



Unilin®

Theophylline

Description

Theophylline is structurally classified as a methylxanthine. It is a bronchodilator that directly relaxes smooth muscle of the respiratory tract and produces relief of bronchospasm.

Mode of action

Theophylline has two distinct actions in the airways of patients with reversible obstruction; smooth muscle relaxation (i.e., bronchodilation) and suppression of the response of the airways to stimuli (i.e., non-bronchodilator prophylactic effects). While the mechanisms of action of theophylline are not known with certainty, studies in animals suggest that bronchodilation is mediated by the inhibition of two isozymes of phosphodiesterase (PDE III and, to a lesser extent, PDE IV) while non-bronchodilator prophylactic actions are probably mediated through one or more different molecular mechanisms, that do not involve inhibition of PDE III or antagonism of adenosine receptors.

Pharmacokinetics

Theophylline is rapidly and completely absorbed after oral administration in solution or immediate-release solid oral dosage form. Theophylline does not undergo any appreciable pre-systemic elimination, distributes freely into fat-free tissues and is extensively metabolized in the liver.

Composition

Unilin® CR 200 mg Tablet: Each controlled release tablet contains Theophylline USP 200 mg.

Unilin® CR 300 mg Tablet: Each controlled release tablet contains Theophylline USP 300 mg.

Unilin® CR 400 mg Tablet: Each controlled release tablet contains Theophylline USP 400 mg.

Unilin® 50 ml Syrup: Each 5 ml syrup contains theophylline sodium glycinate USP 120 mg equivalent to anhydrous theophylline 55 mg.

Unilin® 100 ml Syrup: Each 5 ml syrup contains theophylline sodium glycinate USP 120 mg equivalent to anhydrous theophylline 55 mg.

Indications

Theophylline is indicated for the treatment of the symptoms and reversible airflow obstruction associated with chronic asthma and other chronic lung diseases, e.g., emphysema and chronic bronchitis. Also indicated in control of apnea of pre-maturity.

Dosage & administration

Tablet

| Titration Step | Children (12-15 years) | Adults (16-60 years) |
|--|---|--|
| Starting dose | 12-14 mg/kg/day up to a maximum of 300 mg/day | 300 - 400 mg/day |
| After 3 days, if tolerated, increase dose to: | 16 mg/kg/day up to a maximum of 400 mg/day | 400 - 600 mg/day |
| After 3 more days, if tolerated, and if needed increase dose to: | 20 mg/kg/day up to a maximum of 600 mg/day | As with all theophylline products, doses greater than 600 mg should be titrated according to blood level |

Syrup

| Patient type | Age | Dose |
|--------------|------------|--|
| Children | 1-6 years | 1/2-1 teaspoonful every 6 hours after meal |
| | 6-12 years | 1-1 1/2 teaspoonful every 6 hours after meal |
| Adult | >12 years | 2-4 teaspoonful every 6 hours after meal |

Contraindication

Theophylline is contraindicated in patients with a history of hypersensitivity to theophylline or other components in the product. It is also contraindications in patients with active peptic ulcer.

Side effects

The following adverse reactions reported with theophylline are:

Gastro-intestinal: Nausea, vomiting, epigastric pain and diarrhea

Central nervous system: Headache, irritability, restlessness, insomnia, muscle twitching

Cardiovascular: Palpitation, tachycardia, hypotension, circulatory failure

Respiratory: tachypnoea

Renal: potentiation of diuresis

Others: alopecia, hyperglycemia, rash etc.

Use in pregnancy & lactation

Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women.

Theophylline should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: Theophylline is excreted into breast milk and may cause irritability or other signs of mild toxicity in nursing human infants.

Precautions

Theophylline should not be administered concurrently with other xanthine. Use with caution in patients with hypoxemia, hypertension, or those with history of peptic ulcer. Do not attempt to maintain any dose that is not tolerated.

Drug Interactions

With drugs: Alcohol, Allopurinol, Ciprofloxacin, Clarithromycin, Disulfiram, Enoxacin, Erythromycin, oral contraceptives, Interferon, human recombinant alpha-A, Methotrexate (MTX, Mexiletine, Pentoxyfylline, Propafenone, Propranolol, Tacrine, Thiabendazole, Ticlopidine, Troxandromycin, Verapamil, St John's wort increase serum theophylline level. Aminoglutethimide, Carbamazepine, Isoproterenol (IV), Moricizine, Phenobarbital (PB), Rifampin, Sulfinpyrazone decrease serum theophylline level. It has also interactions with Adenosine, Diazepam, Ephedrine, Flurazepam, Fluvoxamine, Halothane, Ketamine, Lithium, Pancuronium.

With food: The peak plasma concentration and bioavailability of theophylline were increased in case of drug administration with food or meal.

Overdosage

In general, patients who experience an acute overdose are less likely to experience seizures than patients who have experienced a chronic overdosage, unless the peak serum theophylline concentration is >100 mcg/mL. After a chronic overdosage, generalized seizures, life-threatening cardiac arrhythmias, and death may occur at serum theophylline concentrations >30 mcg/mL. The severity of toxicity after chronic overdosage is more strongly correlated with the patient's age than the peak serum theophylline concentration; patients >60 years are at the greatest risk for severe toxicity and mortality after a chronic overdosage. Pre-existing or concurrent disease may also significantly increase the susceptibility of a patient to a particular toxic manifestation, e.g., patients with neurologic disorders have an increased risk of seizures and patients with cardiac disease have an increased risk of cardiac arrhythmias for a given serum theophylline concentration compared to patients without the underlying disease.

Storage

Store in a cool and dry place, protected from light.

Packaging

Unilin® CR 200 mg Tablet: Each box contains 10X10 tablets in blister pack.

Unilin® CR 300 mg Tablet: Each box contains 10X10 tablets in blister pack.

Unilin® CR 400 mg Tablet: Each box contains 10X10 tablets in blister pack.

Unilin® 50 ml Syrup: Each bottle contains 50 ml syrup.

Unilin® 100 ml Syrup: Each bottle contains 100 ml syrup.

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