

Ulfate™

Sucralfate

Presentation

Ulfate™ Suspension: Each 5 ml Suspension contains Sucralfate USP 1 gm.

Descriptions

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

Indications

Ulfate is indicated in adults and adolescents over 14 years old for treatment of duodenal ulcer, gastric ulcer, chronic gastritis and the prophylaxis of gastrointestinal hemorrhage from stress ulceration in seriously ill patients.

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. 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 or after Ulfate.

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 Ulfate.

Side Effects

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

Precautions

In patients with severe or chronic renal impairment, Ulfate 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.

Contraindications

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

Use in pediatric population

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

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 Ulfate 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 Ulfate is administered to breast-feeding women.

Drug Interaction

Concomitant administration of Ulfate 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 Ulfate by two hours. Co-administration of citrate preparations with Ulfate may increase the blood concentrations of aluminium.

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 in a cool and dry place, away from light & moisture. Keep out of the reach of children

Commercial Packaging

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



Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
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Ulfate
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