Sucraid®
(sacrosidase)
Oral Solution

Sucraid® Treats CSID

Indication

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).

Important Safety Information for Sucraid® (sacrosidase) Oral Solution

- Sucraid® may cause a serious allergic reaction. Patients should stop taking Sucraid® and get emergency help immediately if any of the following side effects occur: difficulty breathing, wheezing, or swelling of the face. Care should be taken when administering initial doses of Sucraid® to observe any signs of acute hypersensitivity reaction.
- Do not use Sucraid® with patients known to be hypersensitive to yeast, yeast products, papain, or glycerin (glycerol).

Please see additional Important Safety Information on back cover.

What is CSID?

Congenital Sucrase-Isomaltase Deficiency (CSID) is a rare, inherited disease that causes Sucrose Intolerance. It is equally prevalent in males and females. CSID may also be referred to as Sucrose Intolerance, sucrase-isomaltase (SI) deficiency, disaccharide intolerance, or Genetic Sucrase-Isomaltase Deficiency (GSID).

CSID is a disease that causes a reduction in the activity of the digestive enzyme sucrase-isomaltase, which is responsible for the breakdown and absorption of the complex sugars sucrose (table sugar) and maltose (sugar found in dietary starches). All CSID patients have Sucrose Intolerance; some may also have starch intolerance.

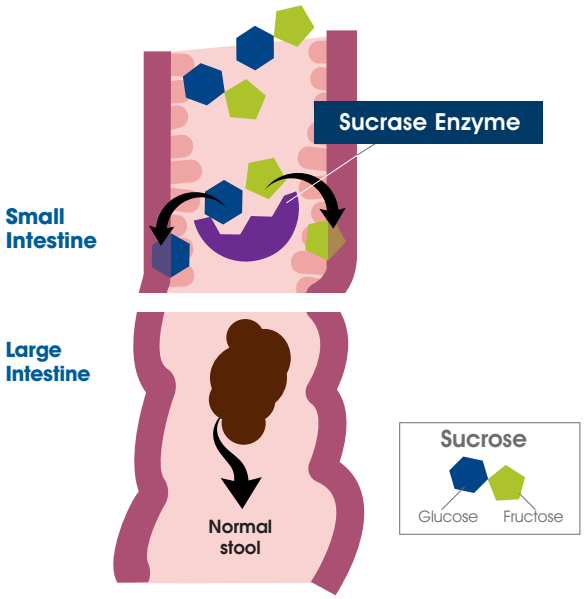
The figure on the next page shows the differences in digestion in someone with healthy intestines where the sucrase-isomaltase enzyme is present, and in the intestines of someone with CSID where the enzyme isn't working.

Sucrose Intolerance may be more common than you think!

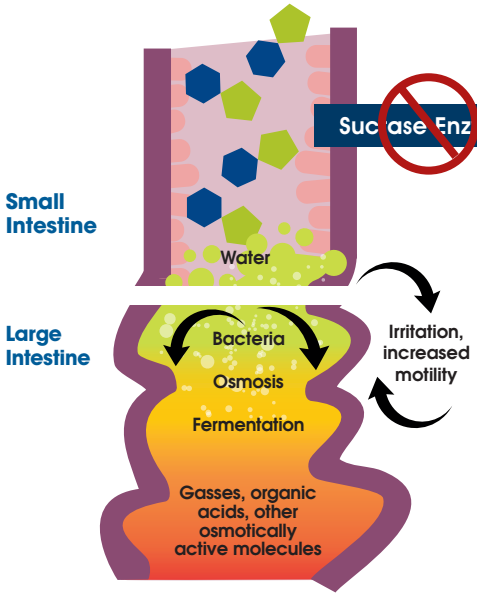
9.3%

In a study of 27,875 symptomatic patients, 9.3% had sucrase deficiency[1]

Normal Sucrose Digestion



Sucrose Intolerance Due to CSID



What are the symptoms of CSID?

Individuals with CSID may experience mild-to-severe gastrointestinal (GI) discomfort after consuming food that contains sucrose, as it moves through the small intestine undigested and enters the large intestine. Resident bacteria in the large intestine (colon) feed on undigested sugars, such as sucrose, through a process called fermentation. The byproducts of fermentation include an increase in gas production.

When undigested substances are not absorbed and move into the large intestine, an osmotic force pulls water from the bloodstream into the large intestine, causing watery diarrhea.

