

For Veterinary Use Only,

Bovimast[®] LC

Intrammmary Suspension
Veterinary Antibacterial



COMPOSITION

Bovimast LC Intrammmary Suspension is yellowish to cream colored, oily suspension containing 50mg clavulanic acid as potassium clavulanate, 200mg amoxicillin as amoxicillin trihydrate and 10mg prednisolone in 3g breast injector.

PHARMACOLOGICAL PROPERTIES

The combination of amoxicillin and clavulanic acid contained in the Bovimast LC Intrammmary suspension has a broad spectrum bactericidal activity against bacteria leading to cattle mastitis. Amoxicillin is an antibiotic belonging to beta-lactam group which has efficiency against both gram positive and gram negative bacteria. It blocks the cell wall synthesis by binding to penicillin specific proteins in the bacteria cell wall and leads to the lysis of the bacteria. Some beta-lactamase enzymes formed by certain bacteria break down antibiotics before it affects the bacteria and lead to resistance development. Clavulanic acid in Bovimast LC Intrammmary Suspension is a molecule with low antibacterial activity in beta-lactamase chemical structure. It neutralizes beta-lactamase enzymes secreted by the bacteria by coupling with them irreversibly and prevents bacteria from developing resistance against amoxicillin. Prednisolone is a glucocorticosteroid with potent activity. It ensures the reduction of oedema and inflammation in the breast with mastitis.

Bovimast LC Intrammmary Suspension has been shown to be in vitro efficient against the following pathogens leading to mastitis in the cattle during lactation: Staphylococcus (including strains producing beta-lactamase), streptococcus (Str. agalactia, Str. dysgalactia, Str. uberis), A. pyogenes and Corynebacteriaspp. affinities, Escherichia coli (including strains producing beta-lactamase). Amoxicillin clavulanic acid combinations have been demonstrated to be in vitro efficient against Bacillus cereus, Bacteroides (including strains producing beta-lactamase), Campylobacter spp., Klebsiellae and Pasteurellae. Citrobacter species, Enterobacter species, Ps. aeruginosa, Serratia species, methicilline resistant Staph. aureus are resistant. When administered intrammmary, amoxicillin and clavulanic acid highly disperse. Serum half life is 90 minutes in cattle for amoxicillin and 2 hours for clavulanic acid. It is eliminated by tubular secretion through the kidneys. Following intrammmary administration prednisolone reaches peak plasma concentration after 1-2 hours of administration. It may be detected in the urine after 12 hours of administration as prednisolone and prednisolone metabolite.

AREA OF USE/INDICATIONS

Laktasyondaki ineklerde Stafilokoklar (beta-laktamaz oluşturan suşlar dahil), streptokoklar (Str. agalactia, Str. dysgalactia, Str. uberis), A. pyogenes ve Corynebacteriaspp., Escherichia coli, Campylobacter spp., ve Pasteurellae türlerinden kaynaklanan klinik ve subklinik mastitis sağtımında kullanılır.

USAGE AND DOSAGE

Unless otherwise recommended by the Veterinary Surgeon one 3g Bovimast LC suspension is completely administered to breast lobe through breast duct after the milking process of cows. The administration is repeated 3 times at an interval of 12 hours. Before the infusion, nipples and breast duct are cleaned with antiseptics. Avoid contamination of the injector tip after opening the injector.

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.

UNDESIRE/SIDE EFFECTS

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

WARNINGS FOR NON-TARGET SPECIES:

As in all other penicillin, oral or parenteral administration of amoxicillin-clavulanic acid combination may affect gastro-intestinal flora of small laboratory animals such as rabbits, guinea pigs, hamsters and gnawing animals from Gerbilinae family, and horses. Therefore, it should not be used for these 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 fenicol.

SYMPTOMS OF OVERDOSE AND ANTIDOTE

Penicillin is known as non-toxic compounds except for the individual sensitivity. No specific antidote has been reported.

LEGAL PURIFICATION TIME:

Withholding period (WHP): Cattle should not be sent for slaughtering during treatment and before 10 days following drug administration. Milk produced should not be offered for human consumption during the treatment and 4 days (8 milkings) following the final administration.

CONTRAINDICATIONS

It is contraindicated in the animals with known allergy to penicillin.

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 LC 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 °C) away from light. Shelf life is 2 years (24 months).

COMMERCIAL PRESENTATION FORM

Offered in market in 3 g polyethylene injectors placed into cardboard boxes of 3 and 40 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: 28 05 2007

MARKETING AUTHORIZATION DATE AND NO: 24.05 2007-18/042

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

Alke Saęlık Ürünleri San. ve Tic. A.Ş

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NAME AND ADDRESS OF MANUFACTURER COMPANY:

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