Ulsanic®

(Sucralfate)

Highnoon

COMPOSITION

Ulsanic 1g/5mL Suspension: Each 5mL contains:
Basic Aluminium Sucrose Sulfate (Sucralfate) 1g
Ulsanic 1g Tablet: Each tablet contains:
Basic Aluminium Sucrose Sulfate (Sucralfate) 1g
Ulsanic 500mg Tablet: Each tablet contains:
Basic Aluminium Sucrose Sulfate (Sucralfate) 500mg

DESCRIPTION

Oral Suspension containing sucralfate and sucralfate is an a-D-glucopyranoside, β-D- fructofuranosyl-, octakis-(hydrogen sulfate), aluminium complex. It is a cytoprotective agent for the treatment of acid peptic disorders.

MECHANISM OF ACTION

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. Studies suggest:

- Sucralfate forms an ulcer-adherent complex with proteinaceous exudate at the ulcer site.
- A sucralfate-albumin film provides a barrier to diffusion of hydrogen ions.
- Sucralfate inhibits pepsin activity.
- Sucralfate adsorbs bile salts.

These observations further suggest that 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 gm dose of sucralfate.

PHARMACOKINETICS

Sucralfate is only slightly absorbed from the gastrointestinal tract after oral doses. However, there can be some release of aluminium ions and of sucrose sulfate; small quantities of sucrose sulfate may then be absorbed and excreted primarily in urine; some absorption of aluminium may also occur.

INDICATIONS

- Benign gastric ulcer
- Benign duodenal ulcer
- Chronic gastritis
- Prophylaxis of stress ulceration in children under intensive care
- Prophylaxis of stress ulceration

DOSAGE AND ADMINISTRATION

It should be administered orally on an empty stomach.

Benign gastric ulcer and benign duodenal ulcer

Child 15 to 17 years: 2gm twice daily, dose to be taken on rising and at bedtime, alternatively 1gm four times a day for 4 to 6 weeks, or in resistant cases up to 12 weeks, dose to be taken 1 hour before meals and at bedtime; maximum 8 gm per day.

Adult: 2gm twice daily, dose to be taken on rising and at bedtime, alternatively 1gm four times a day for 4 to 6 weeks, or in resistant cases up to 12 weeks, dose to be taken 1 hour before meals and at bedtime; maximum 8g per day.

Chronic gastritis

Adult: 2gm twice daily, dose to be taken on rising and at bedtime, alternatively 1gm four times a day for 4 to 6 weeks, or in resistant cases up to 12 weeks, dose to be taken 1 hour before meals and at bedtime; maximum 8gm per day.

Peptic ulcer disease or prophylaxis of stress ulceration in children under intensive care

Child

1 month to 1 year: 250mg 4 to 6 times daily
2 to 11 years: 500mg 4 to 6 times daily
12 to 14 years: 1gm 4 to 6 times daily
15-17 years: 1gm six times a day; maximum 8gm per day

Prophylaxis of stress ulceration

Adult: 1gm six times a day; maximum 8g per day.
Antacids may be prescribed as needed for relief of pain but should not be taken within one-half hour before or after Sucralfate. 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.

Elderly, In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

CONTRAINDICATIONS

Sucralfate is contraindicated for patients with known hypersensitivity reactions to the active substance or to any of the excipients.

WARNINGS AND PRECAUTIONS

- Fatal complications, including pulmonary and cerebral emboli have occurred with inappropriate intravenous administration of Sucralfate. Administer Sucralfate only by the oral route. Do not administer intravenously.
- 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 post healing frequency or severity of duodenal ulceration.
- Episodes of hyperglycaemia have been reported in diabetic patients. Close monitoring of glycemia in diabetic patients treated with Sucralfate is recommended. Adjustment of the anti-diabetic treatment dose during the use of Sucralfate might be necessary.

ADVERSE REACTIONS

The reported adverse reactions are; constipation, diarrhoea, dry mouth, flatulence, gastric discomfort, indigestion, nausea, vomiting, dermatological: pruritus, rash, dizziness, insomnia, sleepiness, vertigo, drowsiness, encephalopathy, back pain, bone disorders, headache, hypersensitivity reactions including anaphylactic reactions, dyspnoea, lip swelling, oedema of the mouth, pharyngeal oedema, pruritus, rash, swelling of the face and urticaria, bronchospasm, laryngeal oedema and respiratory tract oedema, hyperglycaemia and bezoars.

DRUG INTERACTIONS

Simultaneous sucralfate administration in healthy volunteers reduced the extent of absorption (bioavailability) of single doses of the following: cimetidine, digoxin, fluoroquinolone antibiotics, ketoconazole, levothyroxine, phenytoin, quinidine, ranitidine, tetracycline, and theophylline. Subtherapeutic prothrombin times with concomitant warfarin and sucralfate therapy have been reported in spontaneous and published case reports. However, two clinical studies have demonstrated no 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 nonsystemic in nature, presumably resulting from sucralfate binding to the concomitant agent in the gastrointestinal tract. In all cases studied to date (cimetidine, ciprofloxacin, digoxin, norfloxacin, ofloxacin, and ranitidine), dosing the concomitant medication 2 hours before sucralfate eliminated the interaction. Due to Sucralfate's potential to alter the absorption of some drugs, It should be administered separately from other drugs when alterations in bioavailability are felt to be critical. In these cases, patients should be monitored appropriately.

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic effects. Pregnancy Category B. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers

It 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.

Paediatric Use

Safety and effectiveness in paediatric patients have not been established.

Chronic Renal Failure and Dialysis Patients

When sucralfate is administered orally, small amounts of aluminium are absorbed from the gastrointestinal tract. Concomitant use of sucralfate with other products that contain aluminium, such as aluminium-containing antacids, may increase the total body burden of aluminium. Patients with normal renal function receiving the recommended doses of sucralfate and aluminium- containing products adequately excrete aluminium in the urine. Patients with chronic renal failure or those receiving dialysis have impaired excretion of absorbed aluminium. In addition, aluminium does not cross dialysis membranes because it is bound to albumin and transferrin plasma proteins. Aluminium accumulation and toxicity (aluminium osteodystrophy, osteomalacia, encephalopathy) have been described in patients with renal impairment. Sucralfate should be used with caution in patients with chronic renal failure.

Geriatric Use

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

OVERDOSAGE

Due to limited experience in humans with overdosage of sucralfate, no specific treatment recommendations can be given. 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.

DOSAGE AND INSTRUCTIONS

To be sold and used on the prescription of a registered medical practitioner only. Keep out of reach of children. Do not store above 30°C. Keep in a dry place. Protect from light.

PRESENTATION

Ulsanic 1g/5mL Suspension: Glass Bottle of 120mL.
Ulsanic 1g/5mL Suspension: Glass Bottle of 60mL.
Ulsanic 1g Tablets: Alu. PVC. Blister Pack of 1 x 10's.
Ulsanic 500mg Tablets: Alu. PVC. Blister Pack of 2 x 10's.

السانک®

(سُکرلفیٹ)

خوراک و ہدایات:

صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت اور استعمال کی جائے۔
بچوں کی پہنچ سے دور رکھیں۔ 30°C سے زیادہ درجہ حرارت پر نہ رکھیں۔
خشک جگہ پر رکھیں۔ روشنی سے بچائیں۔

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