



Arofil® SR

Theophylline 200 mg, 300 mg & 400 mg sustained release tablet

Presentation

Arofil® 200 SR: Each film coated tablet contains Theophylline BP 200 mg in a sustained release formulation.

Arofil® 300 SR: Each film coated tablet contains Theophylline BP 300 mg in a sustained release formulation.

Arofil® 400 SR: Each film coated tablet contains Theophylline BP 400 mg in a sustained release formulation.

Description

Theophylline is a Xanthine derivative bronchodilator; it directly relaxes the smooth muscle of the bronchial airways and smooth pulmonary blood vessels, thus acting mainly as a bronchodilator and smooth muscle relaxant.

Indication

- 1) Control of acute asthma
- 2) Management of chronic asthma (For both symptomatic and prophylactic treatment)
- 3) For controlling nocturnal asthma and early morning wheezing
- 4) Management of chronic obstructive lung disease (chronic bronchitis and emphysema) and acute exacerbation of chronic obstructive lung disease
- 5) Control of apnea of pre-maturity

Dosage & administration

Usually Arofil SR tablet is given 12 hourly or as directed by the physicians.

Age	Dose/day in bid
1-9 years	24 mg/kg
9-12 years	20 mg/kg
12-16 years	18 mg/kg
Over 16 years	13 mg/kg or 900 mg

Contraindication

Theophylline is contraindicated in individuals who have shown hypersensitivity to Theophylline or other Xanthines. It is also contraindicated in patients with active peptic ulcer disease and in individuals with underlying seizure (unless receiving an appropriate anticonvulsant medication).

Precaution

Smoking and alcohol consumption can increase the clearance of Theophylline and a higher dosage may be necessary. Careful monitoring is recommended for patients with congestive heart failure, chronic alcoholism, hepatic dysfunction or viral infections as they may have lower total clearance of Theophylline which could lead to higher than normal plasma levels. Caution should be exercised in patients with hyperthyroidism, cardiac arrhythmia, hypertension or other cardiovascular diseases.

Side-effects

These usually occur when Theophylline blood levels exceed 20 µgm/ml and include gastric irritation, nausea, vomiting, abdominal discomfort and palpitations, a fall in blood pressure, headache, occasional diarrhoea and insomnia. CNS stimulation and diuresis may also occur, especially in children.

Use in Pregnancy & Lactation

Safety in human pregnancy has not been established. Theophylline crosses the placental barrier & is secreted in breast milk. Theophylline should be used with caution in pregnancy & lactation.

Drug interaction

Theophylline should not be used concurrently with other preparations containing Xanthine derivatives. The clearance of Theophylline is increased by Barbiturate, Carbamazepine, Lithium, Phenytoin, Rifampicin and Sulphyprazole and it may be therefore be necessary to increase dosage. On the other hand the clearance of the drug is reduced by Allopurinol, Cimetidine, Ciprofloxacin, Corticosteroids, Erythromycin, Frusemide, Isoprenaline, Oral Contraceptives and Thiabendazole and a reduced dosage may therefore be needed to avoid side-effects. Theophylline can potentiate hypokalaemia resulting from 2 agonist therapy, steroids, diuretics and hypoxia and so serum potassium levels should be monitored in such instances. Particular caution is advised in severe asthma.

Overdosage

Symptoms may include nausea, vomiting, gastrointestinal irritation, cramps, convulsions, tachycardia & hypotension. The stomach contents should be emptied & supportive measures employed to maintain circulation, respiration & fluid & electrolyte balance. Electrocardiographic monitoring should be carried out & in severe poisoning charcoal haemoperfusion should be used.

Commercial Pack

Arofil® 200 SR: Each box contains 10 blister strips of 10 sustained release tablets.

Arofil® 300 SR: Each box contains 5 blister strips of 10 sustained release tablets.

Arofil® 400 SR: Each box contains 5 blister strips of 10 sustained release tablets.

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