SPMC
THEOPHYLLINE EXTENDED RELEASE TABLETS 125mg

PRESENTATION:

SPMC Theophylline Extended Release Tablets 125mg:
Packs of 500 Tablets or 100 Tablets. Each white, circular, flat beveled tablet of 8mm in diameter with score mark on the one side and 'SPC" or "DHS" letters on the other side, contains Theophylline USP equivalent to 125mg.

PHARMACOKINETICS:
Theophylline is metabolized in the liver. The plasma- theophylline concentration is increased in heart failure, hepatic impairment, and in viral infections. The plasma- theophylline concentration is decreased in smokers, and by alcohol consumption. Differences in the half-life of theophylline are important because the toxic dose is close to the therapeutic dose.

INDICATIONS AND DOSE:
Reversible airways obstruction | Severe acute asthma | Chronic asthma
Adult: 250–500 mg every 12 hours
Chronic asthma
Child 6–11 years: 125–250 mg every 12 hours
Child 12–17 years: 250–500 mg every 12 hours
Chronic asthma
Child 2–5 years: 60–120 mg every 12 hours
Child 6–11 years: 125–250 mg every 12 hours
Child 12–17 years: 250–500 mg every 12 hours
Reversible airways obstruction | Severe acute asthma | Chronic asthma
Adult: 250–500 mg every 12 hours

DOSE ADJUSTMENTS DUE TO INTERACTIONS:
Dose adjustment may be necessary if smoking started or stopped during treatment.

DIRECTIONS FOR ADMINISTRATION:
In adults swallow whole with fluid or swallow enclosed Granules with soft food (e.g. yoghurt).
In children Contents of the capsule (enteric-coated Granules) may be sprinkled on to a spoonful of soft food
(E.g. yoghurt) and swallowed without chewing.

CONTRA-INDICATIONS:
Hypersensitivity to Theophylline and caffeine. Toxic effects of Theophylline, Aminophylline & other Xanthine are additive. Concomitant use with other Xanthine medications should be avoided.

DOSE ADJUSTMENTS DUE TO INTERACTIONS:
Dose adjustment may be necessary if smoking started or stopped during treatment.

SIDE EFFECTS:
Anxiety. Arrhythmias. Diarrhea. Dizziness gastrointestinal discomfort. Gastroesophageal reflux disease. Headache. hyperuricaemia . Nausea. Palpitations.
Seizure. Skin reactions. Sleep disorders. Tremor. Urinary
Disorders. Vomiting.

SIDE-EFFECTS, FURTHER INFORMATION:
Potentially serious hypokalaemia may result from beta2 agonist therapy. Particular caution is required in severe asthma, because This effect may be potentiated by concomitant treatment with theophylline and its derivatives, corticosteroids, and diuretics, and by hypoxia. Plasma-potassium concentration should therefore be monitored in severe asthma.

ADVICE TO PATIENTS:
Do not stop taking the drug without consulting your doctor. Stopping the drug may lead to worsening of the Asthmatic symptoms.

CAUTIONS:
Cardiac arrhythmias or other cardiac disease. Elderly (increased plasma-theophylline concentration). Epilepsy. Fever. Hypertension hyperthyroidism. Peptic ulcer. Risk of hypokalaemia

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HEPATIC IMPAIRMENT:
Dose adjustments Reduce dose.

PREGNANCY:
Neonatal irritability and apnoea have been reported. Theophylline can be taken as normal during pregnancy as it is particularly important that asthma should be well controlled during pregnancy.

BREAST FEEDING:
Present in milk-irritability in infant reported; modified-release preparations preferable. Theophylline can be taken as normal during breastfeeding

OVERDOSE:
Theophylline in overdose can cause vomiting which may be severe and intractable), agitation, restlessness, dilated pupils, sinus tachycardia, and hyperglycaemia. More serious effects are haematemesis, convulsions, and supraventricular and ventricular Arrhythmias. Severe hypokalaemia may develop rapidly.
Management: Symptomatic and supportive treatment. Immediately empty stomach by inducing emesis or by gastric lavage, followed by admin of activated charcoal and a cathartic. Treat seizures with IV diazepam 0.1-0.3 mg/kg up to 10 mg. Admin of phenothiazines for intractable hyperthermia and propranolol for extreme tachycardia may be given in life-threatening situations.

INTERACTIONS:
Increased plasma concentrations with allopurinol, some antiarrhythmics, cimetidine, disulfiram, fluvoxamine, interferon alfa, macrolide antibiotics, quinolones, OCs, tiabendazole, viloxazine, Ca channel blockers. Reduced plasma concentrations with phenytoin and other antiepileptics, ritonavir, rifampicin, sulfinpyrazone, aminoglutethimide, barbiturates, carbamazepine. Enhanced lithium excretion. May potentiate hypokalaemia w/ corticosteroids and diuretics. Risk of synergistic toxicity when given with halothane or ketamine. May antagonise effects of adenosine and competitive neuromuscular blockers. Increased bronchospasm with β-blockers.

MONITORING REQUIREMENTS:
In most individuals, a plasma-theophylline concentration of 10–20 mg/liter (55–110 micromole/liter) is required for satisfactory bronchodilation, although a lower plasma theophylline concentration of 5–15 mg/liter may be effective. Adverse effects can occur within the range 10–20 mg/liter and both the frequency and severity increase at concentrations above 20 mg/liter. Plasma-theophylline concentration is measured 5 days after starting oral treatment and at least 3 days after any dose adjustment. A blood sample should usually be taken 4–6 hours after an oral dose of a modified-release preparation (sampling times may vary—consult local guidelines).

STORAGE:
Protect from light. Keep tightly closed in a cool dry place. Keep all medicines away from children. Store below 30^0C.

Manufactured by:
State Pharmaceuticals Manufacturing Corporation
No. 11, Sir John Kotalawala Mawatha,
Kandawala Estate,
Ratmalana, Sri Lanka.