ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton, Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Qivitan LC 75 mg intramammary ointment for lactating cows
Cefquinome

2. STATEMENT OF ACTIVE SUBSTANCES

1 syringe of 8 g contains:

Cefquinome 75 mg
(as cefquinome sulfate)

3. PHARMACEUTICAL FORM

Intramammary ointment

4. PACKAGE SIZE

3 syringes of 8 g
12 syringes of 8 g
24 syringes of 8 g
36 syringes of 8 g

5. TARGET SPECIES

Cattle (lactating cows)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramammary use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: 4 days
Milk: 5 days (120 hours).

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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

Livisto Int'l S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Valles
Barcelona
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43173/4007

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label Syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Qivitan LC 75 mg intramammary ointment for lactating cows
Cefquinome

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 syringe of 8 g contains:

Cefquinome 75 mg
(as cefquinome sulfate)

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

8 g

4. ROUTE(S) OF ADMINISTRATION

For intramammary use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: 4 days
Milk: 5 days (120 hours).

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Qivitan LC 75 mg intramammary ointment for lactating 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:
Livisto Int'l S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Valles
Barcelona
Spain

Manufacturer responsible for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

OR

Industrial Veterinaria, S.A.
Esmeralda 19, Esplugues de Llobregat
08950 Barcelona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Qivitan LC 75 mg intramammary ointment for lactating cows
Cefquinome

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

Each prefilled syringe of 8 g contains:

Active substance:
Cefquinome 75 mg
(as cefquinome sulfate 88.92 mg)

White to slightly yellow, oily viscous homogeneous ointment.

4. INDICATION(S)

For the treatment of clinical mastitis in the lactating cow caused by the following cefquinome-sensitive organisms: *Streptococcus uberis, Streptococcus dysgalactiae, Staphylococcus aureus* and *Escherichia coli.*

5. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to cephalosporin antibiotics, other ß-lactam antibiotics or to any of the excipients.

6. ADVERSE REACTIONS

Anaphylactic reactions have been noted in animals in very rare cases after administration of the product.

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.

7. TARGET SPECIES

Cattle (lactating cows).

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

For intramammary use.

The content of one syringe should be infused gently into the teat of the infected quarter every 12 hours after each of three successive milkings.

9. ADVICE ON CORRECT ADMINISTRATION

Milk out the affected quarter(s). After thoroughly cleaning and disinfecting the teat and teat orifice with the cleaning towel provided remove the cap from the nozzle without touching the nozzle with the fingers. Gently infuse the contents of one syringe into each affected quarter. Disperse the product by gentle massage of the teat and udder of the affected animal.

The syringe must only be used once. Partly used syringes should be discarded.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 4 days
Milk: 5 days (120 hours).

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.

12. SPECIAL WARNING(S)

Special warnings for each target species:
None.

Special precautions for use in animals:
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 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.
Official, national and regional antimicrobial policies should be taken into account when the product is used.
Use of the product deviating from the instructions given in the package leaflet 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.
The feeding to calves of milk containing residues of cefquinome (i.e. milked during treatment) should be avoided due to selection for antimicrobial-resistant bacteria.
Do not use the cleaning towel if lesions are present on the teat.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
When infusing the product, protective gloves should be worn to avoid skin contact.

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.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

2. Handle this product with great care to avoid exposure, taking all recommended precautions.

3. 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.

The cleaning towels provided with this product contain isopropyl alcohol and benzalkonium chloride, which may cause skin irritation in some people. It is recommended to wear protective gloves when using the towels.
Pregnancy and lactation:
The product is intended for use during lactation. There is no available information indicating reproductive toxicity (inc. teratogenicity) in cattle. In reproductive toxicity studies in laboratory animals cefquinome did not reveal any effect on reproduction or teratogenic potential.

Interaction with other medicinal products and other forms of interaction:
None known.

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

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

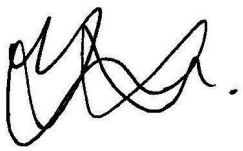
Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes:
Cardboard boxes of 3 syringes and 3 cleaning towels.
Cardboard boxes of 12 syringes and 12 cleaning towels.
Cardboard boxes of 24 syringes and 24 cleaning towels.
Cardboard boxes of 36 syringes and 36 cleaning towels.

Not all pack sizes may be marketed.



Approved: 27 October 2022