ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

INTRAMAMMARY SYRINGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rilexine DC 375 mg intramammary suspension for dry cows

cefalexin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 8 g intramammary syringe contains:
Cefalexin 375 mg (equivalent to 500 mg of cefalexin benzathine)

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

8g

4. ROUTE(S) OF ADMINISTRATION

Intramammary use

5. WITHDRAWAL PERIOD(S)

Meat and offal: 4 days
Milk:

- 12 hours after calving when dry period is more than 42 days
- 42.5 days after treatment when dry period is 42 days or less

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX OF 12; 24; 60 INTRAMAMMARY SYRINGES AND CLEANING TOWELS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rilexine DC 375 mg intramammary suspension for dry cows

cefalexin

2. STATEMENT OF ACTIVE SUBSTANCES

Each 8 g intramammary syringe contains:
Cefalexin 375 mg (equivalent to 500 mg of cefalexin benzathine)

3. PHARMACEUTICAL FORM

Intramammary suspension

4. PACKAGE SIZE

8g

12 intramammary syringes and 12 cleaning towels
24 intramammary syringes and 24 cleaning towels
60 intramammary syringes and 60 cleaning towels

5. TARGET SPECIES

Cattle (dry cows)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For single intramammary use

Milk out thoroughly before starting administration. Before administering the medicinal product, the teats should be thoroughly cleaned and disinfected using the provided cleaning towel, and care should be taken to avoid contamination of the syringe

nozzle. Administer the full content of a syringe in each quarter. Massage after administration. After administration it is recommended to immerse the teat in an approved disinfectant bath. Do not milk after treatment.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Meat and offal: 4 days
Milk:

- 12 hours after calving when dry period is more than 42 days
- 42.5 days after treatment when dry period is 42 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 {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

12. SPECIFIC 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

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/3000

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Rilexine DC 375 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:

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.R.L.
Strada Statale 156 Dei Monti Lepini Km 47,600
04100 Latina
ITALY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rilexine DC 375 mg intramammary suspension for dry cows

cefalexin

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

Each 8 g intramammary syringe contains:
Cefalexin 375 mg (equivalent to 500 mg of cefalexin benzathine).
White to yellowish oily suspension.

4. INDICATION(S)

For the treatment of subclinical mastitis at dry-off and prevention of new intramammary infections occurring during the dry period, caused by *Staphylococcus aureus, Streptococcus dysgalactiae* and *Streptococcus uberis* .

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

Immediate allergic reactions (agitation, trembling, edema of the udders, eyelids and lips), which
can lead to death in certain animals, were rarely observed from spontaneous pharmacovigilance reports.

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

For single intramammary use
375 mg of cefalexin (equivalent to 500 mg of cefalexin benzathine) i.e. the content of one syringe should be infused one into each quarter via the teat canal immediately after the last milking of the lactation.

9. ADVICE ON CORRECT ADMINISTRATION

Milk out thoroughly before starting administration. Before administering the medicinal product, the teats should be thoroughly cleaned and disinfected using the provided cleaning towel, and care should be taken to avoid contamination of the syringe nozzle. Administer the full content of a syringe in each quarter. Massage after

administration. After administration it is recommended to immerse the teat in an approved disinfectant bath. Do not milk after treatment.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 4 days
Milk:

- 12 hours after calving when dry period is more than 42 days
- 42.5 days after treatment when dry period is 42 days or less

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25 °C

Shelf life after first opening the immediate packaging: use immediately.

Do not use this veterinary product after expiry date which is stated on the label after EXP {month/year}. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species

Cross resistance occurs with other β-lactams.

Special precautions for use in animals

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). . If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target bacteria at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to cefalexin and may decrease the effectiveness of treatment with other beta lactam antibiotics due to the potential for cross-resistance.

The rules of asepsis must be scrupulously followed during the administration of the product. The efficacy of the product has only been established against the pathogens mentioned in section INDICATION(S). Consequently, serious acute mastitis (potentially fatal) due to other pathogen species, mainly *Pseudomonas aeruginosa*, can occur after the drying off.

Appropriate veterinary and husbandry measures including good hygienic practices should be taken to reduce that risk. Cows should be housed in a hygienic paddock located apart from the milking parlour. Cows should be regularly checked several days after drying off.

The feeding of waste milk containing residues of cefalexin to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

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-reactions to cephalosporins and vice versa. Allergic reaction to these substances may occasionally be serious.

People with known hypersensitivity to penicillin or cephalosporin , or who have been advised not to work with penicillins or cephalosporins preparations, should avoid contact with the veterinary medicinal product.

Handle this product with great care to avoid exposure. Wear gloves during administration of the product and wash hands after use.

In case of accidental contact with skin or eyes, wash immediately with clean water.

If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Those 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 supplied with the product contain isopropyl alcohol, which may cause skin or eye irritation in some people. The wearing of gloves is recommended during the administration of the product and when handling the cleaning towels.

Pregnancy:

The product is intended for use during pregnancy. The safety of the veterinary medicinal product has not been established during pregnancy in specific target animal safety studies. However, no adverse effects on the foetus were observed in the clinical trial. Moreover, as the quantities of cefalexin absorbed by the intramammary route are low, the use of this medication during pregnancy does not present any particular problem.

Lactation:

Do not use during lactation of lactating dairy cows.

Interaction with other medicinal products and other forms of interaction:

The safety of concomitant use of the medicinal product and other intramammary products has not been established, simultaneous use is discouraged.

Do not use simultaneously with bacteriostatic antibiotics.

Overdose (symptoms, emergency procedures, antidotes):

See section “ADVERSE REACTIONS”

Incompatibilities:

Not applicable.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

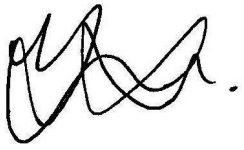
Pack sizes:

Box of 12 x 8g intramammary syringes and 12 cleaning towels.
Box of 24 x 8g intramammary syringes and 24 cleaning towels.
Box of 60 x 8g intramammary syringes and 60 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.

UK(NI): United Kingdom (Northern Ireland)
Virbac Ltd,
Suffolk, IP30 9UP – UK
Tel: +44 (0)-1359 243243



Approved: 29 June 2022