SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Qivitan LC 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 safe 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 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.

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 MIC90 value was found for *Staphylococcus aureus*. This pathogen has a MIC90 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 product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

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 SA

7. MARKETING AUTHORISATION NUMBERS

Vm 36547/5010
Vm 36547/3010

8. DATE OF FIRST AUTHORISATION

07 June 2018

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

November 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 10 November 2025