Ulrif™

Sucralfate

COMPOSITION

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

PHARMACOLOGY

Sucralfate is non-systemic as the drug is only minimally absorbed from the gastrointestinal tract. The minute amount which absorbed primarily excretes in the urine. Sucralfate promotes the healing of gastric and duodenal ulcers by formation of a chemical complex that binds to the ulcer site to establish a protective barrier. Beside, Sucralfate inhibits the action of pepsin and bile.

INDICATION

Ulrif™ is indicated in adults and adolescents over 14 years old for the treatment of-

- Duodenal ulcer
- Gastric ulcer
- Chronic gastritis
- Prophylaxis of gastrointestinal hemorrhage from stress ulceration

DOSAGE & ADMINISTRATION

Duodenal ulcer, gastric ulcer, chronic gastritis:

Adults: The usual dose is 2 grams or 10 ml twice daily to be taken on rising and at bedtime, or 1 gram or 5 ml 4 times a day to be taken 1 hour before meals and at bedtime. Maximum daily dose: 8 grams or 40 ml.

Four to six weeks treatment is usually needed for ulcer healing, but up to twelve weeks may be necessary in resistant cases.

Prophylaxis of gastrointestinal hemorrhage from stress ulceration:

Adults: The usual dose is 1 gram or 5 ml six times a day. A maximum dose of 8 grams or 40 ml 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.

CONTRAINDICATION

Patients with known hypersensitivity to the active substance or to any of the excipients.

USE IN SPECIAL POPULATION

Pregnancy: Safety in pregnant women has not been established and Sucralfate 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 breast-feeding women.

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

In elderly patients: Dose adjustments are not necessary.

Renal Impairment: Sucralfate should be used with caution in renal insufficiency patients.

SIDE EFFECTS

The most common adverse event was headache (3.4%) followed by nausea (2.3%), abdominal pain (2.3%), constipation (1.1%), diarrhea (1.1%), and urticaria (1.1%). The majority of patients who reported bezoars, had underlying medical conditions that may predispose to bezoar formation (such as delayed gastric emptying) or were receiving concomitant enteral tube feedings. Episodes of hyperglycemia have been reported in diabetic patient.

DRUG INTERACTION

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 H_2 antagonists. The bioavailability of these agents may be restored by separating the administration of these agents from Sucralfate by two hours. Co-administration of Sucralfate with Citrate preparations may increase the blood concentrations of Aluminum. The concomitant use of other Aluminum containing medications is not recommended in view of the enhanced potential for Aluminum absorption and toxicity.

PRECAUTION & WARNING

Sucralfate must not be administered intravenously to avoid pulmonary and cerebral emboli, Aluminum intoxication etc. Sucralfate is not recommended for use in individuals on dialysis. In patients with severe or chronic renal impairment, Sucralfate should be used with extreme caution and laboratory testing such as Aluminum, Phosphate, Calcium, and Alkaline Phosphatase is recommended to be periodically performed due to excretion impairment.

The administration of Sucralfate suspension and enteral feeds by nasogastric tube should be separated by one hour to avoid bezoar formation.

STORAGE

Store below 30^0 C temperature, protected from light. Keep out of reach of children.

HOW SUPPLIED

Ulrif™ Suspension: Each bottle contains 200 ml suspension.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH