Contifil®

Theophylline BP

COMPOSITION
Contifil® 300 Tablet: Each sustained release tablet contains Theophylline BP 300 mg.
Contifil® 400 Tablet: Each sustained release tablet contains Theophylline BP 400 mg.

PHARMACOLOGY
Theophylline is a bronchodilator, structurally classified as a Methylxanthine. Theophylline has two distinct actions in the airways of patients with reversible obstruction; smooth muscle relaxation and suppression of the response of the airways to stimuli. Theophylline also increases the force of contraction of diaphragmatic muscles. The half-life of Theophylline is influenced by a number of known variables. In adult nonsmokers with uncomplicated asthma the half-life ranges from 3 to 9 hours.

INDICATION
Contifil® Tablet is indicated for the symptomatic treatment of reversible bronchoconstriction associated with bronchial asthma, chronic obstructive pulmonary emphysema, chronic bronchitis and related bronchospastic disorders.

DOSAGE & ADMINISTRATION
Adult: One **Contifil® 300** tablet every 12 hours or as directed by the physicians. Recommended dose of **Contifil® 400** tablet is once daily in the evening.
Children: 9 mg / kg twice daily or as directed by the physicians.

Dosing initiation and titration (as anhydrous theophylline):

Titration step	Children < 45 kg	Children > 45 kg & adults
Starting dosage:	12-14 mg/kg/day up to a maximum of 300 mg/day administration	300 - 400 mg/day
After 3 days, if tolerated, increase dose to:	16 mg/kg/day up to a maximum of 400 mg/day administration	400 - 600 mg/day administration
After more days, if tolerated, and if needed increase dose to:	20 mg/kg/day up to a maximum of 600 mg/day administration	Doses greater than 600 mg should be titrated according to blood level

SIDE EFFECTS
Side effects associated with Theophylline are generally mild when peak serum Theophylline concentrations are < 20 mcg/ml and mainly consist of transient caffeine like adverse effects such as nausea, vomiting, headache, restlessness and insomnia.
Serum Theophylline concentrations above 20 mcg/ml side effects such as vomiting, cardiac arrhythmias and seizures have been reported.

PRECAUTION
Careful consideration is needed for various interacting drugs and physiologic conditions that can alter Theophylline clearance. Dosage adjustment is required prior to initiation of Theophylline therapy, prior to increases in Theophylline dose, and during follow up. The dose of Theophylline selected for initiation of therapy should be low and, if tolerated, increased slowly over a period of time.

DRUG INTERACTION
Allopurinol, cimetidine, norfloxacin, ciprofloxacin, erythromycin, oral contraceptives and propranolol increase serum theophylline levels.
Phenytoin, methotrexate and rifampicin lead to decreased serum theophylline levels.

Pregnancy
It is not known whether Theophylline can cause foetal harm when administered to pregnant woman. Xanthines should be given to a pregnant woman only if clearly needed.
Nursing mother
Theophylline is excreted into breast milk and may cause irritability or other signs of mild toxicity in nursing human infants. Serious adverse effects in the infant are unlikely unless the mother has toxic serum Theophylline concentrations.
Pediatrics
The clearance of Theophylline is very low in neonates. Careful attention to dosage selection and monitoring of serum Theophylline concentrations are required in pediatric patients.

CONTRAINDICATION
Hypersensitivity to xanthine derivatives. It is also contraindicated in patients with active peptic ulcer disease and in individuals with underlying seizure disorders (unless receiving appropriate anti-convulsing medication).

STORAGE CONDITION
Store in a cool and dry place, protect from light and moisture. Keep out of the reach of children.

HOW SUPPLIED
Contifil® 300 : Box containing 10x10 sustained release tablets in blister packs.
Contifil® 400 : Box containing 3x10 sustained release tablets in blister packs.

Manufactured by :
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH