For Veterinary Use Only

Megasil CLA®

Suspension for Injection

Veterinary Systemic Antibacterial

COMPOSITION

Megasil – CLA Suspension for Injection is off-white or off-yellow suspension containing amoxicillin trihydrate equivalent to 140mg amoxicillin and potassium clavulanate equivalent to 35mg clavulanic acid per each ml.

PHARMACOLOGICAL PROPERTIES

Megasil – CLA Suspension for Injection is a sterile product for injection prepared basing on the combination of amoxicillin strengthened with clavulanic acid for the treatment of infections that are caused by gram-positive and gram-negative bacteria in cattle. The active ingredient amoxicillin demonstrates its efficiency by means of inhibiting the activity of the enzymes functioning in peptidoglycan chain synthesis in sensitive pathogen bacteria during rapid growth and reproduction stage, and blocking the synthesis of murein which forms the basis of peptidoglycan chain and accordingly the cell wall, and deteriorating the synthesis of cell wall. The bacteria whose cell wall integration has been deteriorated are decomposed by meand of transforming into sphaerophorus or L shape and die. Clavulanic acid is closely associated with ß-lactam ring, that is present within the composition of penicillines in terms of structure and is similar with the same ring system in many ways. It selectively and irreversibly inhibits ß-lactamase enzyme which is synthesized and released by different types of pathogen bacteria due to its structure specified. Clavunalic, which used in combination with amoxicillin, rapidly and irreversibly inhibits the same enzyme in pathogen bacteria that become resistant through ß-lactamase enzyme in vitro and in vivo, and sensitizes the sensitive bacteria to the lethal effect of amoxicillin.

Megasil – CLA Suspension for Injection has a broad antibacterial spectrum. This spectrum includes gram-positive bacteria such as Staphylococcus sp., (including the ones secreting beta-lactamase) Streptococcus sp., Corynebacterium sp., Clostridium sp., Bacillus anthracis, A.bovis and Peptostreptokoklar; E. coli strains (including the strains secreting beta-lactamase), Salmonella sp.,(including beta-lactamase positive), Bordetella bronchiseptica, Campylobacter sp., Klebsiella sp., Proteus sp., Pasteurella sp., Fusobacterium necrophorum, Bacteroides sp (including the ones secreting beta-lactamase), Moraxella sp., Actinobacillus lignierensi etc. and gram negative bacteria. It reaches peak serum concentration within 1-3 hours following parenteral administration and its half life in the blood is approximately 2 hours in dairy cattle, 1 hour in calf and swine, and 45 minutes in sheep. It is excreted from the body mainly through urine and bile.

AREA OF USE/INDICATIONS

Megasil – CLA Suspension for Injection is used for the treatment of infections in cattle, dogs and cats which are caused by sensitive bacteria.

It is intended for the treatment of pneumonia, bronchopneumonia, pleuropneumonia and respiratory system infections including upper respiratory infection; articular infections; infections of soft tissue including umbilical cord infections and abscess; urogenital system infections such as nephritis, pyelonephritis and cystitis, and digestive system infections; and as parenteral support for the local treatment in cases of mastitis and metritis in cattle and for the treatment of respiratory and urinary system infections and skin and other soft tissue infections (abscess, pyoderma, anal sacculitis and gingivitis) in dogs and cats.

USAGE AND DOSAGE

Unless otherwise recommended by the veterinary surgeon;

It should be administered intramuscularly to cattle, whereas, intramuscularly and subcutaneously to cats and dogs at the dose of 8.75mg (7mg Amoxicilline and 1.75mg clavulanic acid)/kg live weight /day or 1ml Megasil –CLA /20kg live weight/day. Therapy should proceed once a day for 3-5 days.

