AUGMEX Tabs. 375 MG
Amoxicillin 250 mg &
Clavulanate potassium 125 mg

COMPOSITION

Each tablet contains
Amoxicillin (USP) ---------- 250 mg (potency)
Clavulanate potassium (USP) ---------- 125 mg (potency)

DESCRIPTION
White to off-white, oval film-coated tablet.

INDICATIONS
Susceptible organisms:
**Staphylococcus aureus, *Staphylococcus epidermidis, Streptococcus pyogenes, Streptococcus pneumoniae, viridans* group *Streptococcus, Enterococcus faecalis, Corynebacterium* species, *Bacillus anthracis, Listeria monocytogenes, Clostridium* species, *Peptococcus* species, *Peptostreptococcus* species
**Escherichia coli, *Proteus mirabilis, *Proteus vulgaris, *Klebsiella* species, *Salmonella* species, *Shigella* species, *Bordetella pertussis, *Yersinia enterocolitica, Gardnerella vaginalis, Brucella* species, *Neisseria meningitidis, *Neisseria gonorrhoeae, *Moraxella catarrhalirococcus, *Haemophilus influenzae, *Haemophilus ducreyi, Pasteurella multocida, Campylobacter jejuni, Vibrio cholerae, *Bacteroides* species
(* : Including β-lactamase producing organisms which are resistant to ampicillin and amoxicillin)

Indications:
Acute & chronic bronchitis, lobar- & broncho-pneumonia, empyema, lung abscess, tonsillitis, sinusitis, otitis media
Cystitis, urethritis, nephropyelitis
Septic abortion, puerperal septicemia, pelvic cellulitis, chancroid, gonorrhea
Furuncle & abscess, cellulitis, wound infection, intra-abdominal sepsis
Peritonitis
Osteomyelitis
Septicemia
Post-operative infection

DOSAGE AND ADMINISTRATION
Adults:
The usual adult oral dose is 1 tablet every 8 hours. Dosage may be adjusted according to the patient's age or symptoms.

CONTRAINDICATIONS
Patients with hypersensitivity to penicillins
Patients with contagious mononucleosis
Patients with a history of penicillin-associated jaundice/hepatic dysfunction

CAUTIONS
Patients with severe hepatic impairment
Patients with moderate to severe renal impairment.(Frequency of administration should be modified because of prolonged half-life of the drug.
Patients with a history of hypersensitivity to penicillins or cephems.
Patients whose family are susceptible to cause the allergy symptoms such as bronchial asthma, eruption and urticaria, etc.
Patients who cannot ingest orally, patients receiving parenteral nutrition, elderly patients and patients in systemic bad (poor) condition.(Because avitaminosis K may occur, they should be sufficiently observed.)

ADVERSE REACTIONS
Hypersensitivity: Rarely urticarial and erythematous rashes may occur. Because urticarial rashes correspond to penicillin hypersensitivity, treatment should be discontinued in such a case. Erythematous rashes are usually mild and transient.
Gastrointestinal effects: Diarrhoea, pseudomembranous colitis, indigestion, nausea, vomiting, stomatitis, and candidiasis may occur. Nausea, although uncommon, is often associated with higher oral dosage. These adverse effects may be reduced by taking the drug at the start of meals.
Skin effects: Rarely erythema multiforme, Stevens-Johnson syndrome (mucocutaneous-ocular syndrome), Lyell's syndrome (toxic epidermal necrolysis), Quincke's edema, and rarely dermatitis may occur. If they occur, the administration should be discontinued.
Hepatic effects: Occasionally increases in AST, ALT, AL-P may occur. Hepatitis and cholestatic jaundice may occur rarely. These hepatic reactions have been reported more frequently in adults, elderly patients, and males. Liver dysfunctions are usually reversible but they may be severe and, very rarely, deaths have been reported. Most of the death cases are associated with severe diseases or concomitant use of other drugs.
Skin and subcutaneous tissue disorders
Very rare: Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
Hematological effects: Hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, leukemia, agranulocytosis have been reported during therapy. If they occur, the administration should be discontinued.
Renal effects: Rarely severe renal impairment such as acute renal failure and interstitial nephritis may occur. Therefore patients should be carefully observed and periodically evaluated. If any abnormal symptom is recognized, the drug should be discontinued and appropriate therapy instituted.
Nervous system disorders
Very rare: Aseptic meningitis

GENERAL PRECAUTIONS
Serious and occasionally fatal angioneurotic edema may occur in patients receiving penicillin. These reactions are more likely to occur in individuals with a history of hypersensitivity to penicillin and/or a history of sensitivity to multiple allergens. These reactions are more likely to occur in individuals with parenteral administration than with oral, but oral penicillin-associated reactions have also been reported.

Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity. If an allergic reaction occurs, Augmex must be discontinued and appropriate alternative therapy instituted. Serious anaphylactic reactions require immediate emergency treatment with adrenaline. Oxygen, intravenous steroids and airway management (including intubation) may also be required.

- Long term administration occasionally results in superinfection of unsusceptible strains. Therefore, patients should be carefully observed for signs and symptoms when the therapy is longer than 14 days.
- Signs and symptoms of adverse reactions are reported to occur within 6 weeks after discontinuation of the drug as well as during the therapy.

DRUG INTERACTIONS
Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use of the drug with probenecid may result in increased and prolonged blood levels of amoxicillin.
The concurrent administration of allopurinol and ampicillin increases substantially the incidence of rashes in patients receiving both drugs as compared to patients receiving ampicillin alone. It is not known whether this potentiation of ampicillin rashes is due to allopurinol or the hyperuricemia present in these patients.
AUGMEX should not be used with disulfiram.
There have been rare reports of prolonged bleeding & prothrombin time in patients receiving the drug. Therefore, care should be taken when administering the drug in patients on anticoagulation therapy.
The drug may decrease the action of oral contraceptives and patients should be warned accordingly.

USE IN PREGNANCY AND LACTATION
Reproduction studies performed in animals revealed no evidence of harm to the fetus due to this drug. However, the drug should not be used in pregnant or possibly pregnant women unless clearly needed, because the safety has not been established. The drug, in particular, should not be used in the first 3 months of pregnancy.
Small amount of the drug may be distributed into breast milk.

DRUG / LABORATORY TEST INTERACTIONS
Oral administration of AUGMEX will result in high urine concentrations of amoxicillin. High urine concentrations of amoxicillin may result in false-positive reactions when testing for the presence of glucose in urine using Clinitest, Benedict's Solution or Fehling's Solution.

OVERDOSAGE
Most patients have been asymptomatic following overdosage, but occasionally gastrointestinal symptoms and water-electrolyte imbalance may occur. In the case of overdosage, symptomatic treatment is done observing water-electrolyte balance and supportive measures are instituted as required. The drug is removed from the circulation by hemodialysis.

STORAGE
Preserve in air-tight containers.
Store in a dry place below 25˚C.

PACKAGE
100 Tablets
(The packing size or type may vary on request)

SHELF LIFE
24 months from manufacturing date

REG. NO. : SIN11639P

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