THEON
PHARMACEUTICAL LTD

SUMMARY OF PRODUCTS CHARACTERISTIC

THEOCLAV 1000

Amoxicillin & Clavulanate Potassium Tablet USP (875mg & 125mg)

BRAND NAME: Theoclav 1000

GENERIC NAME: Amoxicillin & Clavulanate Potassium Tablet USP (875mg & 125mg)

DOSAGE FORM

Solid oral dosage from files control tablets.

ROUTE AND CONDITIONS OF ADMINISTRATION

ROUTE: ORAL

Condition of Administration: To be taken/swallowed with a glass of water.

SIDE EFFECTS

Diarrhea, nausea, vomiting, indigestion, gastritis, stomatitis, glossitis, black "hairy" tongue, mucocutaneous candidiasis, enterocolitis, and hemorrhagic/pseudomembranous colitis. Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment.

HYPERSENSITIVITY REACTIONS

Skin rashes, pruritus, urticaria, angioedema, serum sickness - like reactions (urticaria or skin rash accompanied by arthritis, arthalgia, myalgia, and frequently fever), erythema multiforme (rarely stevens-johnson syndrome), acute generalized exanthematious pustulosis,

hypersensitivity vasculitis, and an occasional case of exfoliative dermattis (including toxic epidermal necrolysis)have been reported. These reactions maybe controlled with antihistamines and, if necessary, systemic corticosteroids. Whenever such reactions occur, the drug should be discontinued, unless the opinion of the physician dictates otherwise. Serious and occasional fatal hypersensitive (anaphylactic) reactions can occur with oral penicillin.

HEMIC AND LYMPHATIC SYSTEMS

Anemia, including hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, cosinophilia, lckopena, and arganilocytosis has been reported during therapy with penicillin. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena.

CENTRAL NERVOUS SYSTEM

Agalation, anxiety, behavioural changes, confusion, conclusions, diseases, insonnia.

CONTRAINDICATIONS

Patients with known hypersensitivity to amoxicillin & Clavulanate Potassium Tablet USP 875 mg & 125 mg, other Cophalosporin antibiotics or to any of the excipients.

Amoxicillin & Clavulante Potassium Tablet USP (875mg & 125mg) are also contraindicated in paties with previous, immediate and/or severe hypersensitivit to another beta-lactam agent (e.g. a cephalosporin, carbapenem or monobactam). History of jaundice/hepatic impairment due to amoxicillin/clavulanic acid.

ADVERSE REACTIONS

The ADRs derived from clinical studies and post-marketing surveillance with amoxicillin/clavulanic acid, sorted by MedDRA System Organ Class are listed below.

The following terminologies have used in order to classify the occurrence of undesirable effects.

Very Common ($\geq$ 1/10)

Common ($\geq$1/100 to < 1/10)

Uncommon ($\geq$1/1,000 to < 1/100)

Rare ($\geq$1/10,000 to <1/1,000)

Very Rare (<1/10,000)

Not known (Cannot be estimated from the available data)

INFECTIONS AND INFESTATIONS	
Mucocutaneous Candidosis Common	Common
Overgrowth of non-susceptible organisms	Not Known
Aseptic meningitis	Not Known
BLOOD AND LYMPHATIC SYSTEM DISORDERS	
Reversible leucopenia (Including Neutropenia)	Rare
Thrombocytopenia	Rare
Reversible agranulocytosis	Not Known
Haenolytic anemia	Not Known
CARDIAC DISORDERS	
Kounis Syndrome	Not Known
Angioneurotic Oedema	Not Known
Anaphylaxis	Not Known
Serum sickness-like syndrome	Not Known
Hypersensitivity vasculitis	Not Known
NERVOUS SYSTEM DISORDERS	
Dizziness	Uncommon
Headache	Uncommon

Reversible Hyperactivity	Not Known
GASTROINTESTINAL DISORDERS	
Diarrhea	Very common
Vomiting	Common
Indigestion	Uncommon
Black Hairy Tongue	Not known
HEPATOBILIARY DISORDERS	
Cholangitis	Not known
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	
Skin Rash	Uncommon
Pruritus	Uncommon
Urticaria	Uncommon
Erythema Multiforme	Rare
Toxic Epidermal Necrolysis	Not known
Bullous Exfoliative-Dermatitis	Not known
Acute Generalised Exanthemous Pustulosis (AGEP)	Not known
RENAL AND URINARY DISORDERS	
Interstitial Nephritis	Not known
Crystalluria	Not known

ANTIDOTE IN THE EVENTS OF EVER DOSAGE

SYMPTOMS AND SIGNS OF OVERDOSE

Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident.

Amoxicillin crystalluria, in some cases leading to renal failure, has been observed.

Convulsions may occur in patients with impaired renal function or in those receiving high doses

Amoxicillin has been reported to precipitate in bladder catheters, predominantly after intravenous administration of large doses. a regular check of patency should be maintained.

TREATMENT OF INTOXICATION

Gastrointestinal symptoms may be treated symptomatically, with attention to the water electrolyte balance.

Amoxicillin/clavulanic acid can be removed from the circulation by haemdialysis.

No specific antidote exists.

TERATOGENICITY

PREGNANCY CATEGORY B

Reproduction studies performed in pregnant rates and mice give amoxicillin & clavulanate Potassium at oral dosage up to 1,200mg/kg/day, equivalent to 7,200 and 4,080 mg/m2/day, respectively (4.9 and 2.8 times the maximum human oral dose based on body surface area), revealed no evidence of harm to the fetus due to amoxicillin & clavulanate Potassium. There are, however, no adequate and well-controlled studies in pregnant women. Be case animal reproduction studies are not always predictive is human response, this drug should be used during pregnancy and if clearly needed.

LABOUR AND DELIVERY

Oral ampicillin-class antibiotics are generally pooly absorbed during labor. Studies in guinea pigs have shown that intravenous administration of amoxicillin decreased the uterine tone, frequently of contraction, height of contractions, and duration of contractions; however, it is not known whether the use of amoxicillin & clavulanate Potassium in human during labour or delivery has immediate or delayed adverse effects on the fetus, prolongs the duration of labour, or increases the likelihood that forceps delivery or other obstetrical intervention or resuciation of the newborn will be necessary in a single study in women with premature rupture of fetal membranes, it was reported that prophylates treatment with amoxicillin & clavulanate Potassium may be associated with an increased risk of necrotizing enerolitis in beonates.

NURSING MOTHERS

Amoxicillin-clav antibiotics are excreted in the milk, therefore, caution should be exercised when amoxicillin & clavulanate Potassium is administered to a nursing woman.