

For Veterinary Use Only

Megasil LA[®]

Suspension for Injection

Veterinary Systemic Antibacterial

COMPOSITION

Megasil LA Suspension for Injection is off-white, oily suspension containing amoxicillin trihydrate equivalent to 150mg amoxicillin per each ml.

PHARMACOLOGICAL PROPERTIES

Amoxicillin is broad spectrum semi-synthetic penicillin containing beta-lactam ring. It exhibits its bactericidal effect by means of inhibiting bacteria cell wall biosynthesis.

Sensitive bacteria: Most of gram-positive bacteria including beta haemolytic *Streptococcus* sp. (*Strep. agalactiae*, *S. canis*, *S. zooepidemicus*, *S. dysgalactiae*, *S. suis*, *S. uberis*, *Bacillus anthracis*, *Actinomyces* sp., many *Corynebacter* sp., *Erysipelothrix rhusiopathiae*, many *Listeria monocytogenes*); certain anaerobes (*Clostridium* sp., many *Fusobacterium* sp., certain *Bacteroides* sp.), certain gram-negative aerobes (*Haemophilus somnus*), *Borrelia* sp., *Leptospira* sp., *Actinobacillus* sp., *Haemophilus* sp., *Leptospira* sp., *Moraxella* sp., *Pasteurella* sp., *Proteus* sp., *Taylorella equigenitalis*, *Serpulina* sp., *Campylobacter* sp., Enterococci, *Rhodococcus equi*.

Development of resistance is common in Enterobacteriaceae.

Bacteroides fragilis, *Bordetella bronchiseptica*, *Citrobacter* sp., *Enterobacter* sp., *Klebsiella* sp., other *Proteus* sp., *Pseudomonas aeruginosa*, *Serratia* sp. and *Yersinia enterocolitica* are resistant to amoxicillin. It is ineffective to bacteria secreting beta-lactamase.

When administered parenterally, it is rapidly diffused into blood and tissues. It exhibits a quick absorption following subcutaneous and intramuscular injection. It reaches the desired plasma level within 30-60 minutes.

It concentrates particularly on lung, liver and kidneys. It binds to serum proteins at a lower ratio. Amoxicillin binds to human serum protein with a rate of 17%. It is eliminated by unchanged excretion of the drug and in the form of inactive penicilloic acid (10-25%) through kidneys. It is excreted through bile at lower amounts.

AREA OF USE / INDICATIONS

The following infections caused by sensitive bacteria in cattle, sheep, cats and dogs;

- Respiratory system infection (bronchitis, bronchopneumonia, pneumonia, *Pasteurella pneumonias*, enzootic pneumonias, laryngitis, tonsillitis and secondary infection accompanying viral pneumonias),
- Digestive system infections (bacteria originated enteritis, Salmonellosis),
- Urogenital system infections (including cystitis, nephritis and pyelonephritis)
- Septicaemias and Colibacillosis of offspring and young animals and soft tissue infections (wound, abscess, foot and nail infections)

USAGE AND DOSAGE

It is administered intramuscularly to cattle and sheep; and subcutaneously and intramuscularly to cats and dogs. Unless recommended otherwise by veterinary surgeon,

Pharmacological dose

Cattle, sheep, cats and dogs: 15mg amoxicillin / kg live weight / day .

Practical dose

Cattle, sheep, cats and dogs: Administered at the dose of 1ml Megasil LA / 10 kg live weight / day.

The dose is repeated after 48 hours, if required. Each injection should be performed on different area and the injection area should be rubbed down upon administration. In case of administration to cattle at a dose higher than 20ml and in sheep higher than 4ml, the dose should be divided and injected in two separate areas. Shake well before use.

UNDESIRE/SIDE EFFECTS

The most significant side effects of penicillin are anaphylaxis and collapse. Also, mild but frequent hypersensitivity reactions may be observed (including urticaria, fever and angioneurotic edema). In case anaphylaxis adrenalin, antihistaminic or glicocorticoids should be administered.

DRUG INTERACTIONS

Probenecid slows down the tubular secretion of amoxicillin and extends its elimination half life. Amoxicillin should not be administered concurrently with bacteriostatic antibiotics such as tetracyclines and sulphonamides. As diuretics accelerate the excretion of amoxicillin, they may reduce the concentration of the antibiotic. Inhibitors of uric acid synthesis such as allopurinal increase the risk of skin reaction.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE

Amoxicillin is a highly safe antibiotic. Its acute and chronic toxicity is low. No carcinogenic or mutagenic effect has been reported.

WARNINGS ON DRUG RESIDUES IN FOOD

Withholding Period (WHP) Meat type cattle and sheep should not be sent for slaughtering during the treatment and before 30 days after the final administration following intramuscular administration. Purification time for drug residues is 10 milkings (5 days) for cow and 14 milkings (7 days) for sheep following intramuscular administration. It is not recommended to be administered to sheep from which milk is produced for human consumption as the purification time for drug residues is long in milk. Residue purification time for injection area is 50 days.

CONTRAINDICATIONS

Avoid intravenous and intratracheal administration. Avoid using for serious renal disorders accompanied by anuria or oliguria. It should not be administered to animals with known sensitivity to penicillins.

Use during pregnancy: Penicillins have been reported not to have any effects on the reproductive performance and exhibit teratogenic effects.

GENERAL WARNINGS

Consult your veterinary surgeon before using and in case an unexpected effect is observed. Keep out of reach of children. Shake well before use. Keep away from food products. Do not purchase and use products with damaged packages.

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 hand contact with this product. You can contact the product by hand after you take all recommended precautions.

If ever symptoms increase, consult your doctor immediately. In case of swelling of face, lips and eyes, and respiratory distress take medical precautions. Wash your hands after use.

STORAGE CONDITIONS AND SHELF LIFE

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

WARNINGS FOR NON-TARGET SPECIES:

Amoxicillin is not administered to rabbits and hamsters as in the case of other penicillin derivatives. Also, avoid using in horses, snakes and webbed animals (ducks, goose, etc.)

PRECAUTIONS TO BE TAKEN BY THE USER AND GENERAL WARNINGS

Contamination of penicillin and cephalosporin to sensitive humans via injection, inhalation, digestion and contact may result in allergic reactions (hypersensitization). Allergic reactions associated with these substances may sometimes create serious health problems. Therefore;

- People with known allergy to penicillin and cephalosporin should not administer these group of drugs.
- Necessary precautions should be taken in order not to contact with the drug during administration.
- In case of skin allergy symptoms following contact with the drug, consult a doctor. Swelling of face, lips and eyes and respiratory distress are serious symptoms requiring emergent intervention.
- In case of accidentally contact with eyes, wash with water for 15 minutes.

STORAGE CONDITIONS AND SHELF LIFE

The product should be stored at room temperature (15 – 25 oC) protected from light without being frozen. The shelf life following the initial use is 30 days provided to be stored below 25 oC. Shelf life is 2 years as of the production date.

COMMERCIAL PRESENTATION FORM

Presented to the market in 20, 50, 100 and 250ml colourless vials in cardboard boxes.

PLACE AND CONDITIONS OF SALE

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

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NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

Alke Sağlık Ürünleri San. ve Tic. A.Ş

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

NAME AND ADDRESS OF MANUFACTURER COMPANY:

Alke Sağlık Ürünleri San. ve Tic. A.Ş

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