Surlka
(Sucralfate)

Suspension
1 g / 60 ml
COMPOSITION –

Basic Aluminium Sucrose Sulfate (Sucralfate) U.S.P. …. 5 ml/1g
Suspension 60 ml

THERAPEUTIC INDICATIONS

Sucralfate is indicated in adults and adolescents over 14 years old for the treatment of duodenal ulcer, gastric ulcer, chronic gastritis, and the prophylaxis of gastrointestinal haemorrhage 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 Sucralfate.

Paediatric population: The safety and efficacy of Sucralfate in children under 14 years of age has not been established. but no recommendation on posology can be made.

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 Sucralfate.

Paediatric population The safety and efficacy of Sucralfate in children under 14 years of age has not been established.

Elderly: There are no special dosage requirements for elderly patients but as with all medicines, the lowest effective dose should be used.

CONTRAINDICATIONS

Hypersensitivity to the active substance or to any of the excipients

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Sucralfate 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.

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 only for short-term treatment.

Small amounts of aluminium are absorbed through the gastrointestinal tract and aluminium may accumulate.

Aluminium osteodystrophy, osteomalacia, encephalopathy, and anemia 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.

The concomitant use of other aluminium containing medications is not recommended in view of the enhanced potential for aluminium absorption and toxicity.

Contains sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217) which may cause allergic reactions (possibly delayed).

Bezoars have been reported after administration of sucralfate mainly to severely ill patients in intensive care units. The majority of these patients (including neonates in whom sucralfate is not recommended) had underlying conditions that may predispose to bezoar formation (such as delayed gastric emptying due to surgery, drug therapy or diseases that reduce motility), or were receiving concomitant enteral tube feeding.

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

DRUG INTERCATIONS

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 H2 antagonists

The bioavailability of these agents may be restored by separating the administration of these agents from Sucralfate by two hours. This interaction appears to be non-systemic in origin presumably resulting from these agents being bound by Sucralfate in the gastrointestinal tract. Because of the potential of Sucralfate to alter the absorption of some drugs from the gastrointestinal tract, the separate administration of Sucralfate from that of other agents should be considered when alterations in bioavailability are felt to be critical for concomitantly administered drugs.

Sucralfate should not be co-administered with citrate preparations.

Co-administration of citrate preparations with sucralfate may increase the blood concentrations of aluminium. The mechanism may be due to chelation of aluminium, which is assumed to increase its absorption.

The administration of Sucralfate Suspension and enteral feeds by nasogastric tube should be separated by one hour in patients receiving Sucralfate Suspension for the prophylaxis of stress ulceration. In rare cases bezoar formation has been reported when Sucralfate and enteral feeds have been given too closely together

EFFCTS ON ABILITY TO DRIVE

Do not drive if you feel dizzy or drowsy

FERTILITY, PREGNANCY AND LACTATION

Pregnancy: Teratogenicity studies in mice, rats and rabits at dose 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 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

ADVERSE DRUG REACTIONS

Adverse reactions to sucralfate tablets in clinical trials were minor and only rarely led to discontinuation of the drug. In studies involving over 2,700 patients treated with sucralfate, adverse effects were reported in 129 (4.7%).

Constipation was the most frequent complaint (2%).
Other adverse effects reported in less than 0.5% of the patients are listed below by body system:

Gastrointestinal: diarrhea, dry mouth, flatulence, gastric discomfort, indige stion, nausea, vomiting

Dermatological: pruritus, rash

Nervous System: dizziness, insomnia, sleepiness, vertigo

Other: back pain, headache

Post-marketing cases of hypersensitivity have been reported with the use of sucralfate oral suspension, including anaphylactic reactions, dyspnea, lip swelling, edema of the mouth, pharyngeal edema, pruritus, rash, swelling of the face and urticaria.

Cases of bronchospasm, laryngeal edema and respiratory tract edema hav e been reported with an unknown oral formulation of sucralfate.

Cases of hyperglycemia have been reported with sucralfate.

