1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Cobactan LC, 75 mg, intramammary ointment for lactating cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prefilled syringe of 8g contains:

Active substance:

Cefquinome 75 mg (as cefquinome sulphate)

Excipients:

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

White to slightly yellow, oily viscous homogeneous intramammary ointment.

4 CLINICAL PARTICULARS

4.1 Target Species

Lactating cows.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Not to be administered to animals which are known to be hypersensitive to cephalosporin antibiotics and other ß-lactam antibiotics.
Do not use the cleaning towel if lesions are present on the teat.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies. Inappropriate use of the 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 cephalosporin and vice versa. Allergic reactions to these substances may occasionally be serious.
1. Handle this product with great care to avoid exposure, taking all recommended precautions.
2. Do not handle this product if you know you are sensitive to such preparations, or if you have been advised not to work with them.
3. If you develop symptoms following exposure, such as a 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.
Wash hands after using the cleaning towels and wear protective gloves if skin irritation due to Isopropyl alcohol is known or suspected.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases anaphylactic reactions have been noted in animals 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).

4.7 Use during pregnancy, lactation or lay

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.

4.8 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.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No symptoms expected or emergency procedures required.

4.11 Withdrawal period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for intramammary use, fourth-generation cephalosporins.

ATC vet code: QJ51DE90.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin
Liquid paraffin

6.2 Major incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

White opaque polyethylene syringes and cleaning towels in paper aluminium copolymer laminate sachet.
Packs of 3, 15, 20 and 24 syringes and cleaning towels.
Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/105/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14/05/1998
Date of last renewal: 28/05/2009

10 DATE OF REVISION OF THE TEXT

April 2018