SUCRALOX

Sucralfate and Oxetacaine Suspension

Dosage Form:
Oral- Liquid Suspension

Composition:
Each 10 ml contains:

Sucralfate BP	1000mg
Oxetacaine BP	20mg
Flavoured Sugar Free Base	Q.S
Colour: Sunset Yellow FCF	

Mode of action:
Sucralfate is locally acting substance that in active environment (pH<4) react with hydrochloric acid in the stomach to form a cross linking, viscous, paste like material capable of acting as an acid buffer for as long as 6 to 8 hours after a single dose. It also attaches to proteins on the surface of ulcer such as albumin and fibrinogen to form stable, insoluble complexes. These complexes serve as protective barriers at the ulcer surface preventing further damage from acid, pepsin and bile. In addition it prevents back diffusion of hydrogen ions and absorbs both pepsin and bile acids. Recently it has been indicated that the surface also stimulates the increase of prostaglandin E2, epidermal growth factors and gastric mucous. Oxetacaine is an amide anaesthetic that is stated to have prolonged action. It is administered by mouth in conjugation with Sucralfate for the symptomatic relief of gastro-oesophageal reflux disease.

Pharmacology:
Sucralfate is only minimally absorbed from the gastrointestinal tract. The small amounts of the sulfated disaccharide that are absorbed are excreted primarily in the urine. Although the mechanism of sucralfate's ability to accelerate healing of duodenal ulcers remains to be fully defined, it is known that it exerts its effect through a local rather than systemic action. Sucralfate's antiulcer activity is the result of formation of an ulcer-adherent complex that covers the ulcer site and protects it against further attack by acid, pepsin and bile salts. There are approximately 14 to 16 mEq of acid neutralizing capacity per 1 g dose of Sucralfate. Oxetacaine is a local anaesthetic. In contrast to almost all other local anaethesia, Oxetacaine ionizes only to a very small extent at a low pH such as that of gastric acid. Since the anaesthetic effect is due to the nonionized molecules, which are lipid soluble and can penetrate nerve membranes, Oxetacaine maintains its activity even at a low pH. Oxetacaine relieves pain, bloating, discomfort and fullness. Normally Oxetacaine when administered alone is absorbed into the blood metabolized in the liver and excreted in the urine. But when given with Sucralfate its absorption is retarded and hence it remains in contact with gastric mucosa for a longer time. In course of time, it mixes with the food and passes into the intestines. However, the concentration obtained there is probably so low that no effect is produced on the intestinal mucosa.

Indications:
Sucralox is indicated in the short term treatment of active duodenal ulcer. It's also indicated for gastric ulcer, chronic gastritis and reflux oesophagitis.
Sucralox produces relief of subjective symptoms of peptic ulceration e.g. epigastric pain, hyperchlorhydria, vomiting etc.
Maintenance treatment after successful endoscopically proven, recently healed duodenal ulcer.

Contraindications:
Hypersensitivity to Sucralfate & Oxetacaine.

Dosage and Administration:
Active Duodenal Ulcer:
The recommended adult oral dosage for duodenal ulcer is two 5ml four times daily. Sucralox should be administered on an empty stomach.
It should be taken usually 1 hour before meals. While healing with Sucralfate may occur during the first week or two, treatment should be continued for 4 to 8 weeks unless healing has been demonstrated by x-ray or endoscopic examination.
Maintenance Therapy:
The recommended adult oral dosage is two 5ml teaspoonfuls twice a day.
Reflux oesophagitis:
Two 5ml teaspoonfuls four times a day between meals and bedtime.

Adverse reactions:
The most common side effects seen are constipation and bezoar formation. Less commonly reported include flatulence, cephalgia (headache), hypophosphetemia and xerostomia (dry mouth).

Drug Interactions:
Some studies have shown that simultaneous Sucralfate administration in healthy volunteers reduced the extent of absorption (bioavailability) of single dose of the following: Cimentidine, Digoxin, Flouroquinolone Antibiotics, Ketoconazole. L-thyroxine, Phenytoin, Quinidine, Ranitidine, Tetracycline and Theophylline

Pregnancy and Lactation:
Pregnancy:
Sucralox should be used during pregnancy only, if clearly needed.
Lactation:
Caution should be exercised when Sucralox is administered to nursing women.

Precaution/Warnings:
Sucralox should only be used with caution in patients with renal dysfunction, due to the possibility of increased aluminium absorption.
Sucralox is not recommended for use in individuals on dialysis. The concomitant use of other aluminium containing medications is not recommended in view of the enhanced potential for aluminium absorption and toxicity.

Overdose and Treatments:
Treatment should be symptomatic and supportive

Storage:
Store at a temperature not exceeding 30ºC in a dry place. Protect from light. Keep out of reach of children.

Presentation:
200 ml amber colour PET Bottle

Manufactured for:

Dawa Limited P. O. Box 16633 - 00620, Plot No. 7879/8, Baba Dogo Road. Nairobi, Kenya.
Manufactured by: Stallion Laboratories PVT. Ltd. C-1B, 305/2,3,4 & 5, G.I.D.C. Kerala (Bavla),
Dist.: Ahmedabad-382 220., Gujarat. India.

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