Sucrose Intolerance

Sucrose Intolerance Due to **Congenital Sucrase-Isomaltase Deficiency (CSID)** Is More Common Than You Think!

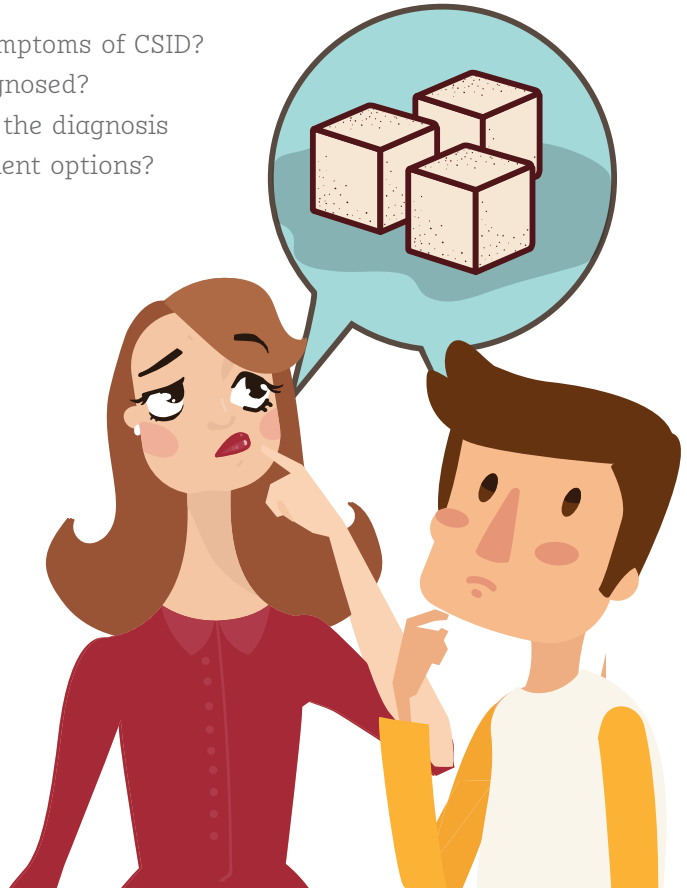
Introduction

For many patients with chronic gastrointestinal symptoms, properly diagnosing **Congenital Sucrase-Isomaltase Deficiency (CSID)** is a difficult journey. With varied health issues and complicated symptoms, it may take months or years to get a correct diagnosis. The time before the deficiency is diagnosed can become a very frustrating experience. However, once a patient receives a **CSID** diagnosis, a positive breakthrough occurs. Finally, proper care and management are within reach.

The information in this booklet is designed to be educational. We encourage you to share it with your healthcare provider. ONLY a doctor can properly diagnose you.

Contents

- What is CSID?
- What are the symptoms of CSID?
- How is CSID diagnosed?
- Tests that aid in the diagnosis
- What are treatment options?

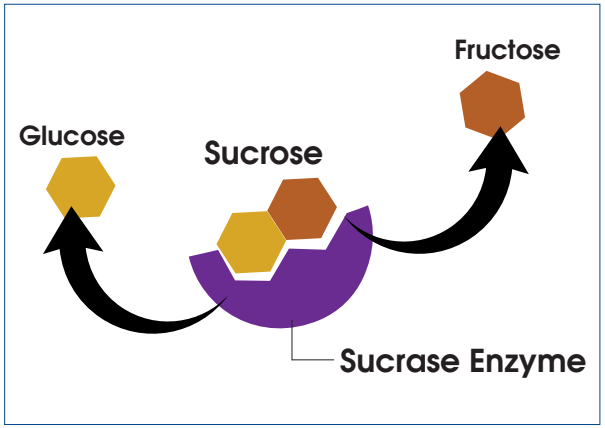


What is CSID?

CSID, sometimes referred to as Genetic Sucrase-Isomaltase Deficiency (GSID), is a rare disease that affects a person's ability to digest sucrose (a type of sugar) due to absent or low levels of the digestive enzyme sucrase-isomaltase.

Sucrase-isomaltase is instrumental in the digestion of sugar and starch. Sucrase-isomaltase is produced in the small intestine and helps break down sucrose into glucose and fructose, which are used by the body as fuel. It is also one of several enzymes that helps digest starches.

Failure to absorb dietary sucrose and starch may impact the absorption of other nutrients and disrupt the regulation of gastrointestinal function. Unabsorbed carbohydrates can inhibit gastric emptying, accelerate small-intestinal transit, and contribute to malabsorption of starch, fat, and other nutrients.*



CSID DISEASE INFO.COM | Patients with Congenital Sucrase-Isomaltase Deficiency may be at risk for chronic malnutrition.

SUCROSE IN FOOD:

Sucrose (sugar) exists in nearly everything we eat. In fact, the list of foods may surprise you. Here are just a few...

Flavored Yogurt
Instant Oatmeal
Salad Dressing
Energy Drinks
Granola
Dried Fruit
Many Frozen Meals
Snack Bars
Bottled Sauces
Coconut Water
Cereal
Some Breads
Apples
Mangos
Oranges
Grapefruits
Carrots
Potatoes
Bananas
Cantaloupe
Pineapples
Gluten-Free Bread
Brown Rice

*Treem WR. Congenital sucrase-isomaltase deficiency. *J Pediatr Gastroenterol Nutr.* 1995;21(1):1-14.

What are the symptoms of CSID?

MOST COMMON SYMPTOMS:

diarrhea, gas, bloating, and abdominal pain

Symptoms can range from **mild to severe chronic, watery, acidic diarrhea to gas, bloating, nausea, and abdominal pain.** Infants may not show symptoms of **CSID** until they begin to eat sucrose- and starch-containing foods such as juices, solid foods, and medications sweetened with sucrose. Watery diarrhea, failure to thrive, diaper rash, irritability, and acidic stools are the most common symptoms in infants and toddlers.* Other symptoms include abdominal distention, gassiness, colic, excoriated buttocks, indigestion, and vomiting.

A small number of patients may require hospitalization for diarrhea and dehydration, malnutrition, muscle wasting, and weakness. Patients with confirmed **CSID** commonly report being examined for toddler's diarrhea/irritable bowel syndrome (IBS)-D, celiac disease, cystic fibrosis, and food allergies.†

*Treem WR. Clinical aspects and treatment of congenital sucrase-isomaltase deficiency. *J Pediatr Gastroenterol Nutr.* 2012;55(suppl 2):S7-13.

†Karakoyun M, Kilicoglu E, Sahan YO, Baran M, Unal F, Aydogdu S. Our cases with sucrase isomaltase deficiency. *J Gastrointest Dig Sys.* 2015;5:6.

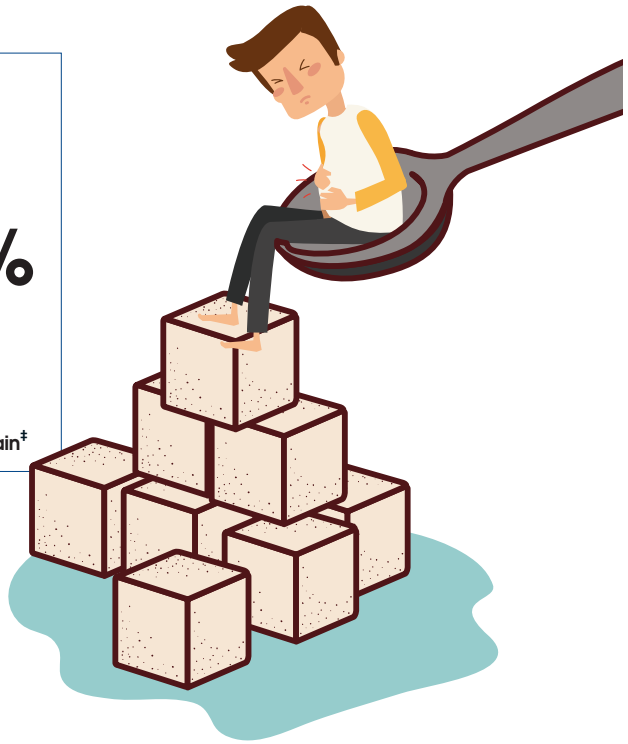
Most common symptoms

CSID sufferers' most common symptoms are...

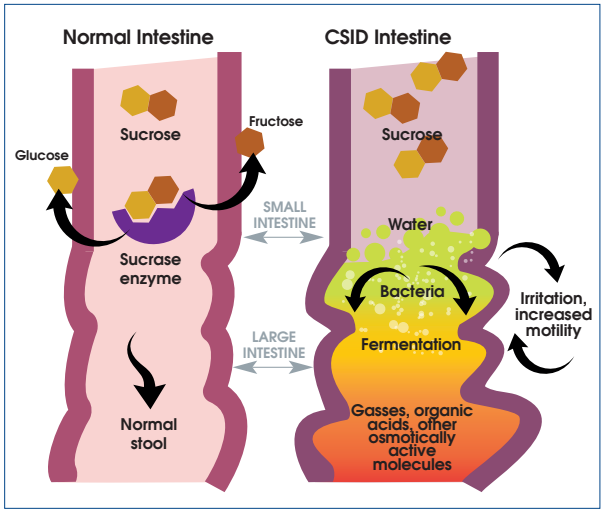
56% Diarrhea‡

33% Stomach pain‡

‡ Data on file



In adults, symptoms persist but may appear to be less severe than those experienced by children. **CSID** is not a disease that a patient can "outgrow." In some adults, symptoms may include an increase in bowel frequency, nausea, abdominal distention, and flatulence, although episodic watery diarrhea upon ingestion of high levels of sucrose may occur. In some patients, diarrhea may alternate with constipation, leading to a misdiagnosis of irritable bowel syndrome (IBS).



