

AMOXICILLIN

Sitimox

500 mg Capsule
Antibacterial (Penicillin)



FORMULATION:

Each capsule contains Amoxicillin Trihydrate equivalent to Amoxicillin 500mg.

PRODUCT DESCRIPTION:

A white or almost white granules or powder.

PHARMACOLOGICAL ACTION:

Amoxicillin Capsules is a semisynthetic aminopenicillin with an *in vitro* bactericidal action against a broad spectrum of gram-positive and gram-negative pathogens. The presence of the enzyme penicillinase has a major influence on the degree and extent of its activity against organisms. Being acid stable it is well absorbed when given orally.

The *in vitro* antibacterial spectrum of **Amoxicillin Capsules** is as follows (care must however be exercised when extrapolating this to the clinical situation):

Amoxicillin Capsules is particularly active against the following organisms:

Gram-positive organisms

*Streptococcus pneumoniae**, *Streptococcus faecalis** (enterococci), *Streptococcus agalactiae* (group B), penicillin-sensitive *Neisseria gonorrhoeae*, *Listeria monocytogenes*.

Amoxicillin Capsules is also active against the following organisms:

Gram-positive organisms

*Staphylococcus aureus** (penicillin sensitive), *Streptococcus pyogenes*, *Streptococcus viridans**, *Streptococcus bovis*, *Neisseria meningitidis* (except the carrier state), *Bacillus anthracis**, *Corynebacterium species**, *Clostridium species**;

Amoxicillin Capsules also has *in vitro* activity against the following gram-negative organisms (these organisms may produce beta-lactamase):

*Escherichia coli**, *Haemophilus influenzae**, (except the type beta-strains causing meningitis in children), *Salmonella**, and *Shigella** species.

Amoxicillin Capsules may also have some effect against the following organisms:

*Bacteroides fragilis**, *Proteus mirabilis** and *Nocardia*.

*sensitivity tests must be performed.

Most species of the following organisms are resistant to **Amoxicillin Capsules**:

Enterobacter, Pseudomonas, Klebsiella, Serratia, Acinetobacter and indole-positive Proteus.

INDICATIONS:

For respiratory tract infections due to H.influenzae and S.pneumoniae sensitive to amoxicillin, Prophylaxis of bacterial endocarditis in dental surgery, first line drug for typhoid fever and anti-Helicobacter pylori in conjunction with clarithromycin and bismuth subcitrate or proton pump in the treatment of gastric ulcer and duodenal ulcer relapses.

CONTRAINDICATIONS:

Allergy to penicillins. Patients with infectious mononucleosis are susceptible to skin rashes.

DOSAGE AND ADMINISTRATION:

One capsule every 8 hours or as prescribed by the physician.

ADVERSE EFFECTS & SPECIAL PRECAUTIONS:

Allergic reactions may occur. Skin rashes (pruritic skin rash, and erythematous skin reaction or urticaria) are the most common side-effects.

Fever, eosinophilia, joint pains, angioneurotic oedema, erythema multiforme and anaphylaxis may occur.

If a serious anaphylactic reaction occurs, **Amoxicillin Capsules** should be discontinued and the

patient treated with the usual agents: adrenaline, corticosteroids and antihistamines.
Treatment with **Amoxicillin Capsules** may give rise to maculopapular eruptions which often appear about 5 days after treatment has finished. The incidence of maculopapular rash is especially high in patients suffering from infectious mononucleosis. Diarrhoea, nausea, vomiting have occurred and raised serum aminotransferase concentrations have been reported. Severe pseudomembranous colitis has also been reported. Super-infections with Pseudomonas and Candida have also occurred. Care must be taken in treating patients with dehydration or oliguria because of the possibility of crystalluria. The use of this antibiotic may lead to the appearance of resistant strains of organisms and sensitivity testing should, therefore, be carried out wherever possible to ensure the appropriateness of the therapy.

REPORTING OF SUSPECTED ADVERSE REACTIONS:

To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reactions is necessary.

Healthcare professionals are encouraged to report any suspected adverse reaction/s directly to the importer/distributor and/or to FDA: www.fda.gov.ph.

Patients are advised to seek immediate medical attention at the first sign/s of adverse reactions.

DRUG INTERACTION:

Probenecid prolongs the renal excretion of Amoxicillin. Amoxicillin is inactivated by beta lactamases and complete cross-resistance has been reported between Amoxicillin and Ampicillin. The spectrum of activity of Amoxicillin may be extended by the concomitant use of a beta-lactamase inhibitor such as Clavulanic Acid.

OVERDOSE AND TREATMENT :

A prospective study of 51 pediatric patients at a poison-control center suggested that overdosages of less than 250 mg/kg of amoxicillin are not associated with significant clinical symptoms:

PRGENANCY AND LACTATION

Can be used during pregnancy and while breast feeding.

SHELF LIFE:

36 months.

AVAILABILITY:

Alu/PVC Blister pack of 10's,Box of 100 capsules

STORAGE CONDITIONS:

Store at temperatures not exceeding 30°C
Keep medicine out of reach of children.

MANUFACTURED BY:

CSPC ZHONGNUO PHARMACEUTICAL(SHIJIAZHUANG) CO.LTD
No. 88 Yangzi Road, Shijiazhuang Economic & Technological Development Zone, Hebei Province, China

IMPORTED & DISTRIBUTED BY:

SAHAR INTERNATIONAL TRADING INC.
#354 Aguirre Ave., Phase III, BF Homes, Parañaque City, Metro Manila

FDA REGISTRATION NUMBER:DR-XY48738

DATE OF INITIAL OF AUTHORIZATION:22 May 2023

DATE OF CREATION OF PACKAGE INSERT:3 JULY 2023