The type of GI symptoms or the severity of the GI symptoms may differ among infants, children, and adults who are born with this enzyme deficiency.

Symptoms of Congenital Sucrase-Isomaltase Deficiency (CSID) may include chronic:

- ☐ **bloating**
- ☐ **diarrhea**
- ☐ **gassiness**
- ☐ **abdominal pain**
- ☐ **nausea**

How is CSID diagnosed?

The simple, free* **^{13}C-Sucrose Breath Test** can be used to help diagnose CSID in combination with a careful analysis of the patient's history. The breath test is noninvasive, short in duration, and can be taken at home or in the office. A positive test helps support a diagnosis of CSID, but may also be a false positive. A CSID diagnosis should also be confirmed with a thorough assessment of patient history; and, where CSID is suspected, Sucraid® (sacrosidase) Oral Solution may be used to help assess therapeutic response. Patients who do not respond to Sucraid® likely do not have CSID.

The **Disaccharidase Assay** can also be used to help diagnose CSID. Tissue biopsies from the distal duodenum are obtained via EGD and frozen. The biopsied tissue is analyzed by a special lab for the level of sucrase enzyme activity that is present.
NOTE: Do not send the disaccharidase assay biopsies to the pathology lab, as the sample handling requirements are very different.
A positive test helps support a diagnosis of CSID but may also be a false positive. A CSID diagnosis should also be confirmed with a thorough assessment of patient history and, where CSID is suspected, Sucraid® (sacrosidase) Oral Solution may be used to help assess therapeutic response. Patients who do not respond to Sucraid® likely do not have CSID.

A short treatment period with Sucraid® may help confirm a diagnosis. If a patient has a positive diagnostic test and shows substantial improvement in GI symptoms while taking Sucraid®, a CSID diagnosis is confirmed.

Breath tests are provided at no charge and are not billed to the patient or any third party payor. This test is being provided at no charge. Test and interpretation charges should not be submitted to payors.

Rule Out CSID

1.

Identify CSID symptoms.

2.

Administer a simple, **at-home ^{13}C-Sucrose Breath Test.**

3.

If positive, consider **Sucraid®** (sacrosidase) Oral Solution. Patients who do not respond to **Sucraid®** likely do not have CSID.

For more information on diagnostic tools for CSID, call 1-800-705-1962.

How is CSID treated?

Sucraid® Treats CSID

Sucraid® is the only FDA-approved enzyme replacement therapy for the treatment of genetically determined sucrase deficiency.[2] CSID patients are sucrose intolerant and **Sucraid®** can help the body break down and absorb sucrose (table sugar) to relieve GI symptoms, such as diarrhea and abdominal pain. Some CSID patients may also be starch intolerant. **Sucraid®** does not break down starch sugars in rice, potatoes, corn, pasta, and bread. If a patient continues to have symptoms after consuming meals containing starch, advice from a registered dietitian may be needed to help restrict the amount of starch in the diet.

Indication

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).

Important Safety Information for Sucraid® (sacrosidase) Oral Solution

- Sucraid® may cause a serious allergic reaction. Patients should stop taking Sucraid® and get emergency help immediately if any of the following side effects occur: difficulty breathing, wheezing, or swelling of the face. Care should be taken when administering initial doses of Sucraid® to observe any signs of acute hypersensitivity reaction.
- Do not use Sucraid® with patients known to be hypersensitive to yeast, yeast products, papain, or glycerin (glycerol).

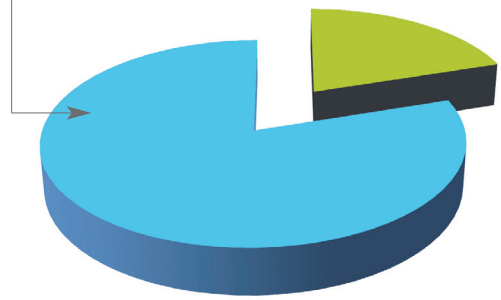
Please see additional Important Safety Information on back cover.

Sucraid®
(sacrosidase)
Oral Solution

81%

Complete Resolution

Patients who became asymptomatic* with **Sucraid®** in long-term clinical trials[3]



Clinical Trial Confirms the Efficacy and Safety of Sucraid® in Both Children and Adults with CSID

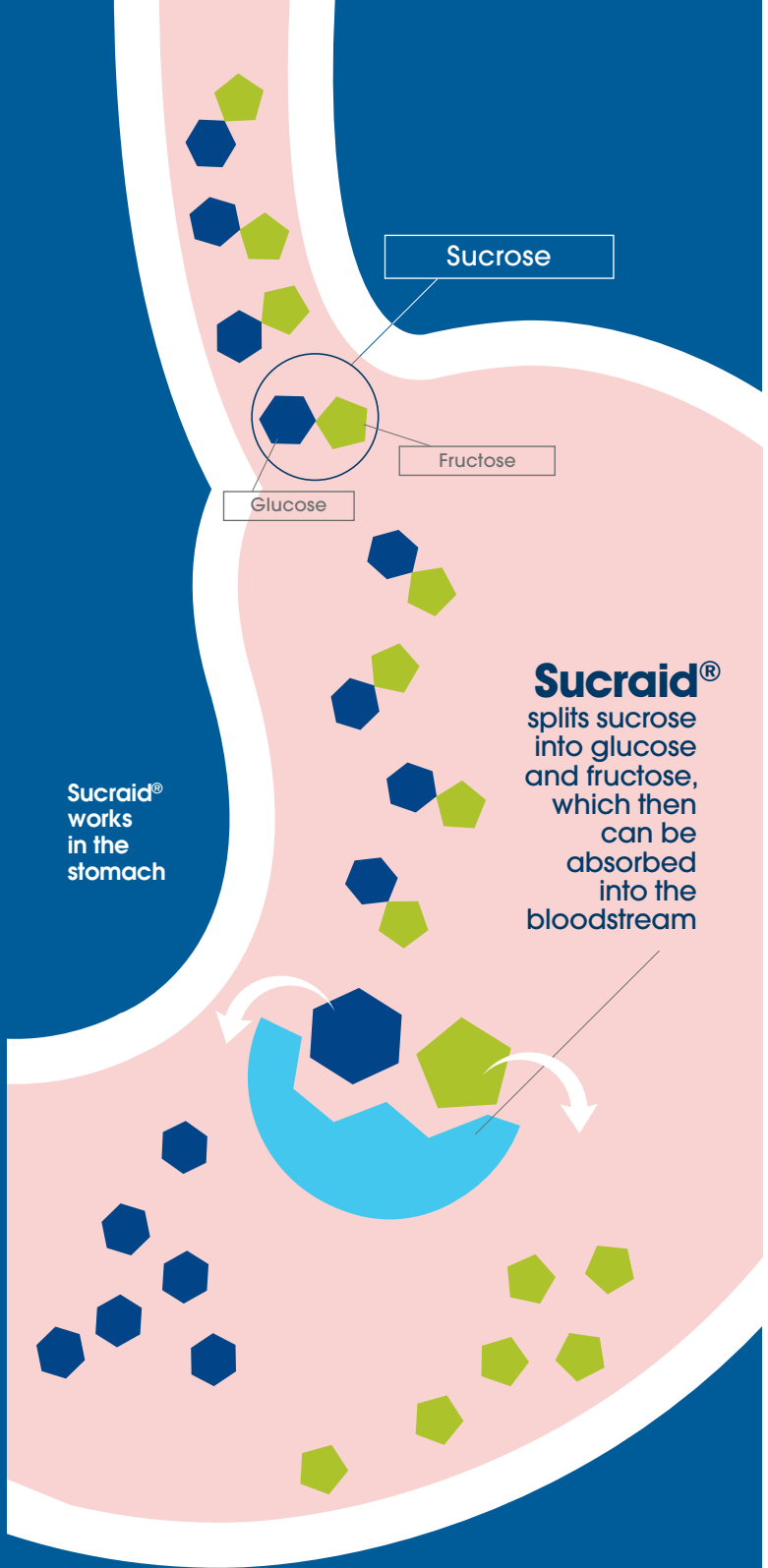
*Patients who took Sucraid® with each meal were considered asymptomatic if they reported no GI symptoms for at least 7 of the 10 study days.

Visit **Sucraid.com**

How does Sucraid® work?

Sucraid® (sacrosidase) Oral Solution is an enzyme replacement therapy that works by replacing the activity of the deficient enzyme sucrase-isomaltase. It breaks down the complex sugar sucrose into the simple sugars **glucose** and **fructose**, which then can be absorbed from the small intestine.

