinome (as sulphate): 150.0 mg

3. PHARMACEUTICAL FORM

Intramammary ointment
Homogenous off-white oily ointment

4. PACKAGE SIZE

Sachet of 4 syringes

4. TARGET SPECIES

Cattle (dry cows)

6. INDICATIONS

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

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

8. 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

9. SPECIAL WARNING(S)

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}.
Do not use after the date shown after EXP on the sachet, syringe or box.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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.

15. 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

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER

Vm 05653/5047

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
(3 g pre-filled syringe)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cephaguard DC 150mg intramammary ointment

2. QUANTITY OF THE ACTIVE SUBSTANCE

Cefquinome (as sulphate): 150.0 mg

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

Each 3 g pre-filled syringe contains 150 mg cefquinome (as sulphate).

4. TARGET SPECIES

Cattle (dry cows)

5. ROUTE(S) OF ADMINISTRATION

Intramammary administration

6. 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

7. BATCH NUMBER

<Batch> <Lot> <BN> {number}

8. EXPIRY DATE

<EXP {month/year}>

9. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Cephaguard DC 150 mg intramammary ointment for dry cow

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

Marketing authorisation holder:
VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Manufacturer responsible for batch release
VIRBAC
1ère avenue 2065m LID
06516 Carros
France

HAUPT PHARMA LATINA
S.S.156 dei Monti Lepini - Km. 47,600
04010 Borgo San Michele - Latina
Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cephaguard DC 150 mg intramammary ointment

Cefquinome sulphate

3. STATEMENT OF THE ACTIVE SUBSTANCE(S)

Each 3 g pre-filled syringe contains:

Active substance
Cefquinome (as sulphate): 150.0 mg

Intramammary ointment
Homogeneous 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 susceptible organisms: *Streptococcus uberis, Streptococcus dysgalactiae, Streptococcus agalactiae, Staphylococcus aureus,* coagulase negative staphylococci.

5. CONTRAINDICATIONS

Not to be administered to animals which are known to be hypersensitive to cephalosporin antibiotics or other β-lactam antibiotics.
Not to be administered to cows with clinical mastitis.

6. ADVERSE REACTIONS

In very rare cases hypersensitivity reactions can occur in animals after administration of cephalosporins.

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.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle (dry cows)

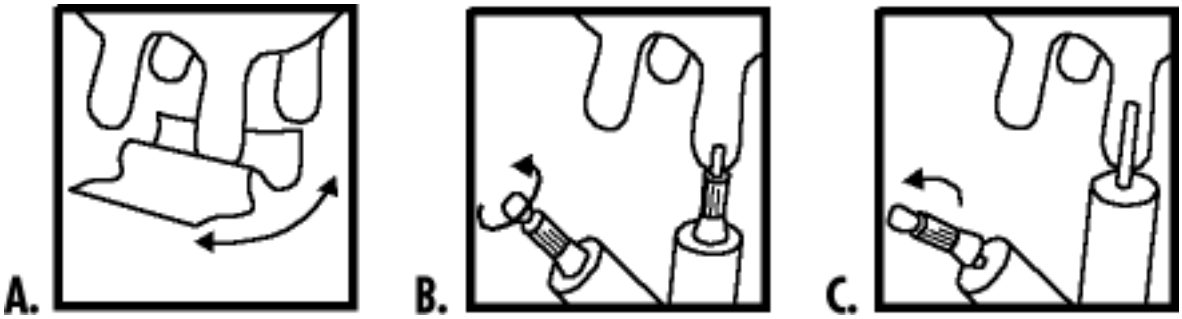
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Single intramammary administration of 150 mg cefquinome.
The content of one 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. 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 instil the content of one syringe into each quarter. Disperse the product by gentle massage of the teat and udder.

The syringe must only be used once.



A. Clean teat with enclosed cleaning towel
B. For partial insertion, break top of cap as shown
C. For full insertion, remove whole cap

Do not touch the tip with your fingers. Infuse the ointment carefully

10. WITHDRAWAL PERIOD(S)

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.

Do not store above 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label 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:

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.
Do not use the cleaning towel on teats with lesions.
In case of erroneous use during lactation the milk should be discarded for 35 days.

The efficacy of the product is only established against the pathogens mentioned in the section “Indications”. Consequently, serious acute mastitis (potentially fatal) due to other pathogen species, mainly *Pseudomonas aeruginosa*, can occur after the drying off. Good hygienic practices should be thoroughly respected in order to reduce that risk; cows should be housed in a hygienic paddock far from the milking parlour and regularly checked several days after drying off.

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 if 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 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. Persons developing a reaction after contact with the product should avoid handling the product (and other cephalosporin and penicillin containing products) in future.

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, lactation or lay:

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.
The product is intended for use during pregnancy. In the clinical trials, no adverse effects on the foetus were observed.
Do not use during lactation.

Interaction with other medicinal products and other forms of interaction:

The neutralizing effect of bacteriostatic acting pharmaceuticals (macrolides, sulfonamides and tetracyclines) on bactericidal effect of cefquinome has not been evaluated yet. Therefore there is no information about the safety and efficacy of this kind of association.

Overdose (symptoms, emergency procedures, antidotes):

Not relevant.

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

November 2023

15. OTHER INFORMATION

Box of 1 sachet with 4 applicators and 4 cleaning towels.
Box of 5 sachets with 4 applicators and 20 cleaning towels
Box of 6 sachets with 4 applicators and 24 cleaning towels.
Box of 15 sachets with 4 applicators and 60 cleaning towels.
Box of 30 sachets with 4 applicators and 120 cleaning towels.

Not all pack sizes may be marketed.

Approved 02 November 2023