SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cobactan MC Intramammary Ointment 75 mg for Lactating Cows

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prefilled syringe of 8 g contains:

Active substance:
Cefquinome (as cefquinome sulphate) 75 mg

Excipients:

Qualitative composition of excipients and other constituents
Paraffin white soft
Liquid paraffin

White to slightly yellow, oily viscous homogeneous intramammary 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 dairy cow caused by the following cefquinome sensitive organisms: *Staphylococcus aureus, Streptococcus uberis, Streptococcus dysgalactiae,* and *Escherichia coli.*

3.3 Contraindications

Do not use in cases of hypersensitivity to cephalosporin antibiotics and other beta-lactam antibiotics.

Do not use the cleaning towel if lesions are present on the teat.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s) and take into account official and local antimicrobial policies. Inappropriate use of the veterinary medicinal product 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 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 cephalosporins and *vice versa*. Allergic reactions to these substances may occasionally be serious.
Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions.
People with known hypersensitivity to penicillins and cephalosporins should avoid contact with the veterinary medicinal product.
If you develop symptoms following exposure, such as a skin rash, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips and eyes or difficulty breathing are more serious symptoms and require urgent medical attention.

Wash hands after using the cleaning towels and wear protective gloves if skin irritation due to isopropyl alcohol is known or suspected.

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):	Anaphylaxis

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 and lactation:
The veterinary medicinal product is intended for use during lactation. There is no available information indicating reproductive toxicity (including teratogenicity) in cattle. In reproductive toxicity studies in laboratory animals cefquinome did not reveal any effect on reproduction or teratogenic potential.

3.8 Interaction with other medicinal products and other forms of interaction

It is known that a cross sensitivity to cephalosporins exists for bacteria sensitive to the cephalosporin group.

3.9 Administration routes and dosage

Intramammary use.

The contents 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, 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, Streptococcus agalactiae* and *Streptococcus uberis.*
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. The highest MIC_{90} value was found for *Staphylococcus aureus*. This pathogen has a MIC_{90} in the range of 1 mcg/ml.

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.

Resorption of cefquinome from the udder is insignificant.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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

White opaque polyethylene syringes and cleaning towels in paper aluminium copolymer laminate sachet.

Pack sizes:
Cardboard box containing 3, 15, 20, 24 or 30 syringes and 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

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4129

8. DATE OF FIRST AUTHORISATION

29 May 1997

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

June 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.

Approved 08 September 2025
Gavin Hall