As with pediatric patients, the symptoms in adults vary. With the introduction of dietary sucrose, some patients may experience several severe effects from this disease, while others may experience only mild symptoms.

ONLINE RESOURCES:

For the Patient

sucroseintolerance.com

sucroseintolerance.com/doctor-directory/

For the Doctor

Call: 1-800-705-1962 to speak with a CSID Support Specialist.

9.3%

CSID may be more common than you think

Sucrase deficiency may be more common than you think. In a recent retrospective analysis of 27,875 small intestinal biopsy samples taken during an endoscopy and sent to a specialty laboratory for a four-panel disaccharidase enzyme activity assessment, **9.3% of the samples showed a sucrase deficiency.***

*Nichols BL Jr, Adams B, Roach CM, Ma CX, Baker SS. Frequency of sucrase deficiency in mucosal biopsies. *J Pediatr Gastroenterol Nutr.* 2012;55(suppl 2):S28-30.

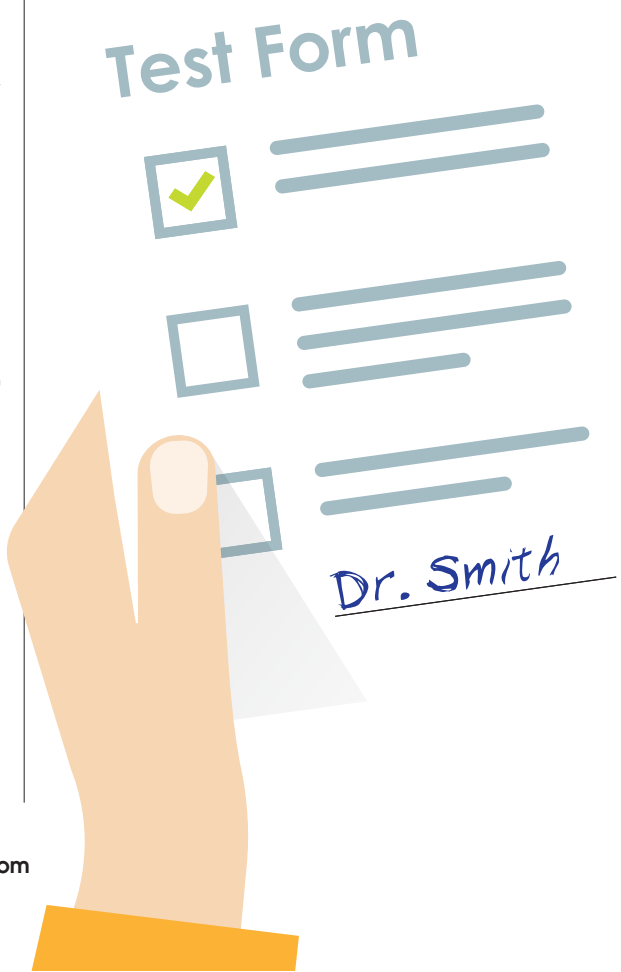
How is CSID diagnosed?

WHO MIGHT HAVE CSID?

Infants, children, and adults can suffer from CSID.

Diagnosing **CSID** can be difficult because the symptoms are similar to other gastrointestinal disorders. Your healthcare provider can choose from several testing methods to help diagnose you. Here is a list of tests and resources for your doctor to consider.

***ONLY YOUR DOCTOR OR HEALTHCARE PROVIDER CAN ORDER A TEST**



Tests that aid in the diagnosis

Endoscopy

- The disaccharidase assay directly measures enzyme activity levels in biopsy samples obtained from the small intestine during an upper GI endoscopy.
- For more information about disaccharidase assay testing, call **1-800-705-1962.**

Sucrose Breath Test

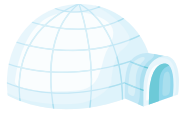
- The test is noninvasive, short in duration, and can be administered by patients at home.
- Patients with CSID may experience symptoms due to consumption of table sugar during the test.
- For more information, call **1-800-705-1962.**

4-4-4 At-Home Food Challenge

- **Step 1:** Stir 4 tablespoons of ordinary table sugar into a 4-ounce glass of water. Mix until sugar is completely dissolved.
- **Step 2:** Drink it on an empty stomach.
- **Step 3:** See if symptoms such as bloating, gas, and diarrhea occur during the next 4-8 hours; this suggests Sucrose Intolerance is possible.
- **NOTE:** This test is not appropriate for infants, young children, geriatric patients, and those with co-morbid conditions like diabetes. Patients may have severe symptoms if they are very sensitive to sugar. A physician should be consulted before this test is taken.

DID YOU KNOW?

In some societies, like Greenland Eskimos and some Alaskan Natives, a low-carbohydrate, high-protein, high-fat diet may mask CSID symptoms.



▶CSID DISEASE INFO.COM

Because CSID symptoms are similar to other gastrointestinal disorders, patients are often misdiagnosed or delayed in reaching a diagnosis.

What are treatment options?

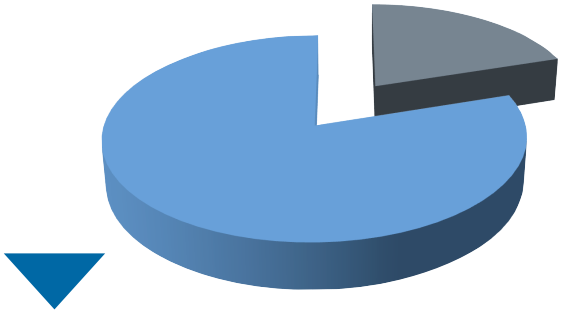
Sucraid® (sacrosidase) Oral Solution is the only FDA-approved enzyme replacement therapy indicated for the treatment of genetically determined sucrase deficiency. Ask your doctor if **Sucraid®** is right for you.

OPEN FLAP

SUCRAID®

The goal with Sucraid® therapy is to eat as normal and as healthy a diet as possible.

Clinical Trials Confirm Efficacy for Use of Sucraid® in Both Children and Adults



81% Relief of Symptoms

Patients who became asymptomatic with Sucraid® in a clinical trial.*†

*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.

†Treem WR, McAdams L, Standford L, Kastoff G, Justinich C, Hyams J. Sacrosidase therapy for congenital sucrase-isomaltase deficiency. *J Pediatr Gastroenterol Nutr.* 1999;28:137-142.

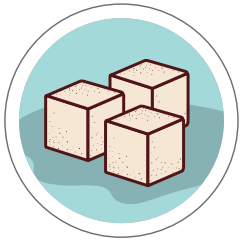
Please see additional Important Safety Information on page S2 and enclosed Full Prescribing Information.

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. If you notice any swelling or have difficulty breathing, get emergency help right away.
- 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).



Sucrose Intolerance™

from Congenital Sucrase-Isomaltase Deficiency

CSID

More Common Than You Think!

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

SUC19.1030 06/2019

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

■ Sucraid® does not break down some sugars that come from the digestion of starch. You may need to restrict the amount of starch in your diet. Your doctor will tell you if you should restrict starch in your diet.

■ Tell your doctor if you have diabetes, as your blood glucose levels may change if you begin taking Sucraid®. Your doctor will tell you if your diet or diabetes medicines need to be changed.

■ Some patients treated with Sucraid® may have worse abdominal pain, vomiting, nausea, or diarrhea. Constipation, difficulty sleeping, headache, nervousness, and dehydration have also occurred in patients treated with Sucraid®. Check with your doctor if you notice these or other side effects.

■ Sucraid® has not been tested to see if it works in patients with secondary (acquired) sucrase deficiency.

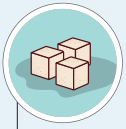
■ **NEVER HEAT SUCRAID® OR PUT IT IN WARM OR HOT BEVERAGES OR INFANT FORMULA.** Do not mix Sucraid® with fruit juice or take it with fruit juice. Take Sucraid® as prescribed by your doctor. Normally, half of the dose of Sucraid® is taken before a meal or snack and the other half is taken during the meal 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.

Sucraid®
(sacrosidase) Oral Solution

Call: 1-800-705-1962
Email: info@sucraid.com



Sucraid® is ONLY available at **US Bioservices** Specialty Pharmacy.

For the Doctor
The physician must complete the Sucraid® Prescription Form and fax it to **1-866-850-9155.**

Please see additional Important Safety Information on page S1 and enclosed Full Prescribing Information.

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 β,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

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:

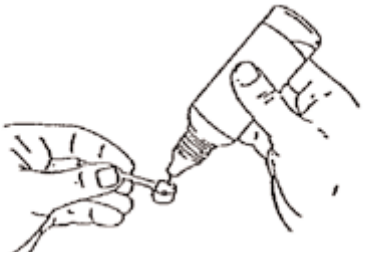
Each bottle of Sucraid is supplied with a plastic screw cap which covers a dropper dispensing tip. Remove the outer cap and measure out the required dose. Reseal the bottle after each use by replacing and twisting the cap until tight.

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.

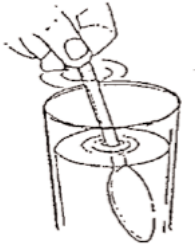
Figure 1. Measure dose with measuring scoop.



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.net
For questions call 1-866-469-3773

Rev 09/18
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.net

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