AXC5e MYS-003
R.O.C. Reg. No.:025866

YSP AMOXICILLIN Capsules 500mg

Amoxicillin is a semisynthetic penicillin, an analogue of ampicillin, with a broad spectrum of bactericidal activity against many gram-positive and gram-negative microorganisms Chemically, it is D-(-)-α-amino-p-Hydroxybenzyl penicillin trihydrate.

Ingredient:
Each capsule contains:
Amoxicillin (as Amoxicillin Trihydrate)…….....…….500mg

Pharmacodynamic:
1. Amoxicillin is bactericidal, effective against the same range of organism as ampicillin such as *Streptococcus faecalis, Streptococcus pneumoniae, Haemophilus influenzae, Escherichia coli, Neisseria qonorrhoeae, N. meningitidis, Bordetella pertusis, Proteus mirabilis, and Brucella spp.*
2. Amoxicillin is slightly more active than ampicillin against some streptococci and Salmonella spp.
3. Amoxicillin predominantly inhibits side-wall synthesis in susceptible bacteria while ampicillin mainly inhibits cross-wall synthesis.

Pharmacokinetics:
1. Orally administered doses of 250mg and 500mg amoxicillin capsules result in average peak blood levels, one to two hours after administration, in the range of 3.5mcg/mL to 5.0mcg/mL, and 5.5mcg/mL to 7.5mcg/mL, respectively.
2. Approximately 60% of an orally administered dose of amoxicillin is excreted in the urine within six to eight hours.

Indications:
For the treatment of infections due to the following susceptible microorganisms:
Gram-negative organisms-*H. influenzae, E. coli, P. mirabilis and N. gonorrhoeae.*
Gram-positive organisms-streptococci (including *S. faecalis*), *D. pneumoniae*, and nonpenicillinase-producing staphylococci.

Route of Administration:
To be taken orally.

Dosage and Administration:
Adults: 500mg (potency) three times daily.
Children: 20-40mg/kg/day in divided doses every eight hours.
To be dispensed according to physician's prescription.

Contraindication:
It is contraindicated in individuals with a history of an allergic reaction to the penicillins.

Warning and Precautions:
1. Possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. The drug should be discontinued and/or appropriate therapy instituted if superinfections occur.
2. Patients intolerant of cephalosporins, cephanmycins or griseofulvin may also be intolerant of penicillins also.
3. Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients receiving therapy with beta-lactams. Before initiating therapy with Amoxicillin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillin, cephalosporins, carbapenems or other beta-lactam agents. If an allergic reaction occurs, Amoxicillin must be discontinued immediately and appropriate alternative therapy instituted.
4. Amoxicillin, amoxicillin and clavulanate combination may cause sore mouth and darkened or discolored tongue.

Interaction with other Medicaments:
1. When amoxicillin and Warfarin are taken concomitantly, the INR can be altered.
2. The simultaneous use of Amoxicillin and an oral contraceptive might be expected to cause breakthrough bleeding or pregnancy on rare occasions, because of reduced absorption owing to diarrhea, on the basis of experience with ampicillin.
3. Administration of probenecid prior to dosing results in a marked increase in the mean serum concentrations of amoxicillin.

Side Effects:
Rash (urticarial, erythematous, morbilliform), exfoliative dermatitis or erythema multiforme, hemolytic anemia, leucopenia, neutropenia, agranulocytosis, thrombocytopenia, thrombocytopenic purpura, black hairy tongue, glossitis, stomatitis, sore mouth or tongue, acute interstitial nephritits, a moderate increase in serum concentration of AST (SGOT).

Skin and subcutaneous tissue disorders:
Frequency 'very rare': Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)

Pregnancy and Lactation:
1. Safety for use in pregnancy has not been established.
2. Amoxicillin cross the placenta. However, problems in humans have not been documented.
3. Amoxicillins are excreted in breast milk in low concentrations. Although significant problems in humans have not been documented, the use of this drug by nursing mothers may lead to sensitization, diarrhea, candidiasis, and skin rash.

Symptoms and Treatment of Overdose:
1. Gastrointestinal effects such as nausea, vomiting and diarrhea may be evident and symptoms of water / electrolyte imbalance should be treated symptomatically.
2. In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures as required. If the overdosage is very recent and there is no contraindication, an attempt at emesis or other means of removal of drug from the stomach may be performed.
3. Amoxicillin may be removed from circulation by hemodialysis.

Storage conditions:
Protect from heat and direct light.
Store at temperature below 30°C.

Shelf life:
2 years from the date of manufacture

Packing(s):
Blister packing of 10's x 100

Product description:
Red cap and yellow body hard gelatin capsules, containing with off-white powder; both cap and body impressed with "YSP".

AXC5

Manufacturer:
Yung Shin Pharmaceutical Ind. Co., Ltd.
Taichung Youth Factory III
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Importer & Product Registration Holder:
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Acknowledgement

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