

UNIKON

THEIPHYLINE USP

Compositions:

Unikon 400 SR Tablet: Each film-coated tablet contains Theophylline USP 400 mg in a sustained release formulation. Unikon Syrup: Each 5 ml syrup contains Theophylline Sodium Glycinate USP 120 mg which is equivalent to 60 mg of Theophylline.

Pharmacology:

Unikon (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.

Dosage And Administration:

Age Dose (mg/kg/day) 1-6 months 10 6 months-1 year 15 1-9 years 18 10-16 years 24 Adults 10-15

Contraindications:

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.

Warning And 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.

Side Effects:

These usually occur when Theophylline blood levels exceed 20 mgm/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 and Lactation:

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 barbiturates, carbamazepine, lithium, phenytoin, rifampicin and sulphapyrazole 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.

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.

Storage:

Store in cool and dry place (below 30°C), protect from light. Keep out of reach of children.

Packing:

Unikon 400 SR Tablet: Each box contains 10x10 tablets in blister pack. Unikon Syrup: Bottle contains 100 ml syrup and a measuring spoon

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.