INDICATIONS AND USAGE

Acute Duodenal Ulcer

Data from placebo-controlled studies longer than 1 year are not available. The following trial had the following results:

Completeness of Healing After 4 Weeks of Therapy

<table>
<thead>
<tr>
<th>Group</th>
<th>Placebo</th>
<th>Sucralfate</th>
<th>OR</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>24h Liquid</td>
<td>46/31 (58%)</td>
<td>117/33 (87%)</td>
<td>2.77</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>24h Tablets</td>
<td>54/31 (80%)</td>
<td>19/31 (61%)</td>
<td>0.32</td>
<td>0.04</td>
</tr>
</tbody>
</table>

Maintenance Therapy After Healing of Duodenal Ulcers

In a double-blind, multicenter trial, patients were treated for 4 to 8 weeks. At the end of this period, 82% of the patients treated with sucralfate were healed as compared to 74% of those in the placebo group. Treatment should be continued for 4 weeks unless healing has been demonstrated by x-ray or endoscopic examination.

CONTRAINDICATIONS

There are no known contraindications to the use of sucralfate.

PRECAUTIONS

Duodenal ulcer is a chronic, recurrent disease. While short-term treatment with sucralfate can result in complete healing of the ulcer, a successful course of treatment with sucralfate should not be expected to alter the subsequent course of the disease in the majority of patients.

Special Populations: Chronic Renal Failure and Dialysis Patients

When sucralfate is administered to hospitalized patients, it is recommended that the medication be instigated in the dialysis unit during the maintenance phase of hemodialysis for the prevention of ulcer recurrence.

Drug Interactions

Sucralfate is not expected to affect other drugs. Inadvertent injection of insoluble sucralfate and its insoluble excipients has led to fatal complications, including pulmonary and cerebral embolism. Sucralfate is not intended for intravenous administration.

OVERDOSAGE

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Dosage and Administration

Active Duodenal Ulcer

The recommended adult oral dosage for duodenal ulcer is 1 g four times a day on an empty stomach. Antibiotics may be prescribed as needed for Helicobacter pylori. Montelukast (Singulair) should not be taken within one-half hour before or after sucralfate. In cases of acute overdose, treatment should be supportive and symptomatic. No definitive antidote is known for sucralfate. Reports of prothrombin time with the addition of sucralfate to chronic warfarin therapy have not demonstrated any change in either serum warfarin concentration or prothrombin time with the addition of sucralfate to chronic warfarin therapy.

The mechanism of these interactions appears to be a non-stereospecific inhibition of the cyclooxygenase enzyme. A decrease in the concentration of prostaglandins in the gastrointestinal tract should be monitored for patients taking cyclooxygenase inhibitors concomitantly with sucralfate. To date, no clinical consequences have been observed with the use of sucralfate in patients taking cyclooxygenase inhibitors. However, patients should be monitored for any signs of bleeding or decreased symptoms.

Teratogenicity studies have not been performed in mice, rats, or rabbits at doses up to 12 g/kg body weight. Results from other studies, however, suggest that no specific effects on reproduction can be predicted by animal studies. The majority of patients had underlying medical conditions that may predispose to increases in bleeding tendency or failure of drug absorption. Thus, caution should be used in patients with any indication of renal disease.

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Sucralfate tablets, USP are indicated in:

- Short-term treatment (up to 8 weeks) of active duodenal ulcer. While treatment should be continued for 4 to 8 weeks unless healing has been demonstrated by x-ray or endoscopic examination.

**CONTRAINDICATIONS**

Succralfate tablets, USP are contraindicated in patients with known hypersensitivity reactions to the active substance or to any of the excipients.

**PRECAUTIONS**

The physician should read the PRECAUTIONS section when considering the use of this drug in pregnant or pediatric patients, or patients of childbearing potential.

**DOSAGE AND ADMINISTRATION**

**Active Duodenal Ulcer**

The recommended adult oral dosage for duodenal ulcer is 1 g four times per day on an empty stomach.

**Pregnancy**

Sucralfate is not known to be a teratogen but is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when sucralfate is administered to a nursing woman.

**Pediatric Use**

Safety and effectiveness in pediatric patients have not been established.

**Geriatric Use**

Clinical studies of sucralfate tablets did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosage range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy (see PRECAUTIONS, Geriatric Use). Call your doctor for medical advice about side effects. You may report side effects to Actavis Pharma, Inc. at 1-800-686-1600 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

**OVERDOSAGE**

Due to limited experience in humans with overdosage of sucralfate, no specific treatment recommendations can be given. Acute oral toxicity 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, described hospitalizations, most patients remained asymptomatic. Those few reports where adverse events were described included symptoms of dyspepsia, abdominal pain, nausea, and vomiting.

**ADVERSE REACTIONS**

Reactions to sucralfate in clinical trials were minor and only rarely led to discontinuation of the drug. In studies involving over 3700 patients treated with sucralfate tablets, adverse effects were reported in 32% (1). Constipation was the most frequent complaint (2%). Other adverse effects reported in less than 5% of the patients listed below by body system:

- Gastrointestinal:
  - diarrhea, nausea, vomiting, gastric discomfort, indigestion, flatulence, dry mouth
- Dermatological:
  - pruritus, rash
- Nervous System:
  - dizziness, insomnia, sleepiness, vertigo
- Other:
  - back pain, headache

**How SUPPLIED**

Sucralfate tablets, USP are available as white, capsule-shaped, biconvex, scored tablets, debossed “TEVA” on one side, and “22” and “10” on the scored side, containing 1 gram of sucralfate USP, packaged in bottles of 100 (NDC 0951-3892-01) and 500 (NDC 0951-3892-05) tablets.

**STORAGE**

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]. Do not use any of the contents if the container has been returned with an child-resistant closure (as required).