Protecto™

Sucralfate USP Suspension

DESCRIPTION

Protecto™ is a suspension of sucralfate. Sucralfate exerts a generalized gastric cytoprotective effect by enhancing natural mucosal defense mechanisms. Studies conducted in animals and clinical trials in humans have demonstrated that sucralfate can protect the gastric mucosa against various irritants such as Alcohol, Acetylsalicylic acid (ASA), Hydrochloric acid, Sodium hydroxide or Sodium Taurocholate.
In addition, sucralfate has been demonstrated to have a greater affinity for ulcerated gastric or duodenal mucosa than for non-ulcerated mucosa.
Sucralfate produces an adherent and cytoprotective barrier at the ulcer site. This barrier protects the ulcer site from the potential ulcerogenic properties of acid, pepsin and bile. Furthermore, sucralfate blocks acid diffusion across the sucralfate protein barrier and also complexes directly with pepsin and bile.

INDICATIONS

- Treatment of duodenal ulcer.
- Prophylaxis of duodenal ulcer recurrence.
- Prophylaxis of gastrointestinal hemorrhage due to stress ulceration in seriously ill patients.

DOSAGE AND ADMINISTRATION

Treatment of	Adults	Paediatric
Duodenal ulcer, gastric ulcer, chronic gastritis	2 grams (10 mL) twice daily to be taken on rising and at bedtime or 1 gram (5 mL) 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.	The safety and efficacy of **Protecto**™ in children under 14 years of age has not been established.
Prophylaxis of gastrointestinal haemorrhage from stress ulceration	1 gram (5 mL) 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 **Protecto**™ suspension.

CONTRAINDICATIONS

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

SIDE EFFECTS

- Anaphylactic reaction including pruritus, urticaria, oedema, dyspnoea
- Dizziness, headache, drowsiness • Vertigo • Constipation • Dry mouth • Nausea • Bezoar formation

PRECAUTION AND WARNING

Protecto™ suspension must not be administered intravenously. Inadvertent intravenous administration of insoluble sucralfate and its insoluble excipients may induce fatal complications including pulmonary and cerebral emboli. Other severe complications including aluminium intoxication are reported after intravenous administration.
The product should only be used with caution in patients with renal dysfunction, due to the possibility of increased aluminium absorption.
Protecto™ is not recommended for use in individuals on dialysis.

USE IN PREGNANCY AND LACTATION

Use in Pregnancy
Teratogenicity studies have been performed in mice, rats, and rabbits at doses up to 50 times the human dose and have revealed no evidence of harm to the fetus due to Sucralfate. Safety in pregnant women has not been established and sucralfate 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 Sucralfate is administered to a nursing woman.

PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of the reach of children.

PACKAGING

Protecto™ Suspension: Box containing 1 bottle of 200 mL Suspension. Each 5 mL suspension contains Sucralfate USP 1 gm.

SK+F
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
TONGI, GAZIPUR, BANGLADESH
TM. TRADEMARK
PM08362 V01