A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbactan 150 mg intramammary ointment (AT BE CY CZ DE EE EL ES FR IT LT LU LV NL PL PT SI SK)
Cephaguard DC 150 mg intramammary ointment (UK/NI IE)

2. STATEMENT OF ACTIVE SUBSTANCES

Each 3 g pre-filled syringe contains:
Cefquinome (as sulphate): 150.0 mg

3. 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.

3. TARGET SPECIES

Cattle (dry cows).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramammary administration.

7. 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

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Sachet / Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbactan 150 mg intramammary ointment (AT BE CY CZ DE EE EL ES FR IT LT LU LV NL PL PT SI SK)
Cephaguard DC 150 mg intramammary ointment (UK NI IE)

2. STATEMENT OF ACTIVE SUBSTANCES

Each 3 g pre-filled syringe contains:
Cefquinome (as sulphate): 150.0 mg

3. TARGET SPECIES

Cattle (dry cows).

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

Intramammary administration.

5. 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. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

3 g pre-filled syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbactan (AT BE CY CZ DE EE EL ES FR IT LT LU LV NL PL PT SI SK)
Cephaguard DC (UK/NI IE)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

150.0 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp.{ mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Virbactan 150 mg intramammary ointment (AT BE CY CZ DE EE EL ES FR IT LT LU LV NL PL PT SI SK)
Cephaguard DC 150 mg intramammary ointment (UK/NI IE)

2. Composition

Each 3 g pre-filled syringe contains:

Active substance
Cefquinome (as sulphate): 150.0 mg

Homogeneous off-white oily intramammary ointment.

3. Target species

Cattle (dry cows).

4. Indications for use

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

Do not use in cases of hypersensitivity to cephalosporin antibiotics or other β-lactam antibiotics.
Do not use in cows with clinical mastitis.

6. Special warnings

Special precautions for safe use in the target species:

Use of the veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product with great care to avoid exposure. Personal protective equipment consisting of impervious gloves should be worn when handling the veterinary medicinal product. Wash exposed skin after use.

If you develop symptoms following exposure, such as skin rash, you should seek medical advice 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 veterinary medicinal 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 and lactation:

There is no evidence of reproductive toxicity (incl. teratogenicity) in cattle. Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.
The veterinary medicinal 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:

Not relevant.

Major incompatibilities:

None known.

7. Adverse events

Cattle (dry cows):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Hypersensitivity reaction

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian . You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

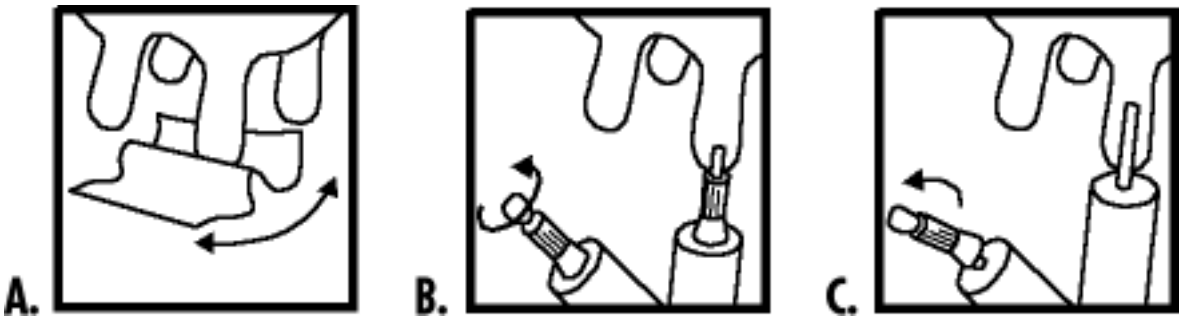
Intramammary use.

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.

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 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

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 precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

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.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

VIRBAC
1ère avenue 2065m LID

06516 Carros
France

Manufacturer responsible for batch release:

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

OR

HAUPT PHARMA LATINA
S.S.156 dei Monti Lepini - Km. 47,600
04100 Borgo San Michele - Latina
Italy

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.