Bezoars have been reported in patients treated with sucralfate. The majority of patients had underlying medical conditions that may predispose to bezoar formation (such as delayed gastric emptying) or were receiving concomitant enteral tube feedings.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at pv@searlecompany.com

OVERDOSE

Due to limited experience in humans with overdosage of sucralfate, no specific treatment recommendations can be given. Acute oral studies in animals, however, using doses up to 12 g/kg body weight, could not find a lethal dose. Sucralfate is only minimally absorbed from the gastrointestinal tract. Risks associated with acute overdosage should, therefore, be minimal. In rare reports describing sucralfate overdose, most patients remained asymptomatic.
Those few reports where adverse events were described included symptoms of dyspepsia, abdominal pain, nausea, and vomiting.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: Alimentary tract and metabolism, ATC code: A02B X02

Mechanism of action: The action of Sucralfate is non-systemic as the drug is only minimally absorbed from the gastro-intestinal tract. The small amounts that are absorbed are excreted primarily in the urine. Sucralfate exerts a generalized cytoprotective effect by preventing gastro-intestinal mucosal injury. Studies in humans and animal models show that Sucralfate forms an ulcer adherent complex with the proteinaceous exudate of the ulcer site. This property enables Sucralfate to form a protective barrier over the ulcer lesion giving sustained protection against the penetration and action of gastric acid, pepsin and bile. Studies both in humans and animals demonstrate that Sucralfate protects the gastric mucosa against various irritants such as alcohol, acetylsalicylic acid and sodium taurocholate. Sucralfate also directly inhibits pepsin activity and absorbs bile salts. It has only weak antacid activity. It does not alter gastric emptying time, nor normal digestive function. Sucralfate has no demonstrated pharmacological effect on the cardiovascular or central nervous systems.

Paediatric population: In the literature, there are limited clinical data on the use of sucralfate in children, mainly for stress ulcer prophylaxis, reflux esophagitis and mucositis. The dose used in these studies was 0.5-1g four times a day, depending on the children's age and the severity of the underlying disease, and was applied without major safety concerns. In view of the limited data, use of sucralfate in children under 14 years of age is currently not recommended

Pharmacokinetic properties

Sucralfate is only minimally absorbed from the gastro-intestinal tract. The small amounts that are absorbed are excreted primarily in the urine. Absorption of aluminium from sucralfate may be increased in patients on dialysis or with renal dysfunction.

Summary of Clinical Studies

In a multicenter, double-blind, placebo-controlled study of CARAFATE Oral Suspension, a dosage regimen of 1 gram (10 mL) four times daily was demonstrated to be superior to placebo in ulcer healing.

Results from Clinical Trials Healing Rates for Acute Duodenal Ulcer

Treatment	n	Week 2 Healing Rates	Week 4 Healing Rates	Week 8 Healing Rates
CARAFATE Oral Suspension	145	23(16%)*	66(46%)†	95(66%)‡
Placebo	147	10(7%)	39(27%)	58(39%)

*P=0.016 †P=0.001 ‡P=0.0001

Equivalence of sucralfate oral suspension to sucralfate tablets has not been demonstrated.

PRECLINICAL SAFETY DATA

There was no evidence of carcinogenesis in mice and rats receiving oral sucralfate in dosages of up to 1g/kg daily (12 times the usual human dosage) for 2 years. In animal studies there was no effect evidence of impaired fertility. The effect of sucralfate on human fertility is not known

PRESENTATION

Suspension: Bottle containing 60 ml suspension.

STORAGE INSTRUCTIONS

Shake well before use

To be sold on prescription of a registered medical practitioner

Protect from moisture, freezing, excessive heat and sunlight

Keep out of the reach from children

For better results take Surlka before meal

As prescribed by the physician

REGISTRATION NUMBER

M.L 000647

R.N 054571

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION – As per registrations letter

Mg. Searle Spac

SEARLE

Manufactured by:

The Searle Company Limited

32-Km, Lahore Road .Lahore –Pakistan

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