To get the full benefits of treatment, patients must take **Sucraid®** exactly as prescribed. **Sucraid®** is taken with each meal or snack, mixed into 2-4 ounces of water or milk. Never heat **Sucraid®** or put it in hot beverages, and do not add to fruit juices. It is best to take half of the dose at the beginning of the meal or snack and the other half during the meal or snack



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Important Safety Information for Sucraid® (sacrosidase) Oral Solution

- Sucraid® may cause a serious allergic reaction. Patients should stop taking Sucraid® and get emergency help immediately if any of the following side effects occur: difficulty breathing, wheezing, or swelling of the face. Care should be taken when administering initial doses of Sucraid® to observe any signs of acute hypersensitivity reaction.
- Do not use Sucraid® with patients known to be hypersensitive to yeast, yeast products, papain, or glycerin (glycerol).

Please see full Prescribing Information on back cover.

Visit **Sucraid.com**

Please see accompanying Full Prescribing Information.

Sucraid® (sacrosidase) Oral Solution is ONLY available from the **US Bioservices** Specialty Pharmacy.

Physicians must complete the Sucraid® Prescription Form and fax it to

1-866-850-9155

Questions? Call

1-833-800-0122

How to get Sucraid®

A prescription for **Sucraid®** (sacrosidase) Oral Solution cannot be filled at your corner drug store. It is filled by only one specialty pharmacy that ships **Sucraid®** to you or your prescribing physician. **The specialty pharmacy is US Bioservices, and their phone number is 1-833-800-0122.**

Here are the steps for filling a prescription for **Sucraid®** from US Bioservices:

+ The prescribing physician must complete the Sucraid® Prescription Form and fax it to **1-866-850-9155**
+ The patient's current health insurance information must be provided for review
+ Financial information will be collected if the patient requests or needs assistance
+ **Sucraid®** will be shipped directly to the patient's home or the physician's office
+ If it is shipped to the patient's home, US Bioservices will contact the patient to schedule the delivery of **Sucraid®**

References
1. Nichols BL, Adams B, Roach CM, Ma C, Baker S. Frequency of Sucrase Deficiency in Mucosal Biopsies. *J Pediatr Gastroenterol Nutr.* 2012; 55 (Suppl 2):S28-S30. 2. Sucraid® (package insert). Vero Beach, FL: QOL Medical, LLC; 2020. 3. Treem WR, McAdams L, Standford L, Kastoff G, Justinich C, Hyams J. Sacrosidase Therapy for Congenital Sucrase-Isomaltase Deficiency. *J Pediatr Gastroenterol Nutr.* 1999;28(2):137-42.

Additional Important Safety Information for Sucraid® (sacrosidase) Oral Solution

■ Although Sucraid® provides replacement therapy for the deficient sucrase, it does not provide specific replacement therapy for the deficient isomaltase.

■ Adverse reactions as a result of taking Sucraid® may include worse abdominal pain, vomiting, nausea, diarrhea, constipation, difficulty sleeping, headache, nervousness, and dehydration.

■ Before prescribing Sucraid® to diabetic patients, the physician should consider that Sucraid® will enable sucrose hydrolysis and the absorption of those hydrolysis products, glucose and fructose.

■ The effects of Sucraid® have not been evaluated in patients with secondary (acquired) disaccharidase deficiency.

■ **DO NOT HEAT SOLUTIONS CONTAINING SUCRAID®.** Do not put Sucraid® in warm or hot fluids. Do not reconstitute or consume Sucraid® with fruit juice since the acidity of the juice may reduce the enzyme activity of Sucraid®. Half of the reconstituted Sucraid® should be taken at the beginning of the meal or snack and the other half during the meal or snack.

■ Sucraid® should be refrigerated at 36°F-46°F (2°C-8°C) and should be protected from heat and light.

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

Find out more

Call: 1-800-705-1962
Email: info@sucraid.com
Visit: Sucraid.com
or CSIDDiseaseInfo.com

Sucraid®
(sacrosidase) Oral Solution

Visit **Sucraid.com**

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 pale yellow to colorless, clear solution with a pleasant sweet taste. Each milliliter (mL) of Sucraid contains 8,500 International Units (I.U.) of the enzyme sacrosidase, the active ingredient. The chemical name of this enzyme is ß,D-fructofuranoside fructohydrolase. 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 g/mole for the glycosylated monomer (range 66,000-116,000 g/mole). Reports also suggest that the protein exists in solution as a monomer, dimer, tetramer, and octomer ranging from 100,000 g/mole to 800,000 g/mole. It has an isoelectric point (pI) of 4.5.

Sucraid may contain small amounts of papain. Papain is known to cause allergic reactions in some people. Papain is a protein-cleaving enzyme that is introduced in the manufacturing process to digest the cell wall of the yeast and may not be completely removed during subsequent process 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 (glycerin) in the amount consumed in the recommended doses of Sucraid has no expected toxicity.

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

CLINICAL PHARMACOLOGY

Congenital sucrase-isomaltase deficiency (CSID) is a chronic, autosomal recessive, inherited, phenotypically heterogeneous disease with very variable enzyme activity. CSID is usually characterized by a complete or 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 the disaccharide sucrose into its component monosaccharides, glucose and fructose. Isomaltase breaks down disaccharides from starch into simple sugars. Sucraid does not contain isomaltase.

In the absence of endogenous human sucrase, as in CSID, sucrose is not metabolized. Unhydrolyzed sucrose and starch are not absorbed from the intestine and their presence in the intestinal lumen may lead to osmotic retention of water. This may result in loose stools.

Unabsorbed sucrose in the colon is fermented by bacterial flora to produce increased amounts of hydrogen, methane, and water. As a consequence, excessive gas, bloating, abdominal cramps, nausea, and vomiting may occur.

Chronic malabsorption of disaccharides may result in malnutrition. Undiagnosed/untreated CSID patients often fail to thrive and fall behind in their expected growth and development curves. Previously, the treatment of CSID has required the continual use of a strict sucrose-free diet.

CSID is often difficult to diagnose. Approximately 4% to 10% of pediatric patients with chronic diarrhea of unknown origin have CSID. Measurement of expired breath hydrogen under controlled conditions following a sucrose challenge (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 of the difficulties in diagnosing CSID, it may be warranted to conduct a short therapeutic trial (e.g., one week) to assess response in patients suspected of having CSID.

CLINICAL STUDIES

A two-phase (dose response preceded by a breath hydrogen phase) double-blind, multi-site, crossover trial 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 while receiving each 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 no 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 two higher and the 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 hard and formed stools as well as with fewer watery and soft stools, the secondary efficacy end-points.

Analysis of the overall symptomatic 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), 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 breath hydrogen output when they received sacrosidase in comparison to placebo.

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

Patients known to be hypersensitive to yeast, yeast products, glycerin (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 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

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 rechallenge has been used to verify hypersensitivity in one asthmatic child who displayed

PATIENT PACKAGE INSERT

INFORMATION FOR PATIENTS

0110-0620

Sucraid® (sacrosidase) Oral Solution

Please read this leaflet carefully before you take Sucraid® (sacrosidase) Oral Solution or give Sucraid to a child. Please do not throw away this leaflet. You may need to read it again at a later date. This leaflet does not contain all the information on Sucraid. For further information or advice, ask your doctor or pharmacist.

BEFORE TAKING SUCRAID

WARNING: Sucraid may cause a serious allergic reaction. 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.

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 (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:

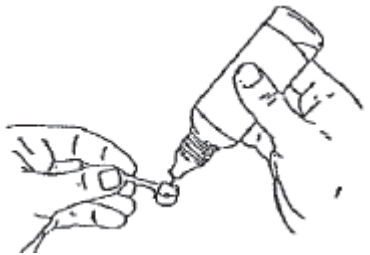
Each bottle of Sucraid is supplied with a plastic screw cap which covers a dropper dispensing tip. Remove the outer cap and measure out the required dose. Reseal the bottle after each use by replacing and twisting the cap until tight.

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 2 mL = 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.

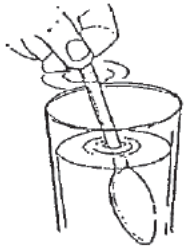
Figure 1. Measure dose with measuring scoop.



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. 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.

QOL Medical, LLC
Vero Beach, FL 32963

www.sucraid.com
For questions call 1-866-469-3773

Rev 06/20
Part No. 0110

wheezing after oral sacrosidase.

GENERAL
Although Sucraid provides replacement therapy for the deficient sucrase, it does not provide specific replacement therapy for the deficient isomaltase. Therefore, restricting starch in the diet may still be necessary to reduce symptoms as much as possible. The need for dietary starch restriction for patients using Sucraid should be evaluated in each patient.

It may sometimes be clinically inappropriate, difficult, or inconvenient to perform a small bowel biopsy or breath hydrogen test to make a definitive diagnosis of CSID. If the diagnosis is in doubt, it may be warranted to conduct a short therapeutic trial (e.g., one week) with Sucraid to assess response in a patient suspected of sucrase deficiency.

The effects of Sucraid have not been evaluated in patients with secondary (acquired) disaccharidase deficiencies.

INFORMATION FOR PATIENTS
See Patient Package Insert. Patients should be instructed to discard bottles of Sucraid 4 weeks after opening due to the potential for bacterial growth. For the same reason, patients should be advised to rinse the measuring scoop with water after each use.

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 fruit juice, since its acidity may reduce the enzyme activity.

USE IN DIABETICS
The use of Sucraid will enable the products of sucrose hydrolysis, glucose and fructose, to be absorbed. This fact must be carefully considered in planning the diet of diabetic CSID patients using Sucraid.

LABORATORY TESTS
The definitive test for diagnosis of CSID is the measurement of intestinal disaccharidases following small bowel biopsy.

Other tests used alone may be inaccurate: for example, the breath hydrogen test (high incidence of false negatives) or oral sucrose tolerance test (high incidence of false positives). Differential urinary disaccharide testing has been reported to show good agreement with small intestinal biopsy for diagnosis of CSID.

DRUG INTERACTIONS
Neither drug-drug nor drug-food interactions are expected or have been reported with the use of Sucraid. However, Sucraid should not be reconstituted or consumed with fruit juice, since its acidity may reduce the enzyme activity.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY
Long-term studies in animals with Sucraid have not been performed to evaluate the carcinogenic potential. Studies to evaluate the effect of Sucraid on fertility or its mutagenic potential have not been performed.

PREGNANCY
Teratogenic effects. Pregnancy Category C. Animal reproduction studies have not been conducted with Sucraid. Sucraid is not expected to cause fetal harm when administered to a pregnant woman or to affect reproductive capacity. Sucraid should be given to a pregnant woman only if clearly needed.

NURSING MOTHERS
The Sucraid enzyme is broken down in the stomach and intestines, and the component amino acids and peptides are then absorbed as nutrients.

PEDIATRIC USE
Sucraid has been used in patients as young as 5 months of age. Evidence in one controlled trial in primarily pediatric patients shows that Sucraid is safe and effective for the treatment of the genetically acquired sucrase 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 number of patients reporting each event (in parenthesis) were as follows: abdominal pain (4), vomiting (3), nausea (2), diarrhea (2), constipation (2), insomnia (1), headache (1), nervousness (1), and dehydration (1).

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

One asthmatic child experienced a serious hypersensitivity reaction (wheezing) probably related to sacrosidase (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 (8,500 to 17,000 I.U.) or 1 or 2 full measuring scoops (each full measuring scoop equals 1 mL; 28 drops from the Sucraid container tip equals 1 mL) taken orally with each meal or snack diluted with 2 to 4 ounces (60 to 120 mL) of water, milk, or infant formula. The beverage or infant formula should be served cold or at room temperature. The beverage or infant formula should not be warmed or heated before or after addition of Sucraid because heating is likely to decrease potency. 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.

The recommended dosage is as follows:

1 mL (8,500 I.U.) (one full measuring scoop or 28 drops) per meal or snack 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.

Dosage may be measured with the 1 mL measuring scoop (provided) or by drop count method (1 mL equals 28 drops from the Sucraid container tip).

HOW SUPPLIED
Sucraid® (sacrosidase) Oral Solution is available in 118 mL (4 fluid ounces) translucent plastic bottles, packaged two bottles per box. Each mL of solution contains 8,500 International Units (I.U.) of sacrosidase. A 1 mL measuring scoop is provided with each bottle. A full measuring scoop is 1 mL.

Store in a refrigerator at 2°- 8° C (36°- 46°F). Discard four weeks after first opening due to the potential for bacterial growth. Protect from heat and light.

Rx only.

Distributed by:
QOL Medical, LLC
Vero Beach, FL 32963

To order, or for any questions, call 1-866-469-3773
www.sucraid.com

NDC# 67871-111-04