

Only for Veterinary Use

Cephanom LC[®]

Intramammarian Cream for Milking Period

Veterinary Antibacterial

COMPOSITION

Cephanom LC is a sterile cream which contains 89 mg cefquinom sulphate equivalent to 75 mg cefquinom in 8 g intra-mammarian injector.

PHARMACOLOGICAL PROPERTIES

The active ingredient of Cephanom, cefquinome, is a 4th generation, wide-spectrum and Beta-lactamase resistant cephalosporin which exerts bactericidal effect. Cephalosporins kill bacteria by inhibiting synthesis of cell wall in bacteria. It has wide spectrum involving many Gram positive and Gram negative bacteria including Beta-lactamase positive and penicillinase positive bacteria. Bacteria susceptible to cefquinome include Gram-positive and Gram-negative bacteria such as *Escherichia coli*, *Klebsiella* sp., *Pasteurella* sp., *Salmonella* spp., *Proteus mirabilis*, *Haemophilus* spp., *Corynebacterium pyogenes*, *Staphylococcus aureus*, *Streptococcus dysgalactia*, *Streptococcus agalactia*.

Rhodococcus spp. are *Pseudomonas* spp. are moderately susceptible to cefquinome, whereas *Campylobacter* spp. and *Enterococcus* spp. are resistant.

Similar to all 4th generation cephalosporin compounds, cefquinome features good tissue distribution and cellular penetration. When it is administered into mammarian tissue, it is easily dispersed in milk and thus, distribution of cefquinome is ensured. Dispersion to systemic circulation is limited and it is completely eliminated from the tissue within 5 days following administration.

AREA OF USE/INDICATIONS

Cephanom LC is used for treatment of clinical mastitis in cows, which are in lactation, arising from bacteria susceptible to cefquinome.

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE

Unless otherwise advised by veterinary surgeon, one Cephanom LC suspension is completely administered, via mammarian duct, into breast lobe after cow is milked. Following administration, breast is massaged and thus, distribution of the drug is facilitated. The administration is repeated 3 times in 12-hour intervals.

Teat and mammarian duct is cleaned with antiseptic before it is infused. Contamination of injector tip should be avoided after original package is opened.

Appropriate parenteral antibacterial therapy in conjunction with intra-mammarian Cephanom LC administration provides particular benefit to bacterial treatment in acute cases.

ADVERSE / SIDE EFFECTS

Anaphylactic reactions may develop in animals hypersensitive to penicillin and cephalosporins.

DRUG INTERACTIONS

Cephalosporins are antagonistic to tetracyclines and other bacteriostatic antibiotics. It has synergistic effect with aminoglycosides.

WARNINGS FOR THE DRUG RESIDUES IN NUTRIENTS

Withholding Period (WHP): Cattle should not be transferred to slaughtering throughout the treatment or within 4 days following the last administration of the drug. Withholding Period is 5 days, corresponding to 10 milking intervals.

CONTRAINDICATIONS

It should not be used in animals hypersensitive to beta-lactam antibiotics.

Use in pregnancy: Embryotoxic and teratogenic effects were not observed in studies conducted on rats and rabbits.

GENERAL WARNINGS

Please refer to the veterinary surgeon before use and in case of an unexpected effect. Keep away from children.

PRECAUTIONS TO BE TAKEN BY ADMINISTRATOR AND GENERAL WARNINGS

Contact of penicillin and cephalosporin with allergic subjects via injection, inhalation, digestion and direct contact may lead to allergic reactions (hypersensitization).

Allergic reactions to those substances may sometimes lead to serious health problem. Therefore; these groups of drugs should not be administered to subjects with known allergy to penicillin and cephalosporin.

- Necessary precautions should be taken in order not to contact with the drug during administration.
- If allergic symptoms such as pustules occur due to contact with the drug, a doctor should be contacted. Facial, ocular and lip swelling and breath shortness are more serious symptoms which require emergency intervention.

STORAGE CONDITIONS AND SHELF LIFE

Store at room temperature (15-25°C) away from sun light. Shelf life is 2 years from the date of production.

FORM OF COMMERCIAL SUPPLY

Cephanom LC is supplied in 8 g polyethylene white injectors in cardboard boxes which may house 3 or 40 preparations.

SALE PLACE AND CONDITIONS

It is sold in the veterinary offices and the pharmacies with prescription written by veterinary surgeon (VP).

PROSPECTUS APPROVAL DATE: 29.06.2011

DATE AND NUMBER OF LICENSE AWARDED BY THE MINISTRY OF AGRICULTURE AND RURAL AFFAIRS: 15.06.2011-24/051

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

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