

Teolex[®]

Theophylline

Description

Teolex[®] is a preparation of Theophylline which is a xanthine derivative. Theophylline has two distinct actions in the airways of patients with reversible obstruction; smooth muscle relaxation (i.e. bronchodilation) & suppression of the response of the airways to stimuli (i.e. non bronchodilator prophylactic effects).

Indications

It is indicated for the treatment of the symptoms of reversible airflow obstruction associated with asthma and other chronic lung diseases e.g. emphysema and chronic bronchitis.

Dosage and administration

Tablet

Titration step	Children 6-15 years (<45kg)	Children (>45kg) & Adults (16-60 years)
Starting dose	12 -14mg/kg/day up to a maximum of 300mg/day in 2 divided doses	300 mg/day in 2 divided
After 3 days,if tolerated, increase dose to	16 mg/kg/day up to a maximum of 400mg/day	400 mg/day in 2 divided
After 3 more days, if tolerated, increase dose to	20 mg/kg/day up to a maximum of 600mg/day	600 mg/day in 2 divided

Syrup

Titration step	Children 1-15 years (<45kg)	Children (>45kg) & Adults (16-60 years)
Starting dose	12 -14 mg/kg/day up to a maximum of 300mg/day divided in every 4 to 6	300mg/day divided in
After 3 days, if tolerated, increase dose to	16 mg/kg/day up to a maximum of 400mg/day divided in every 4 to 6 hours	400mg/day divided in
After 3 more days, if tolerated, increase dose to	20 mg/kg/day up to a maximum of 600mg/day divided in every 4 to 6 hours	600mg/day divided in

Use in pregnancy and lactation

Although Theophylline has a Category A rating, it does cross the placental barrier. The effect on foetal development is not known. Theophylline clearance is significantly decreased in premature infants. Therefore, if this drug is administered to the mother near the time of delivery, the neonate should be monitored closely for the pharmacological effects of Theophylline. Hence the use of Theophylline in pregnant women should be balanced against the risk of uncontrolled asthma.

Theophylline is secreted in breast milk and irritability has been reported in infants of nursing mothers taking Theophylline. It is advisable to keep serum Theophylline concentrations as low as possible in nursing mothers while maintaining adequate asthma control.

Side effects

The most common side effects are gastric irritation, nausea, vomiting, anorexia, epigastric pain, reactivation of peptic ulcer, gastro-oesophageal reflux, haematemesis, tachycardia, palpitation, headache, CNS stimulation, reflex hyperexcitability, insomnia and tremor. The less common adverse reactions are diarrhoea, extrasystoles, flushing, hypotension, tachypnoea, potentiation of diuresis, albuminuria, haematuria, rash, hyperglycaemia, hypokalaemia, alopecia and inappropriate ADH secretion (high dose). More serious signs of high serum levels (usually above 30µg/mL), such as cardiac arrhythmias and convulsions may appear rarely without prior warning.

Contraindications

Theophylline is contraindicated in individuals who have known hypersensitivity to Theophylline or other xanthine derivatives.

Precautions

Theophylline should be given with caution to patients with peptic ulceration, hyperthyroidism, hypertension, cardiac arrhythmias or other cardiovascular disease or epilepsy, as these conditions may be exacerbated. It should also be given with caution to patients with heart failure, hepatic dysfunction or chronic alcoholism and acute febrile illness.

Drug interactions

Theophylline clearance may be reduced by cimetidine, high dose allopurinol, propranolol, macrolide antibiotics (e.g., erythromycin, clarithromycin), quinolone antibiotics (e.g., ciprofloxacin and enoxacin), alcohol, oral contraceptives, mexilitene, tacrine, thiabendazole, disulfiram, Interferon alpha and verapamil. Theophylline clearance may be increased by tobacco or marijuana smoking, phenobarbitone, phenytoin, carbamazepine and rifampicin.

Ventricular arrhythmias have been reported when halothane is used concurrently with Theophylline. Concurrent use of ketamine with Theophylline may lower the seizure threshold. Theophylline has been reported to enhance the renal clearance of lithium, thus reducing serum lithium levels. Synergism with adrenaline and other sympathomimetic amines has been reported with Theophylline. The effect of ranitidine, diltiazem, nifedipine, isoniazid, frusemide, influenza vaccine and corticosteroids on Theophylline is uncertain, but concomitant use of these drugs should be monitored closely.

Overdose

Overdose may lead to agitation, diuresis, repeated vomiting (sometimes haematemesis), consequent dehydration, cardiac arrhythmias including tachycardia, hypotension, and electrolyte disturbances including profound hypokalaemia, hyperglycemia, metabolic acidosis, convulsions and death.

Pharmaceutical precautions

Store in a cool and dry place. Protect from light. Keep away from the reach of children.

Presentation

Teolex® SR 200 tablet: Each sustained released tablet contains Theophylline BP 200mg.

Teolex® SR 300 tablet: Each sustained released tablet contains Theophylline BP 300mg.

Teolex® SR 400 tablet: Each sustained released tablet contains Theophylline BP 400mg.

Teolex® syrup: Each 5 ml contains Theophylline Sodium Glycinate USP 120 mg equivalent to Anhydrous Theophylline 55 mg.

Package quantities

Teolex® SR 200 tablet: Carton of 100 tablet in blister pack.

Teolex® SR 300 tablet: Carton of 100 tablet in blister pack.

Teolex® SR 400 tablet: Carton of 100 tablet in blister pack.

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