For Veterinary Use Only.

Bovimast® DC

Intrammmary Suspension

Veterinary Antibacterial

COMPOSITION:

It contains Cloksacillin Benzathine, equivalent to 600mg Cloksacillin, in 4.0g intramammary administration injector. Bovimast DC is white and has an oily suspension form.

PHARMACOLOGICAL PROPERTIES:

Bovimast DC intramammary suspension has a formula based on slow release developed specifically for intramammary administration to dry cows. Due to its being penicillin derivative resistant to beta lactamase enzyme, cloksacillin is also effective on staphylococcus that are resistant to penicillin G. Streptococcus and staphylococcus which are among the primary factors of subclinical mastitis are the most frequent factors of acute mastitis seen at the beginning of the new yield period. Cloksacillin has a bactericidal effect over the elimination of mastitis factors originated from Gram (+) bacteria in the dry period. Staph. aureus, Str. agalactia, Str. dysgalactia, Str.uberis, Str.pyogenes, Str.pneumoniae, Clostridium spp., Borrelia, Leptospira and Morexella species are highly sensitive (EKEY<1 kg/ml); Camphylobacter and Enterococcus species are moderately sensitive (EKEY<2.5 kg/ml); Bac. fragilis, Enterobacter spp, B.bronchiseptica, Citrobacter spp, Klepsiella, Proteus, Pseudomonas aureginosa, Serratia, Y. Enterocolitica (EKEY > 5 kg/ml) are resistant to Cloksacillin.

As in all beta-lactam antibiotics, the mechanism of action of cloksacillin is base on the inhibition of cell wall formation by assimilating the transpeptidase enzyme functioning in the formation of murein layer by peptidoglycan chains during the formation of cell wall.

Due to the long-term efficiency and slow release properties of cloksacillin benzathin salt contained in the Bovimast DC intramammary suspension, it reaches a maximum concentration within the first week following administration. It maintains its effective concentration for Str. agalactia, Str. uberis and Staph. Aureus in the breast tissue for 7 weeks. Cloksacillin benzathine is the organic salt of cloksacillin which is insoluble in water. Due to this nature, it is slowly adsorbed and slowly excreted. Its persistency is extended to 7 weeks by the aluminium monostereate and mineral oily carrier properties. The binding ratio of cloksacillin benzathine to breast secretions in the dry period is 80%, whereas to tissue homogenisates is 25%. As its systemic absorption is very low, no pharmacokinetic parameters have been established. It reaches peak concentration (25g/ml) in the breast tissue within 6-8 days.

AREA OF USE / INDICATIONS:

It is indicated in the treatment of clinical and subclinical mastitis arising from Str. agalactia, Str. dysalactia, Str. uberis and Staph. aureus during dry period.

USAGE AND DOSAGE:

Unless otherwise recommended by the Veterinary Surgeon; the milk within the breast is completely discharged and one 4 g Bovimast DC suspension is administered to each breast lobe through breast duct. Before the infusion, nipples and breast duct are cleaned with antiseptics. Avoid contamination of the injector tip after opening the injector. Following administration, antisepsis should be performed for the nipples.

UNDESIRED/SIDE EFFECTS

Penicillin may cause allergic reactions (type 1 allergy) in sensitive humans and animals.

DRUG INTERACTIONS:

Penicillin develops synergistic interaction with aminoglycoside antibiotics and cephalosporins. It should not be used in combination with antibacterial drugs of beta lactam group, macrolids, tetracyclins and fenicols.

SYMPTOMS OF OVERDOSE AND ANTIDOTE:

Penicillin is known as non-toxic compounds except for the individual sensitivity. LD50 intramuscular is 5 g/kg for cloksacillin in mice. No specific antidote has been reported.

LEGAL PURIFICATION TIME:

Withholding period (WHP): It should not be administered to cows during lactation. In case of inadvertent administration in cows during lactation, milk should not be offered to human consumption before its amount in milk drops below 0.03 mcg/ml. Avoid administrating in cows for which dry period is less than 42 days. Milk obtained should not be offered for human consumption before 46 days following the administration in the dry period. The meat type cows should not be sent for slaughter before 35 days following the final drug administration and during the treatment.

CONTRAINDICATIONS:

Avoid administrating in animals with known hypersensitivity to penicillin and cephalosporin. In case of hypersensitivity perform antihistaminic treatment.

GENERAL WARNINGS:

Consult your veterinary surgeon before using and in case an undesired effect is observed. Keep out of reach of children. Avoid using products with damaged packages.

SPECIAL WARNINGS FOR APPLIER AND VETERINARY SURGEON:

The contact of the drug within the injector with human skin may cause allergic reactions in people who are sensitive to penicillin. Use surgical gloves during administration. It is not recommended for the appliers who are sensitive to penicillinic products to use Bovimast DC suspension. In case of symptoms such as skin rash following contact through any routes, consult your doctor immediately. In case of swelling of face, lips and eyes or respiratory distress, seek for medical assistance immediately.

STORAGE CONDITIONS AND SHELF LIFE:

Store at room temperature of (15-25℃) away from light. Shell life is 2 years (24 months).

COMMERCIAL PRESENTATION FORM:

Offered in market in 4g polyethylene injectors placed into cardboard boxes of 4, 40 and 120 parts which can contain multi packages and pvc plastic packages of 12 parts.

PLACE AND CONDITIONS OF SALE:

Sold with Veterinary Surgeon's prescription in pharmacies and veterinary surgeries.

APPROVAL DATE OF PACKAGE INSERT: 11.12.2006

MARKETING AUTHORIZATION DATE AND NO: 23.11.2006 - 17/028

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

Alke Sağlik Ürünleri San. ve Tic. A.Ş

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NAME AND ADDRESS OF MANUFACTURER COMPANY:

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Merkez Organize Sanayi Bölgesi 2. Kısım 10. Cadde No:7 Tokat