**Sucraid® (sacrosidase) Oral Solution**

**DESCRIPTION**
Sucraid® (sacrosidase) Oral Solution is an enzyme replacement therapy for the treatment of congenital sucrase-isomaltase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID). The enzyme is derived from baker's yeast (Saccharomyces cerevisiae).

It has been reported that the primary secretory cell structure of this protein consists of 513 amino acids with an apparent molecular weight of 100,000 for the glycoprophophatase isozyme. Sucrose is the enzyme used in the gastrointestinal lumen to produce increased amounts of hydrogen, methane, and water. As a consequence, excessive gas, loose stools, and their presence in the intestinal lumen may lead to osmotic retention of water. This may result in loose stools.

Sucrose in the colon is fermented by bacterial flora to produce hydrogen under controlled conditions following the digestion of starch. Therefore, you may need to restrict the amount of starch in your diet. Your doctor will tell you if you should restrict the amount of starch in your diet.

**INDICATIONS AND USAGE**
Sucraid® (sacrosidase) Oral Solution is indicated as oral replacement therapy of the genetically determined sucrase-isomaltase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID).

**CONTRAINDICATIONS**
Patients known to be hypersensitive to yeast, yeast products, papain, or glycerin (glycerol).

**WARNINGS**
Some patients may have worse abdominal pain, vomiting, nausea, or diarrhea. Constipation, difficulty sleeping, headache, nervousness, and dehydrogenation have also occurred. Other side effects may also occur. If you notice any of these or any other side effects during treatment with Sucraid, check with your doctor.

**PRECAUTIONS**
Cap should be taken to administer initial doses of Sucraid near (within a few minutes of) a meal to ensure the continued intake of Saccharomyces cerevisiae. Ingestion may be required for a period of 10 days.

**INFORMATION ABOUT YOUR MEDICINE**
Sucraid can help improve the breakdown and absorption of sucrose (table sugar) from the intestine and can help relieve the gastrointestinal symptoms of CSID.

Sucraid does not break down some sugars resulting from the digestion of starch. Therefore, you may need to restrict the amount of starch in your diet. Your doctor will tell you if you should restrict the amount of starch in your diet.

**SIDE EFFECTS TO WATCH FOR:**
Some patients may have worse abdominal pain, vomiting, nausea, or diarrhea. Constipation, difficulty sleeping, headache, nervousness, and dehydrogenation have also occurred. Other side effects may also occur. If you notice any of these or any other side effects during treatment with Sucraid, check with your doctor.

**How to take your medicine:**
Each bottle of Sucraid is supplied with a plastic screw cap which covers a dropper dispensing tip. Remove the outer cap and measure out the required dose. Reseal the bottle after each use by replacing and twisting the cap until tight.
Write down the date the sealed bottle is first opened in the space provided on the bottle label. Always throw away the bottle four weeks after first opening it because Sucraid contains no preservatives. For the same reason, you should rinse the measuring scoop with water after each time you finish using it.

To get the full benefits of this medicine, it is very important to take Sucraid as your doctor has prescribed. The usual dosage is 1 to 2 milliliters (mL) with each meal or snack: 1mL = 1 full measuring scoop (28 drops from the bottle tip) and 2mL = 2 full measuring scoops (56 drops from the bottle tip).

Measure your dose with the measuring scoop provided (see Figure 1). Do not use a kitchen teaspoon or other measuring device since it will not measure an accurate dose.

**Figure 1. Measure dose with measuring scoop.**

Mix your dose in 2 to 4 ounces of water, milk, or infant formula (see Figure 2). Sucraid should not be dissolved in or taken with fruit juice.

NEVER HEAT SUCRAID OR PUT IT IN WARM OR HOT BEVERAGES OR INFANT FORMULA. Heating Sucraid causes it to lose its effectiveness. The beverage or infant formula should be taken cold or at room temperature.

**Figure 2. Mix dose in beverage or infant formula.**

It is recommended that approximately half of your dosage be taken at the beginning of each meal or snack and the remainder of your dosage be taken during the meal or snack.

**Storing your medicine:**

Sucraid is available in 4 fluid ounce (118 mL) see-through plastic bottles, packaged two bottles per box. 1 mL measuring scoop is provided with each bottle. Always store Sucraid in a refrigerator at 36°F - 46°F (2°C - 8°C). Protect Sucraid from heat and light.

If your bottle of Sucraid has expired (the expiration date is printed on the bottle label), throw it away.

Keep this medicine in a safe place in your refrigerator where children cannot reach it.

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effective for the treatment of the genetically acquired saccharide deficiency, which is part of CSID.

**ADVERSE REACTIONS**

Adverse experiences with Sucraid in clinical trials were generally minor and were frequently associated with the underlying disease.

In clinical studies of up to 54 months duration, physicians treated a total of 52 patients with Sucraid. The adverse experiences and respective numbers of patients reporting each event (in parentheses) were as follows: abdominal pain (4), vomiting (2), nausea (2), diarhoea (2), constipation (2), insomnia (1), headache (1), nervousness (1), and dehydration (1).

Nausea, diarrhea and abdominal pain can be a part of the clinical presentation of the genetically determined saccharide deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID).

One autistic child experienced a serious hypersensitivity reaction (wheezing) probably related to sucrosed (see Warnings). The event resulted in withdrawal of the patient from the trial but resolved with no sequelae.

**OVERDOSAGE**

Overdosage with Sucraid has not been reported.

**DOSAGE AND ADMINISTRATION**

The recommended dosage is 1 or 2 mL (0.530 to 1/3,000 I.U.) or 1 or 2 full measuring scoops (each full measuring scoop equals 1 mL) of Sucraid given orally with fruit juice. It is recommended that approximately half of the dosage be taken at the beginning of the meal or snack and the remainder be taken during the meal or snack.

The recommended dosage is as follows:

- 1 mL (8,500 I.U.) (one full measuring scoop or 28 drops from the Sucraid container tip) equal to 56 drops of Sucraid taken orally with fruit juice for patients, over 15 kg in body weight.
- 2 mL (17,000 I.U.) (two full measuring scoops or 56 drops from the Sucraid container tip) equal to 112 drops of Sucraid taken orally with fruit juice for patients up to 15 kg in body weight.
- 2 mL (17,000 I.U.) (two full measuring scoops or 56 drops) per meal or snack for patients over 15 kg in body weight.

**OVERDOSAGE**

Sucraid should not be reconstituted or consumed with fruit juice since its acidity may reduce the enzyme activity.

It is recommended that approximately half of the dosage be taken at the beginning of the meal or snack and the remainder be taken during the meal or snack.

**DIARRHEA**

Diarrhoea rarely occurred in patients taking Sucraid. This occurred because of bacterial growth. For the same reason, patients should be advised to rinse the measuring scoop with water after each use.

**DIABETIC PATIENTS**

Sucraid is not expected to cause an increase in blood glucose levels.

**DIABETIC CSID PATIENTS**

Sucraid provides replacement therapy for the deficient sucrase, and isomaltase (see Warnings). The event resulted in withdrawal of the patient from the trial but resolved with no sequelae.

**LABORATORY TESTS**

The use of Sucraid will enable the products of sucrose hydrolysis, glucose, and fructose, to be absorbed. Therefore, in the postprandial state, the patient will usually have a higher blood sugar concentration than an age-matched control subject. Therefore, patients should have their blood sugars monitored frequently and have their diet regulated by their physicians.

**PATIENT INFORMATION**

Sucraid is available in 4 fluid ounce (118 mL) see-through plastic bottles, packaged two bottles per box. A 1 mL measuring scoop is provided with each bottle. Always store Sucraid in a refrigerator at 36°F - 46°F (2°C - 8°C). Protect Sucraid from heat and light.

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