180 X 120

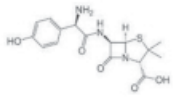
Pack Insert

THEOMOX-250

(Amoxicillin Capsules USP 250 mg)

COMPOSITION:
Each hard gelatin capsule contains:
Amoxicillin Trihydrate USP
Eq. to Amoxicillin……250 mg
Excipients……q.s.

DESCRIPTION:
Amoxicillin moderate-spectrum, bacteriolytic, β-lactam antibiotic used to treat bacterial infections caused by susceptible microorganisms. It is usually the drug of choice within the class because it is better absorbed, following oral administration, than other β-lactam antibiotics. Amoxicillin is one of the most common antibiotics prescribed for children.



PHARMACODYNAMICS:
ATC code: J01C A04
Amoxicillin is a broad spectrum antibiotic.
It is rapidly bactericidal and possesses the safety profile of a penicillin.
The wide range of organisms sensitive to the bactericidal action of Amoxicillin includes:
Gram-positive bacteria
Gram-negative bacteria
Staphylococcus aureus (penicillin*-sensitive)
Neisseria gonorrhoea*
Streptococcus pyogenes
Neisseria meningitidis
Streptococcus viridans*
Haemophilus influenzae**
Streptococcus faecalis
Bordetella pertussis
Diplococcus pneumoniae*
Escherichia coli*
Corynebacterium species*
Salmonella typhi
Clostridium species*
Salmonella species
Bacillus anthracis*
Shigella species
Proteus mirabilis
Brucella species

PHARMACOKINETICS:
Amoxicillin is well absorbed. Oral administration, usually at convenient t.d.s dosage, produces high serum levels independent of the time at which food is taken. Amoxicillin gives good penetration into bronchial secretions and high urinary concentrations of unchanged antibiotic.
In preterm infants with gestational age 26-33 weeks, the total body clearance after intravenous dosing of amoxicillin, day 3 of life, ranged between 0.75 – 2 ml/min, very similar to the inuline clearance (GFR) in this population. Following oral administration, the absorption pattern and the bioavailability of amoxicillin in small children may be different to that of increase in exposure may in part be diminished by decreased bioavailability when given orally.

INDICATIONS:
Treatment of infection:
Amoxicillin is a broad spectrum antibiotic indicated for the treatment of commonly occurring bacterial infections such as: Upper respiratory tract infections, otitis media, Acute and chronic bronchitis, Chronic bronchial sepsis, Lobar and bronchopneumonia, Cystitis, urethritis, pyelonephritis, Bacteriuria in pregnancy, Gynaecological infections including puerperal sepsis and septic abortion, Gonorrhoea, Peritonitis, Intra abdominalsepsis, Septicaemia, Bacterial endocarditis, Typhoid and paratyphoid fever, Skin and soft tissue infections, Dental abscess (as an adjunct to surgical management), Helicobacter pylori eradication in peptic (duodenal and gastric) ulcer disease. In children with urinary tract infection the need for investigation should be considered. Prophylaxis of endocarditis, Amoxicillin may be used for the prevention of bacteraemia, associated with procedures such as dental extraction, in patients at risk of developing bacterial endocarditis Consideration should be given to official local guidance (e.g. national requirements) on the appropriate use of antibacterial agents. "Susceptibility of the causative organisms to the treatment should be tested (if possible), although the therapy may be initiated before the results are available.

DRUG INTERACTION:
Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use with amoxicillin may result in increased and prolonged blood levels of amoxicillin. In common with other antibiotics, amoxicillin may affect the gut flora, leading to lower oestrogen reabsorption and reduce efficacy of combined oral contraceptives. Concurrent administration of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions. In the literature there are rare cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxicillin It is recommended that when testing for the presence of glucose in urine during amoxicillin treatment, enzymatic glucose oxidase methods should be used. Due to the high urinary concentrations of amoxicillin, false positive readings are common with chemical methods.

