Sucrate

Suspension

Sucralfate USP

Composition
Each 5 ml suspension contains Sucralfate USP 1 g.

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 Sucrate is non systemic as the drug is only minimally absorbed from the gastro-intestinal tract.

Indications
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.

Dosage & Administration
Route of administration : Oral.
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. Maximum daily dose 8 grams.
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 of after Sucrate.
Prophylaxis of gastrointestinal hemorrhage 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 Sucrate.
OR AS DIRECTED BY THE PHYSICIAN.

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

Warnings & Precautions
In patients with severe or chronic renal impairment, Sucrate 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
Common: Side effects like anaphylactic reaction, dizziness, headache, drowsiness, vertigo, constipation, dry mouth, nausea may appear.
Rare: Rare side effects are skin rash, hives, itching, throat swelling etc.

Use in Pregnancy and Lactation
Use in 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 Sucrate should be used during pregnancy only if clearly needed.
Use in Lactation : It is not known whether this drug is excreted in human milk. Caution should be exercised when Sucrate is administered to breast-feeding women.

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

Drug Interactions
With Medicine: Concomitant administration of Sucrate may reduce the bioavailability of certain drugs including fluoroquinolones such as ciprofloxacin and norfloxacin, tetracycline, ketoconazole, sulpiride, digoxin, warfarin, phenytoin, theophylline, levothyroxine, quinidine and H_2 antagonists. The bioavailability of these agents may be restored by separating the administration of these agents from Sucrate by two hours. Co-administration of citrate preparations with Sucrate may increase the blood concentrations of aluminium.
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 g/ kg body weight, could not find a lethal dose.

Storage
Store below 30^0 C temperature and dry place, protected from light.
Keep all medicines out of reach of children.

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

* Further information is available on request.

Manufactured by:
The ACME Laboratories Ltd.
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For Health, Vigour and Happiness

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