1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AT, BE, CY, DE, EL, FR, HR, HU, IE, IT, NL, PL, PT, RO, SI, SK, UK(NI):
Qivitan LC 75 mg intramammary ointment for lactating cows

ES:
Qivitan Lactación 75 mg intramammary ointment for lactating cows

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prefilled syringe of 8 g contains:

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

Excipients:

Qualitative composition of excipients and other constituents
White soft paraffin
Liquid paraffin

White to slightly yellow, oily viscous homogeneous ointment.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (lactating cows).

3.2 Indications for use for each target species

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

3.3 Contraindications

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

3.4 Special warnings

Use of the veterinary medicinal product deviating from the instructions given in the SPC 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The veterinary medicinal 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 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 pathogens at farm level, or at local/regional level.

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

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 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.

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (lactating cows):

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

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
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.

Lactation:
The product is intended for use during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No symptoms expected or emergency procedures required.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ51DE90

4.2 Pharmacodynamics

Cefquinome is an antibacterial drug of the cephalosporin group which acts by inhibition of cell wall synthesis. It is characterised by its broad therapeutic spectrum of activity and a high stability against beta-lactamases.

In vitro, Cefquinome has antibiotic activity against common Gram-negative and Gram-positive bacteria including *Escherichia coli, Staphylococcus aureus, Streptococcus dysgalactiae* and *Streptococcus uberis*. The highest MIC_{90} value was found for *Staphylococcus aureus*. This pathogen has a MIC_{90} in the range of 1 mcg/ml.

As a fourth generation cephalosporin, cefquinome combines high cellular penetration and a high beta-lactamases stability. In contrast to cephalosporins of previous generations, cefquinome is not hydrolysed by chromosomally–encoded cephalosporinases of the Amp-C type or by plasmid mediated cephalosporinases of some enterobacterial species.

Resistance mechanism in Gram-negative organisms due to extended spectrum beta-lactamases (ESBL) and in Gram-positive organisms due to alteration of penicillin binding proteins (PBPs) may lead to cross-resistance with other beta-lactams.

4.3 Pharmacokinetics

After intramammary administration, a mean concentration of 19 mcg/ml in milk is observed 12 hours post last infusion.
At the second milking following the last infusion the mean concentration is still approximately 2.5 mcg/ml and then falls to 0.75 mcg/ml at the third milking post last infusion.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

Prefilled 8 g single-dose intramammary syringe consisting of white opaque LDPE barrel with white opaque LDPE plunger and white opaque LDPE cap.
Cleaning towels (smooth, white crepe paper impregnated with isopropyl alcohol/benzalkonium chloride) individually wrapped.
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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Industrial Veterinaria, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

<Date of first authorisation:> <{DD/MM/YYYY}>.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

<{DD/MM/YYYY}>

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Qivitan LC 75 mg intramammary ointment

2. STATEMENT OF ACTIVE SUBSTANCES

1 syringe of 8 g contains:

Cefquinome 75 mg
(as cefquinome sulfate)

3. PACKAGE SIZE

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

4. TARGET SPECIES

Cattle (lactating cows).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramammary use.

7. WITHDRAWAL PERIODS

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

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

Industrial Veterinaria, S.A.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{ Syringe }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Qivitan LC 75 mg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 syringe of 8 g contains:

Cefquinome 75 mg
(as cefquinome sulfate)

3. WITHDRAWAL PERIODS

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

4. BATCH NUMBER

Lot {number}

5. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Qivitan LC 75 mg intramammary ointment for lactating cows

2. Composition

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.

3. Target species

Cattle (lactating cows).

4. Indications for use

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

5. Contraindications

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

6. Special warnings

Special warnings:
Use of the veterinary medicinal 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.
Special precautions for safe use in the target species:
The veterinary medicinal 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 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 pathogens at farm level, or at local/regional level.
Use of the product should be in accordance with official, national and regional antimicrobial policies.
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 veterinary medicinal 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.

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

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

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.

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.

Lactation:
The product is intended for use during lactation.

Pregnancy:
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:
No symptoms expected or emergency procedures required.

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

7. Adverse events

Cattle (lactating cows):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Anaphylactic-type 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 its local representative 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.

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 periods

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. 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

Marketing authorisation number:

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.

15. Date on which the package leaflet was last revised

<{DD/MM/YYYY}>

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:
Industrial Veterinaria, S.A.
Esmeralda, 19
08950 Esplugues de Llobregat (Barcelona)
Spain
Tel: +34 934 706 270

Manufacturer responsible for batch release:

aniMedica GmbH	Industrial Veterinaria, S.A.
Im Südfeld 9	Esmeralda, 19
48308 Senden-Bösensell	08950 Esplugues de Llobregat (Barcelona)
Germany	Spain

Local representatives and contact details to report suspected adverse reactions: