

For Veterinary Use Only

# Megasil-WSP<sup>®</sup>

Powder for Oral Solution

Veterinary Systemic Antibacterial

## COMPOSITION:

Megasil-WSP 50% Powder for Oral Solution is an antibacterial powder for solution of whitish color containing amoxicillin trihydrate equivalent to 500 mg of amoxicillin base in each gram.

## PHARMACOLOGIC PROPERTIES:

Amoxicillin trihydrate (D(-)- $\alpha$ -amino-p-hydroxybenzyl penicillin) is a member of  $\beta$ -Lactam group antibiotics and is a semi-synthetic penicillin. When administered orally, it is absorbed easily and almost completely through digestive track of target animals and is distributed to the whole body. After being absorbed, it is distributed in muscles, liver, kidneys and urinary track. Transition of the drug through biological membranes and blood-brain or blood-cerebrospinal fluid barriers increases in case of inflammation.

It was shown in vitro that amoxicillin is effective against both gram-positive and gram-negative bacteria.

Sensitive bacteria: Staphylococcus and streptococcus strains sensitive to penicillin, Bacillus anthracis, Actinomyces sp., most Corynebacterium sp., Erysipelothrix rhusiopathiae, Listeria monocytogenes, certain anaerobics (Clostridium sp., Fusobacterium sp., certain Bacteroides sp.), certain gram-negative aerobics (Borrelia sp., Leptospira sp., Actinobacillus sp., Haemophilus sp., Moraxella sp., Pasteurella sp.).

Bacteria with medium sensitivity due to acquired immunity: Campylocater sp., Enterococci, Proteus mirabilis, Salmonella sp..

Resistant bacteria: Bacteroides fragilis, Bordetella bronchiseptica, Citrobacter sp., Enterobacter sp., Klebsiella sp., other Proteus sp., Pseudomonas aeruginosa, Serratia sp., Yersinia enterocolitica.

It builds a bactericide effect developing rapidly on bacteria by deteriorating cell wall. Amoxicillin binds to serum protein with a rate of 17%. It is eliminated by excretion of unchanged drug and in the form of inactive penicilloic acid (10-25%) through kidneys. Renal excretion occurs by means of glomerular filtration and tubular excretion. Excretion half-life of amoxicillin is 1.13 hours in poultry.

## AREA OF USE/INDICATIONS:

Amoxicillin is used successfully in broiler chickens and turkeys for treatment of systemic and local infections caused by gram-positive and gram-negative bacteria within the spectrum. Megasil-WSP 50% Powder for Oral Solution is indicated in the treatment of infections induced by Staphylococci, Streptococci, Pasteurella, Salmonella, Haemofilus, Clostridium strains, Ornithobacterium rhinotracheale and E. coli.

## USAGE AND DOSAGE:

Megasil-WSP 50% Powder for Oral Solution is used orally in broiler and layer chickens by adding in drinking water. Unless recommended otherwise by veterinary surgeon, treatment dose is 20 mg/kg L.W./day. Administration is carried for 3-5 days. Continuity is not necessary for daily administrations. Daily dose is not necessarily administered constantly. Dose can be practically calculated as specified below:

Megasil-WSP 50% Powder for Solution

$$\text{amount required for one-day treatment (g)} = \frac{\text{Number of animals} \times \text{Average live weight (kg)} \times 20}{500}$$

Average live weight (kg)	Daily Megasil-WSP 50% Powder for Oral Solution Amount per 10,000 Animals (g)
0.25	100
0.50	200
0.75	300
1.0	400
1.25	500
1.50	600
1.75	700
2.0	800

Drugged water should be consumed in 2-3 hours. Unused drugged water should be disposed after 8 hours.

#### **UNDESIRE / SIDE EFFECTS**

In hypersensitive members to penicillin, hypersensitivity reactions such as fever, angioneurotic edema and rarely acute, peracute anaphylaxis and collapse may be observed. Treatment should be discontinued when intolerance symptoms are seen, and symptomatic and assistive treatments (adrenalin, antihistaminic, glycocorticoids) should be carried out if necessary.

#### **DRUG INTERACTIONS**

As amoxicillin increases the penetration of aminoglycosides through bacteria, combination of two drugs may cause a synergic effect. It should not be used in combination with antibacterial drugs of beta lactam group, macrolids, tetracyclins and fenicol.

#### **SYMPTOMS OF OVERDOSE AND ANTIDOTE**

No undesired and toxic effect occurs if used in prescribed administration areas and at recommended doses.

#### **WARNINGS ON DRUG RESIDUES IN FOOD:**

Withholding Period (WHP) is 7 days for broider chickens and turkeys. The drug should not be used in layer chickens and turkeys whose eggs are offered for human consumption.

#### **CONTRAINDICATIONS**

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

#### **GENERAL WARNINGS:**

Consult your veterinary surgeon before using and in case an undesired effect is observed. Keep out of reach of children. Use only for target species.

#### **SPECIAL WARNINGS FOR USER AND VETERINARY SURGEON:**

Individuals with known sensitivity to cefalosporins and penicillin should not contact with the drug. Immediate medical intervention will be required in case sensitive individuals suffer from symptoms such as swelling on face, eyes and lips and difficulty in respiration upon being exposed to the drug through mouth, skin or inhalation. In such cases consult your doctor together with the drug and package insert. Wash your hands after using.

**STORAGE CONDITIONS AND SHELF LIFE:**

The product should be stored at room temperature (15 – 25 oC) and should be protected from light. Shelf life is 2 years (24 months).

**DISPOSAL AFTER USE AND WARNINGS FOR NON-TARGET SPECIES:**

The drug whose shelf life is expired, that is opened or kept for a long time without complying with storage conditions should be disposed together with inner package (bottle).

It should not be used in small rodents such as guinea pigs, hamsters and rabbits, in totipalmate poultry such as ducks and geese and horses.

**COMMERCIAL PRESENTATION FORM**

Offered for market in 100 g (10 pieces) aluminum folio bags in cardboard boxes and 250g, 500 g and 1000 g HDPE jar packages without boxes.

**PLACE AND CONDITIONS OF SALE:**

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

**APPROVAL DATE OF PACKAGE INSERT:** 13.09.2006

**MINISTRY OF AGRICULTURE AND RURAL AFFAIRS MARKETING AUTHORIZATION DATE AND NO:**

28.07.2006-16/067

**NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:**

**Alke Saęlık Ürünleri San. ve Tic. A.Ş**

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

**NAME AND ADDRESS OF MANUFACTURER COMPANY:**

**Alke Saęlık Ürünleri San. ve Tic. A.Ş**

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