1.3.1. SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

INN Name: Sucralfate Oral Suspension 1g/10mL

Trade Name: Sucralfate

Strength: 1g/10mL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10ml of suspension contains 1*g* of Sucralfate.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pink color homogeneous suspension with cherry flavor.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Sucralfate Oral Suspension is indicated in the short-term (up to 8 weeks) treatment of active duodenal ulcer.

For Evacuation of the bowel prior to radiological, endoscopic or surgical procedures.

4.2 Posology and method of administration

Route of administration: Oral

Active Duodenal Ulcer: The recommended adult oral dosage for duodenal ulcer is 1 gram (10 mL) four times per day. Sucralfate Oral Suspension should be administered on an empty stomach.

Antacids may be prescribed as needed for relief of pain but should not be taken within one-half hour before or after Sucralfate Oral Suspension.

While healing with Sucralfate may occur during the first week or two, treatment should be contin ued 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

4.3 Contraindications

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

4.4 Special warnings and special precautions for use

Warnings:

Fatal complications, including pulmonary and cerebral emboli have occurred with inappropriate Intravenous administration of sucralfate oral suspension. Administer Sucralfate Oral Suspension only by the oral route. Do not administer intravenously.

Precautions:

The physician should read the "**PRECAUTIONS**" section when considering the use of Sucralfate Oral Suspension in pregnant or pediatric patients, or patients of childbearing potential.

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 hyperglycemia have been reported in diabetic patients. Close monitoring of glycemia in diabetic patients treated with Sucralfate Oral Suspension is recommended. Adjustment of the anti-diabetic treatment dose during the use of Sucralfate Oral Suspension might be necessary.

Special Populations: Chronic Renal Failure and Dialysis Patients

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

4.5 Interaction with other medicinal products and other forms of interaction

Some studies have shown that simultaneous Sucralfate administration in healthy volunteers reduced the extent of absorption (bioavailability) of single doses of the following: cimetidine, digoxin, fluoroquinolone antibiotics, ketoconazole, l-thyroxine, phenytoin, quinidine,

ranitidine, tetracycline, and theophylline. Sub-therapeutic 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 non systemic 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 Oral Suspension's potential to alter the absorption of some drugs, Sucralfate Oral Suspension should be administered separately from other drugs when alterations in bioavailability are felt to be critical. In these cases, patients should be monitored appropriately.

4.5 Fertility, pregnancy and lactation

Teratogenic effects

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 foetus due to Sucralfate. 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.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

Clinical studies of Sucralfate Oral Suspension 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 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.

4.7 Effects on ability to drive and use machines

Do not drive if you feel dizzy or browsy.

4.8 Undesirable effects

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, adver se 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, indigestion, 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, lipswelling, edema of the mouth, pharyngeal edema, pruritus, rash, swelling of the face and urticaria.

Cases of bronchospasm, laryngeal edema and respiratory tract edema have 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.

4.9 Overdose

Due to limited experience in humans with over dosage of Sucralfate, no specific treatment recommendations can be given. Acute oral studies in animals, however, using doses up to 12g/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, abdomi nal pain, nausea, and vomiting.

5. Pharmacological Properties

Pharmacotherapeutic group: Alimentary tract and metabolism, **ATC code:** A02BX02
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 . The following observations also appear pertinent:

1.Studies in human subjects and with animal models of ulcer disease have shown that Sucralfate forms an ulcer-adherent complex with proteinaceous exudate at the ulcer site.

2. *In vitro*, a Sucralfate-albumin film provides a barrier to diffusion of hydrogen ions.
3.In human subjects, Sucralfate given in doses recommended for ulcer therapy inhibits pepsin activity in gastric juice by 32%.

In vitro, Sucralfate adsorbs bile salts.
These observations suggest that Sucralfate's antiulcer activity is the result of formation of an ulce r- 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.

5.2 Pharmacokinetic properties

Absorption

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

5.3 Preclinical safety data

Chronic oral toxicity studies of 24 months' duration were conducted in mice and rats at doses up to 1 g/kg (12 times the human dose).

There was no evidence of drug-related tumorigenicity. A reproduction study in rats at doses up to 38 times the human dose did not reveal any indication of fertility impairment. Mutagenicity studies were not conducted.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl paraben, Simethicone Emulsion, Glycerin, Colloidal silicon dioxide, Methyl Cellulose, Sorbitol, Spectracol Dual FD&C Red#40, Art Cherry flavor, Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Stored below 30°C.

6.5 Nature and contents of container

420ml in Amber PET Bottle Pack:

6.6 Instructions for use, handling and disposal

No Special requirements.

7. Marketing Authorisation Holder and Manufacturing Site Addresses

7.1 Name and Address of Manufacturer

Name	**:**	**Annora Pharma Limited,**
Business Address	**:**	Sy. No.261, Annaram Village, Gummadidala Mandal, Sangareddy District – 502313, Telangana,
Country	**:**	INDIA
Telephone	**:**	+ 91-8458-284200

7.2 Name and Address of Principal

Name	**:**	**Hetero Labs Limited,**
Business Address	**:**	Hetero Corporate, 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad – 500018, Telangana

Country	**:**	INDIA
Telephone	**:**	0091-40-23704923/24/25

Category for Distribution

Prescription only medicine-List I (POM)

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT