Sucraide® (sacrosidase) Oral Solution:

DESCRIPTION
Sucraide® Oral Solution is an enzyme replacement therapy for the treatment of genetically determined sucrose deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID).

CHEMISTRY
Sucrase is a yellow protein, soluble in solution with a pI of 4.7. It is eluted from an ion exchange column with NaCl concentrations between 0.8 and 0.9 M. The molecular mass of the enzyme is 29,000-31,000 Da. The enzyme is derived from baker's yeast (Saccharomyces cerevisiae).

It has been reported that the primary amino acid structure of this protein consists of 513 amino acids with an apparent molecular weight of 100,000 Daltons for the glycodelin-like fragment (residues 66-116,300,000). Reports also suggested that the protein exists in solution as a monomer, dimer, tetramer, and hexamer, and its molecular weight slightly increases from 100,000 Daltons to 300,000 Daltons. Sucrase is considered a dimeric protein with an apparent molecular weight of 100,000 Da.

Sucrase may contain small amounts of apapain. Papain is known to cause allergic reactions in some people. Papain is a proteolytic enzyme that is stomach-produced. In the manufacturing process to digest the cell wall of the yeast and may not be completely removed during subsequent process steps.

Sucrase contains sacrose in a vehicle comprised of glycine (0.5%), water, and citric acid to maintain the pH at 4.0 to 4.7. Glycine (glycin) is in the unknown concentration in the recommended doses of Sucraide has no reported toxicity.

This enzyme preparation is fully suitable with water, oral, and parenteral formulas. Do NOT heat SOLUTIONS CONTAINING Sucraide. Do not put Sucraide in warm or hot liquids.

CLINICAL PHARMACOLOGY
Congenital sucrase-isomaltase deficiency (CSID) is a chronic, autosomal-recessive, inherited, multifunctional deficiency. CSID is associated with a severe decrease in isomaltase activity, a moderate decrease in sucrase activity, and normal lactase levels. Sucrase deficiency is present in the brush border of the small intestine, primarily the distal duodenum and jejunum.

Soluble fructose in the lumen breaks down into fructose and fructose monomers. Fructose monomers are absorbed from the small intestine, and the synthesis of fructose-1-phosphate may lead to somatic hypertrophy of the liver and muscle.

Sucrase deficiency is an inherited metabolic disorder, which is characterized by the following: stool pH < 6, an increased breath hydrogen of > 10 ppm when challenged with sucrose after fasting and a negative lactose tolerance test. The presence of increased breath hydrogen in patients suspected of having CSID.

CLINICAL STUDIES
A two-phase study was performed by a breath hydrogen profile double-blind, multi-site crossover trial that was conducted in 25 patients (aged 6 months to 11.5 years) with confirm CSID. Patients were challenged with an energy-restricted, sucrose-containing diet while receiving four doses of sacrosidase: full strength (9000 I.U./mL), 1:1000 (9 I.U./mL), 1:10,000 (0.9 I.U./mL), and 1:100,000 (0.09 I.U./mL) in random order for a period of 10 days. Patients who weighed more than 15 kg received 1 mL per meal, those weighing more than 10 kg received 0.5 mL per meal. The dose did not vary with age or sucrose intake. A dose-response relationship was shown between the two higher and the two lower doses. The two higher doses of sacrosidase were associated with significantly lower stool output and higher proportions of patients having lower stool volumes across the primary efficacy endpoints. In addition, higher doses of sacrosidase were associated with the significantly greater number of full and semi-formed stools, the secondary efficacy endpoints.

Analysis of the overall symptomatic response as a function of age indicated that in CSID patients aged 3 to 5 years, 86% became asymptomatic; in patients over 5 years of age, 77% became asymptomatic. Thus, a younger age was associated with significantly greater symptomatic response according to age.

A second study of similar design and execution as the first used 4 different dilutions of sacrosidase: 1:100 (90 I.U./mL), 1:1000 (9 I.U./mL), 1:10,000 (0.9 I.U./mL), and 1:100,000 (0.09 I.U./mL). There were consistent results with regards to the primary efficacy parameters. In both trials, patients showed a marked decrease in breath hydrogen output when they received sacrosidase in comparison to placebo.

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

CONTRAINDICATIONS
Patients known to be hypersensitive to yeast, yeast products (gluten, glycin), or papain.

WARNINGS
Slight wheezing, 90 minutes after a second dose of sacrosidase, was reported in 12 of 25 patients (4.8%) aged 4 years or less. Other side effects may also occur. If you notice these or any other side effects during treatment with Sucraide, check with your doctor.

Stop taking Sucraide and get emergency help immediately if any of the following side effects occur: difficulty breathing, wheezing, or swelling of the face.

Each bottle of Sucraide 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.

Sucraide can help improve the breakdown and absorption of sucrose (table sugar) from the intestine and can help relieve the gastrointestinal symptoms of CSID.

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Sucraide 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. 

DISCUSS THE FOLLOWING IMPORTANT INFORMATION WITH YOUR DOCTOR BEFORE YOU BEGIN TO TAKE Sucraide:

Tell your doctor if you have diabetes. With Sucraide, table sugar (table sugar) can be absorbed from your diet and your blood glucose levels may change. Your doctor will tell you if your diet or diabetes medicines need to be changed.

Side effects to watch for:
Some patients may have more abdominal pain, vomiting, nausea, or diarrhea. Constipation, difficulty sleeping, headache, nervousness, and dehydration have also occurred. Other side effects may also occur. If you notice these or any other side effects during treatment with Sucraide, check with your doctor.

How to take your medicine:
Each bottle of Sucraide 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. 

The symptoms of CSID often include frequent watery diarrhea, abdominal pain, bloating, and gas. In many cases, the symptoms of CSID are similar to other medical problems. Only your doctor can make a definitive diagnosis of CSID.
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. 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.

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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Rev 11/14
Part No. 0110