Sucraid® (sacrosidase) Oral Solution:

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

CHEMISTRY
Sucraid is a white to yellowish, clear solution with a pleasant sweet taste. Each milliliter (mL) of Sucraid contains 60 I.U. of the sucrase-isomaltase, the active ingredient. The chemical name of Sucraid is alpha-D-glucosidase.

It has been reported that the primary amino acid structure of this protein consists of 313 amino acids with an apparent molecular weight of 32,000 daltons for the protein and 40,000 mol wt for the enzyme molecule. Reports also suggest that the protein exists in solution as a monomer, dimer, trimer, and tetramer ranging from 100,000 to 400,000 g/mol. It has an isoelectric point of 4.5.

Sucraid may contain small amounts of papain. Papain is known to cause allergic reactions in some people. Papain is a protein-splitting enzyme that is introduced in the manufacturing process to digest the cell wall of the yeast and may not be completely removed during subsequent processing steps.

Sucraid contains sacrosidase in a vehicle comprised of glycerol (50% wt/wt), water, and citric acid to maintain the pH at 4.0 to 4.7. Glycerol (glycerol) is the amount consumed in the recommended doses of Sucraid that has no expected toxicity.

This enzyme preparation is fully suitable with water, milk, and infant formula. DO NOT HEAT SOLUTIONS CONTAINING SUCRAID. Do not put Sucraid in hot or warm liquids.

CLINICAL PHARMACOLOGY
Congenital sucrase-isomaltase deficiency (CSID) is a chronic, heterogeneous disease with very variable enzyme activity (sucrase, isomaltase, and maltase). It is an almost complete lack of endogenous sucrase activity, a very marked reduction in isomaltase activity, a moderate decrease in maltase activity, and normal lactase levels.

Sucrase is naturally produced in the brush border of the small intestine, primarily the distal duodenum and jejunum. Sucrase hydrolyzes sucrose into its component monosaccharides, glucose and fructose. Isomaltase breaks down disaccharides from starch into simple sugars. Sucrase does not contain fructose. Isomaltase breaks down disaccharides from starch into simple sugars. Sucrase enzyme does not contain fructose. Isomaltase breaks down isomaltose and sucrose into two lower doses. The two higher doses of sacrosidase were associated with significantly fewer total stools and higher proportions of patients having lower total symptom scores, the primary efficacy end-points. In addition, higher doses of sacrosidase were associated with a significantly greater number of frequent and formed stools and a decrease in abdominal pain and flatulence, secondary efficacy end-points.

Analysis of the overall symptom response as a function of age indicated that in CSID patients up to 3 years of age, 86% became asymptomatic. In patients over 3 years of age, 77% became asymptomatic. Thus, the therapeutic response did not differ significantly 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), and 1:10,000 (0.9 I.U./mL), and 1:100,000 (0.09 I.U./mL). There were inconsistent results with regards to the primary efficacy parameters. In both trials, however, patients showed a marked decrease in hydrogen output when they received sacrosidase in comparison to placebo.

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

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

WARNINGS
Severe wheezing, 90 minutes after a second dose of sacrosidase, necessitated admission into the ICU for a 4-year-old boy. The wheezing was probably caused by sucrase deficiency. He had asthma and was being treated with steroids. A skin test for sacrosidase was positive. He had asthma and was being treated with steroids. Other serious events have not been linked to Sucraid.

PRECAUTIONS
Care should be taken to administer initial doses of Sucraid near (within a few minutes of travel) a facility where acute hypersensitivity reactions can be adequately treated. Alternatively, the patient may be tested for hypersensitivity to Sucraid through skin abrasion testing. Should symptoms of hypersensitivity appear, discontinue medication and initiate symptomatic and supportive therapy.

Skin testing as a research tool has been used to verify hypersensitivity in one autistic child who displayed a positive reaction to sacrosidase.

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.

Discuss the following important information with your doctor before you begin to take Sucraid:

Tell your doctor if you are allergic to, have ever had a reaction to, or have ever had difficulty taking yeast, yeast products, papain, or glycerin (glycerol).

Tell your doctor if you have diabetes. With Sucraid, sucrose 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 worse 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 Sucraid, check with your doctor.

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

How to take your medicine:

Each bottle of Sucraid is supplied with a plastic screw cap which covers a drop dispenser 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.

INDICATIONS AND USAGE
Sucraid is an enzyme replacement therapy for the treatment of the genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID). CSID is a condition where your body lacks the enzymes needed to break down and absorb sucrose (table sugar) and other sugars from starch.

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 definite diagnosis of CSID.

Before taking Sucraid:

If you notice any swelling or have difficulty breathing, get emergency help right away. Before taking your first and second doses, be sure that there are health professionals nearby (within a few minutes of travel) just in case there is an allergic reaction.

INFORMATION ABOUT YOUR MEDICINE

The name of your medicine is Sucraid® (sacrosidase) Oral Solution. It can be obtained only with a prescription from your doctor.

The purpose of your medicine:

Sucraid is an enzyme replacement therapy for the treatment of the genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID). CSID is a condition where your body lacks the enzymes needed to break down and absorb sucrose (table sugar) and other sugars from starch.

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 definite 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 06/20
Part No. 0110

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.