SUCRASOL

Sucralfate USP

Compositions:
Each 5 ml Suspension contains Sucralfate USP 1 gm.

Pharmacology:
Sucralfate is a sucrose sulfate-aluminium complex that binds to the ulcer, creating a physical barrier that protects the gastrointestinal tract from stomach acid and prevents the degradation of mucus. It also promotes bicarbonate production and acts like an acid buffer with cytoprotective properties. The action of Sucrasol is non-systemic as the drug is only minimally absorbed from the gastro-intestinal tract.

Dosage And Administration:
Duodenal ulcer, gastric ulcer, chronic gastritis: Adults: The usual dose is 2 grams twice daily to be taken on rising and at bedtime or 1 gram 4 times a day to be taken 1 hour before meals and at bedtime. A maximum dose of 8 grams daily should not be exceeded. Four to six weeks' treatment is usually needed for ulcer healing, but up to twelve weeks may be necessary in resistant cases. Antacids may be used as required for relief of pain, but should not be taken half an hour before or after Sucrasol. Prophylaxis of gastrointestinal haemorrhage from stress ulceration: Adults: The usual dose is 1 gram six times a day. A maximum dose of 8 grams daily should not be exceeded. Antacids may be used as required for relief of pain, but should not be taken half an hour before or after Sucrasol. Sucrasol is not recommended for use in children under 14 years of age due to insufficient data on safety and efficacy.

Contraindications:
undefined

Warning And Precaution:
In patients with severe or chronic renal impairment, Sucrasol should be used with extreme caution and only for short-term treatment. Small amounts of aluminium from Sucralfate are absorbed through the gastrointestinal tract and aluminium may accumulate. Aluminium osteodystrophy, osteomalacia, encephalopathy and anaemia have been reported in patients with chronic renal impairment. For patients with impairment of renal function, laboratory testing such as aluminium, phosphate, calcium and alkaline phosphatase is recommended to be periodically performed due to excretion impairment.

Side Effects:
Side effects like anaphylactic reaction, dizziness, headache, drowsiness, vertigo, constipation, dry mouth, nausea may appear.

Use in Pregnancy and Lactation:
Teratogenicity studies in mice, rats and rabbits at doses up to 50 times the human dose have revealed no evidence of harm to the fetus. Safety in pregnant women has not been established and Sucrasol should be used during pregnancy only if clearly needed. It is not known whether this drug is excreted in human milk. Caution should be exercised when Sucrasol is administered to breast-feeding women.

Drug Interaction:
undefined

Overdosage:
In a clinical trial overdose with Sucralfate most cases remained asymptomatic, but symptoms

of abdominal pain, nausea and vomiting were reported in a few cases. Acute oral toxicity studies in animals, using doses up to 12 g/kg body weight, could not find a lethal dose.

Storage:
Store in a cool (below 300C) and dry place, away from light & moisture. Keep out of the reach of children

Packing:
Each box contains 200 ml oral suspension in PET bottle with a measuring cup.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.