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
SucraLase® (sacrosidase) is a pale yellow to colorless, clear solution containing 82 percent sacrosidase in comparison to placebo.

CLINICAL PHARMACOLOGY
Congenital sucrase-isomaltase deficiency (CSID) is a chronic, autosomal recessive, inherited, phenotypically heterogeneous disease with very variable enzyme activity and severity. In the absence of endogenous human sucrase, as in CSID, the small intestine is unable to break down and absorb sucrose (table sugar) and therefore, the gastrointestinal symptoms of CSID.

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

WARNINGS
Severe wheezing, 90 minutes after a second dose of sacrosidase, necessitated admission to the ICU for a 4-year-old boy. The wheezing was probably related to sacrosidase. He had asthma and was being treated with steroids. A skin test for sacrosidase was positive.

Other serious events have not been linked to Sucraid.

PRECAUTIONS
Sucraid® (sacrosidase) is excreted in exhalation (a measurement of excess hydrogen excreted in exhalation) in CSID patients has shown levels as great as 6 times that in normal subjects.

A generally accepted clinical definition of CSID is a condition characterized by the following: stool pH < 6, an increase in breath hydrogen of > 10 ppm when challenged with sucrose after fasting and a negative lactose breath test; however, because the effectiveness is delayed, it is necessary to continue therapy for at least one week to assess response in patients suspected of having CSID.

CLINICAL STUDIES
A two-phase dose response phase of a breath hydrogen challenge was conducted in 28 patients (aged 4 months to 11.5 years) with confirmed CSID. During the dose response phase, the patients were challenged with an ordinary sucrose-containing diet and receiving one of four doses of sacrosidase: full strength (9000 I.U./mL) and three dilutions (1:10 [900 I.U./mL], 1:100 [90 I.U./mL], and 1:1000 [9 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 15 kg received 2 mL per meal. The dose did not vary with age or sucrose intake. A dose-response relationship was shown between the higher and lower doses, the higher two doses of sacrosidase were associated with significantly lower total stools and higher proportions of patients having lower total symptom scores, the primary efficacy endpoints. In addition, higher doses of sacrosidase were associated with a significantly greater number of hard and formed stools compared to sucrose and soft stools, the secondary efficacy endpoint.

Succinylcholine, in the manufacturing process to digest the cell wall of Saccharomyces cerevisiae (yeast) to release the enzyme, has an iso-electric point (pI) of 4.5.

Chemical name of your medicine: Sucraid® (sacrosidase) Oral Solution

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

The purpose of your medicine: Sucraid® is an enzyme replacement therapy for the treatment of genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID).

Sucraid® (sacrosidase) Oral Solution can only be used to help 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.

Sucraid® (sacrosidase) Oral Solution can help improve the breakdown and absorption of sucrose (table sugar) from the intestine and can help relieve the gastrointestinal symptoms of CSID.

Sucraid® (sacrosidase) Oral Solution 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, glycerin, or papain (glycerol).

Tell your doctor if you have diabetes. With Sucraid®, sucrose (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 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 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.

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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Figure 2. Mix dose in beverage or infant formula.

It is recommended that you give the full amount of your dosage during mealtime or snacktime to get the full benefit of Sucraid. Sucraid may be taken with fruit juice since its acidity may reduce the enzyme activity.

Sucraid is fully soluble with water, milk, and infant formula, but it is important to note that this product is sensitive to heat. Sucraid should not be reconstituted or consumed with hot juice, since its acidity may reduce the enzyme activity.

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It is recommended that 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 = 1 full measuring scoop (28 drops from the bottle tip) or 2 mL = 2 full measuring scoops (56 drops from the bottle tip).

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

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