DOSAGE AND ADMINISTRATION :
The average adult dose for Amoxicillin is 750 mg —1.5 g/day, but in serious infections up to 6 g daily has been administered.
General dosages:
Oral
Adults: 250 mg (1 x 250 mg capsule three times a day.)
Children 2 —10 years: 125 mg three times a day.
Children 6 months —2 years: 125 three times a day.
Infants 0 —6 months: 62.5 mg (half pipette measure of paediatric suspension) three times a day.
Premature infants 1.0 —2.5 kg: 30.0 —62.5 mg once daily for the first 1-2 weeks depending on the size and maturity of the infant, thereafter dose may be given 2-3 times daily.

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SIDE EFFECTS:
Blood:
Blood dyscrasias have been reported less frequently. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena.
Liver:
A moderate rise in SGOT and for SGPT has been reported in exceptional cases.at high doses of parenteral Amoxycillin, caution must be exercised in treating patients with dehydration or oliguria because of the possibility of cristalluria. 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. Gastro-intestinal disturbance including diarrhoea, nausea and vomiting have been reported. Pseudo-membranous colitis has been reported, if this condition occurs, treatment should be discontinued and appropriate therapy, e.g. vancomycin, should be initiated. The dose should be reduced in patients with renal failure. Periodic assessment of renal, hepatic, and haematopoietic function should be made during prolonged therapy. Prolonged use may also occasionally result in overgrowth of non-susceptible organisms Amoxycillin should preferably not be used in patients with infectious mononucleosis and should also be used with caution in patients glandular fever, lymphatic leukaemia, and patients treated with allopurinol since they are especially susceptible to ampicillin-induced skin rashes. Due to Amoxycillin's effect on intestinal flora, the absorption of other medicine may be affected. Amoxycillin may reduce the efficacy of oral contraceptives and patients should be warned accordingly. The absorption of concurrently administered digoxin may be increased during treatment with Amoxycillin.Caution is needed when administering Amoxycillin to patients with syphilis, as the Jarisch-Herxheimer reaction may occur in these patients

PREGNANCY AND LACTATION:
Animal reproduction studies have failed to demonstrate a risk to the foetus. There are no adequate and well controlled studies in pregnant women. Amoxycillin is excreted in breast milk, and should be used with caution when administered to lactating women.

PRECAUTIONS:
Allergic reactions presenting as a skin rash, pruritis and urticaria have been reported less frequently. Other reactions including angio-oedema, anaphylaxis, erythema multiforma, Stevens-Johnson syndrome and exfoliative dermatitis may occur in exceptional cases. If a skin rash occurs, treatment should be discontinued. In the event of an anaphylactic reaction, immediate treatment with adrenalin, oxygen, corticosteroids and antihistamines should be initiated.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
If encountered, gastro-intestinal symptoms and disturbance of the fluid and electrolyte balance may be evident. They may be treated symptomatically and supportive with attention to the water/electrolyte balance. In the absence of an adequate fluid intake and urinary output, crystalluria is a possibility and the antibiotic may be removed from the circulation by haemodialysis. Oral administration can cause gastro-intestinal symptoms such as transient diarrhoea, nausea and colic which are dose related and a result of local irritation not toxicity.

CONTRAINDICATION:
Allergy to penicillins or any of the cephalosporins is an absolute contra-indication to the use of Theomox-500.

WARNINGS:
Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. Before commencing therapy with any penicillin, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, or other allergies. If an allergic reaction occurs, appropriate therapy should be instituted and amoxycillin therapy discontinued.there is insufficient evidence at present to show that Amoxicillin penetrates into the cerebro-spinal fluid in therapeutic quantities and it should, therefore, not be used in the treatment of cerebro-spinal infections.

PRESENTATION:
THEOMOX-250: A Blister pack of 10 capsules & 10 such Blister packs in one carton with package insert.

THEOMOX-250:1000 capsules packed in HDPE jar with package insert.

THEOMOX-250-500 capsules packed in HDPE jar with package insert.

STORAGE INSTRUCTIONS:
Store below 30°C. Protect from light and moisture.

Keep the medicine out of reach of children.

THEON
PHARMACEUTICALS LTD

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