1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Plenix LC 75 mg, intramammary ointment for lactating cows [AT BE BG HR CY CZ EE FR DE EL HU IE IT LV LT PL PT RO SK SI]

Plenix Lactación 75 mg, intramammary ointment for lactating cows [ES]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prefilled syringe of 8 g contains:

Active substance:
Cefquinome (as sulfate) 75 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Intramammary ointment.
White to slightly yellow, oily, viscous homogeneous ointment.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (lactating cows).

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in cases of hypersensitivity to cephalosporin antibiotics and other ß-lactam antibiotics or to any of the excipients.
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
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 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.
The feeding of waste milk containing residues of cefquinome to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria

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.
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 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, which may cause skin irritation in some people. It is recommended to wear protective gloves when using the towels.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases (less than 1 animal in 10,000 animals treated, including isolated reports) anaphylactic reactions have been noted in animals after administration of cefquinome containing intramammary products.

4.7 Use during pregnancy or 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.

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

For intramammary administration.
The syringe must only be used once. Partly emptied syringes due to the unsuccessful use should be discarded.

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, 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.

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 PROPERTIES

Pharmacotherapeutic group: Antibacterials for intramammary use, fourth-generation cephalosporins.
ATCvet 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 µg/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 µg/ml.

At the second milking following the last infusion the mean concentration is still approximately 2.5 µg/ml and then falls to 0.75 µg/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 30°C.

6.5 Nature and composition of immediate packaging

Pre-filled 8 g syringe consisting of white opaque high density polyethylene (HDPE) cylinders with white opaque low density polyethylene (LDPE) plungers and white opaque (HDPE) cap.
Cleaning towel (30% viscose / 70% polyester, alcohol impregnated) in a paper aluminium copolymer laminate sachet
Pack of 3 syringes and 3 cleaning towels
Pack of 15 syringes and 15 cleaning towels
Pack of 20 syringes and 20 cleaning towels
Pack of 24 syringes and 24 cleaning towels Pack of 60 syringes and 60 cleaning towels

Not all pack sizes may be marketed

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

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

7. MARKETING AUTHORISATION HOLDER

8. MARKETING AUTHORISATION NUMBER(S)