

Sulfate

Sucralfate USP 1 gm/5 ml

Composition

Sulfate 200 ml Suspension: Each 5 ml suspension contains Sucralfate USP 1 gm.

Pharmacology

Sucralfate is a sucrose sulfate-aluminum 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 Sulfate is non-systemic as the drug is only minimally absorbed from the gastrointestinal tract.

Indication

It is indicated for the treatment of duodenal ulcer, gastric ulcer, chronic gastritis and the prophylaxis of gastrointestinal hemorrhage from stress ulceration in seriously ill patients.

Dose & Administration

a) *Route of administration:* Oral.

Duodenal ulcer, gastric ulcer, chronic gastritis:

Adults: The usual dose is 2 gm twice daily to be taken on rising and at bedtime or 1 gm 4 times a day to be taken 1 hour before meals and at bedtime. Maximum daily dose 8 gm.

Four to six weeks of 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 Sucralfate.

Prophylaxis of gastrointestinal hemorrhage from stress ulceration:

Adults: The usual dose is 1 gm six times a day. A maximum dose of 8 gm 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 Sucralfate or as directed by the Physician.

Contra-indication

It is contraindicated in patients with known hypersensitivity to the active substance or to any of the excipients.

Warning & Precaution

In patients with severe or chronic renal impairment, Sucralfate should be used with extreme caution and only for short term treatment. Small amount 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

a) *Common:* Side effects like anaphylactic reaction, dizziness, headache, drowsiness, vertigo, constipation, dry mouth and nausea may appear.

b) *Rare:* Rare side effects are skin rash, hives, itching, throat swelling etc.

Use in Pregnancy & Lactation

Pregnancy: 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 it should be used during pregnancy only if clearly needed.

Lactation: It is not known whether this drug is excreted in human milk. Caution should be exercised when Sucralfate is administered to breastfeeding women.

Use in children & adolescents

Sucralfate is not recommended for use in children under 14 years of age due to insufficient data on safety and efficacy.

Drug Interaction

a) *With Medicine:* Concomitant administration of Sucralfate may reduce the bioavailability of certain drugs including fluoroquinolones such as ciprofloxacin and norfloxacin, tetracycline, ketoconazole, sulpiride, digoxin, warfarin, phenytoin, theophylline, levothyroxine, quinidine and H₂ antagonists. The bioavailability of these agents may be restored by separating the administration of these agents from Sucralfate by two hours. Co-administration of citrate preparations with Sucralfate may increase the blood concentrations of aluminium.

b) *With food & others:* Milk & dairy products may interact with this medicine.

Overdose

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 gm/ kg body weight, could not find a lethal dose.

Storage

Store below 30°C. Protect from light and moisture. Keep all medicines out of reach of children. Do not refrigerate or freeze.

Packing

Sulfate 200 ml Suspension: Each box contains a Pet bottle of 200 ml suspension with a measuring cup.