In order to ensure a good mixture of the contents, the bottle should be fairly shaken prior to administration. Following subcutaneous and intramuscular administration the injection area should be rubbed down. Due to the sensitivity of clavulanic acid to moisture, the injector to be used for the administration should completely be dry. Otherwise, loss of effect may occur. Avoid mixing water into the remaining suspension in the bottle following administration. Therefore, a completely dry injector should be used for the application. Since clavulanic acid is moisture-sensitive, the contact of the product with water should be avoided. The development of such case becomes evident with the dark brown colour of the suspension and with the formation of bubbles. Antibacterial activity of the product that has undergone such change is reduced distinctly. In this case, avoid using the drug.

UNDESIRED/SIDE EFFECTS

Following administration of the drug certain local tissue reactions may be observed. Penicillins and cephalosporins may lead to hypersensitivity (allergy) as a result of intake via injection, inhalation and digestion, and skin contact. Hypersensitivity to penicillins may result in hypersensitivity to cephalosporins. The opposite is possible, either. Allergic reactions may sometimes lead to serious consequences.

DRUG INTERACTIONS

As amoxicillin increases the penetration of aminoglycosides through bacteria, combination of two drugs may cause a synergic effect. They have an antagonist interaction with tetracyclines. As diuretics accelerate the excretion of amoxicillin, they may reduce the concentration of the antibiotic.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE

Neurotoxic and nephrotoxic effects may develop depending on the dose administered and the time extention.

WARNINGS ON DRUG RESIDUES IN FOOD

Withholding Period (WHP): Cattle should not be sent for slaughtering during treatment and before 20 days after the last drug administration. Milk produced should not be offered for human consumption during the treatment and 4 days (8 milkings) following the final administration in dairy cattle.

CONTRAINDICATIONS

Avoid intravenous and intratracheal administration. Avoid using for serious renal disorders accompanied by anuria or oliguria. It is contraindicated in animals with known sensitivity to penicillins.

Use during pregnancy: No negative effect have been observed in the studies up to today over foetus.

GENERAL WARNINGS

Consult your veterinary surgeon before using and in case an unexpected effect is observed. Keep away from foodstuff and out of reach of children. Shake well before use. Avoid using products with damaged packages.

WARNING FOR NON-TARGET SPECIES

It may deteriorate gastro-intestinal flora in small ruminants such as rabbits, guinea pig and hamsters, and in horses. Therefore, it should not be used for these animals. Also, avoid administrating to webbed animals.

PRECAUTIONS TO BE TAKEN BY THE USER AND WARNINGS FOR VETERINARY SURGEONS:

People with sensitivity to substances such as penicillin, cephalosporin and etc. are likely to be sensitive to amoxicillin. Sensitive people may develop allergic reactions in cases of skin contact and intake through inhalation, injection or any route.

If you know you are sensitive to, or if you have to work with these preparations; avoid manual contact with this product and take all necessary precautions.

In case of swelling of the face, lips or eyes, or respiratory distress; immediately consult to your doctor with the product and the relative package insert.

STORAGE CONDITIONS AND SHELF LIFE

Store below 25° C protected from direct light without freezing. Consume the product within 28 days after the bottle is opened. Shelf life is 2 years as of the production date.

COMMERCIAL PRESENTATION FORM INDICATING THE QUALITY AND QUANTITY OF THE PACKAGE

Megasil – CLA Suspension for Injection is presented in 20, 50, 100 and 250ml type II, colourless glass vials and cardboard boxes.

PLACE AND CONDITIONS OF SALE

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

APPROVAL DATE OF PACKAGE INSERT: 21.10.2008

MINISTRY OF AGRICULTURE AND RURAL AFFAIRS AUTHORIZATION DATE AND NO : 26.09.2008-20/058

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

Alke Sağlik Ürünleri San. ve Tic. A.Ş

Dolayoba, Çınardere Mh. 3. Petek Sk. No: 18, 34896 Pendik-ISTANBUL

NAME AND ADDRESS OF MANUFACTURER COMPANY:

Alke Sağlik Ürünleri San. ve Tic. A.Ş

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