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 sucrose-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.*

Most common symptoms

Diarrhea, gas, bloating, 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, diarrhea, and vomiting are the most common symptoms in infants and toddlers. Other symptoms include abdominal distention, gassiness, colic, diarrhea, and vomiting.

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). 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.

What are the symptoms of CSID?

Symptoms can range from mild to severe chronic, watery, acidic diarrhea to gas, bloating, nausea, and abdominal pain. Infants may not show symptoms 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, diarrhea, and vomiting are the most common symptoms in infants and toddlers. Other symptoms include abdominal distention, gassiness, colic, diarrhea, 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.

What is CSID?

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.

The symptoms of CSID can range from mild to severe and vary depending on the patient. Infants may not show symptoms 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, diarrhea, and vomiting are the most common symptoms in infants and toddlers. Other symptoms include abdominal distention, gassiness, colic, diarrhea, and vomiting.

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How is CSID diagnosed?

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.

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 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.

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.

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

Sucraid® is ONLY available at US Bioservices Specialty Pharmacy.

Sucraid® (sacrosidase) Oral Solution

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

Full Prescribing Information

Sucread.com
What are treatment options?

SucraID® (sucrosidase) 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.

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.* †

Indication

SucraID® (sucrosidase) 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® (sucrosidase) 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).

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

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OPEN FLAP

More Common Than You Think!

Please see additional Important Safety Information on page 52 and enclosed Full Prescribing Information.
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**Tests that aid in the diagnosis**

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.

ENDOSCOPY

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**FOR MORE INFORMATION ABOUT DISACCHARIDASE TESTING, CALL 1-800-705-1962.**

**SUCROSE BREATH TEST**

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**4-4-4 AT-HOME FOOD CHALLENGE**

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**SUCROSE INTOLERANCE**

Patients with CSID may experience symptoms due to consumption of table sugar during the test.

**FOR MORE INFORMATION, CALL 1-800-705-1962.**
Sucraid® (sacrosidase) Oral Solution:

DESCRIPTION

Sucraid (sacrosidase) 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

Sucraid is a pale yellow to colorless, clear solution with a faint odor. Each mL of Sucraid contains 9000 I.U. (sacrosidase) per mL (sacrosidase, the active ingredient). The chemical name of this enzyme is ß,D-fructofuranoside fructohydrolase. Sucraid is from the yeast, Saccharomyces cerevisiae.

It has been reported that the primary active site and structure of this protein consists of 513 amino acids with an apparent molecular weight of 100,000 in the glycoprotein resear. (0.09 I.U./mL). Parenteral also suggested that the proteolytic products in solution as a monomer, dimer, tetramer, and oligomer ranging from 100,000 to 500,000 daltons. 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 proteolytic enzyme and is eliminated 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 water, citric acid to maintain the pH at 4.0 to 4.7. Glycerin (glycerol) is the only excipient contained in the recommended doses of Sucraid has no reported toxicity. This enzyme preparation is fully soluble with water, milk, and infant formula.

CLINICAL PHARMACOLOGY

Congenital sucrase-isomaltase deficiency (CSID) is a rare, autosomal recessive disorder, characterized by a marked decrease in sucrase activity. CSID is usually characterized by a complete or nearly complete lack of endogenous sucrase activity, a heterogeneous disease with very variable enzyme activity. CSID is usually characterized by a complete or nearly complete lack of endogenous sucrase activity, a relatively homogeneous disease with very variable enzyme activity.

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 yeasts, yeast products, papain, or glycogen (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.

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).

CONTRAINDICATIONS

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

WARNINGS

Severe reactions, 90 minutes after a second dose of sucrose, implicated reaction rate the fall 28% for a 4-year-old boy. The breathing was probably caused by sucrose. The boy had asthma and was being treated with steroids. A skin test for sucrose was positive.

Other serious events have not been linked to Sucraid.

PRECAUTIONS

Swarovski (sacrosidase) Oral Solution may be taken to administer initial doses of Sucraid near (within a few minutes to travel) a facility where emergency hyperglycemic reactions can be observed and treated.

Implications, the patient may be treated immediately. Sucraid contained use it a short testing. Should symptoms of hypersensitivity appear, discontinuation and may indicate the use of supportive therapy.

Side effects may be observed in one child who displayed hypersensitivity in one event.

INFORMATION FOR PATIENTS

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.

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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).
Write down the date the sealed bottle is first opened in the space provided on the 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

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.

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 64 months duration, physicians treated a total of 52 patients with Sucraid. The adverse experiences and respective number of patients reporting each event (in parentheses) were as follows: abdominal pain (4), vomiting (3), nausea (2), diarrhea (2), constipation (2), insomnia (1), headache (1), nervousness (1), and dehydration (1).

NURSING MOTHERS can be part of the clinical presentation of the genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID). One autistic child experienced a serious hypersensitivity reaction (nephritis) probably related to sucrose-
dose (see Warnings). The event resulted in withdrawal of the patient from the trial and resolution with no sequelae.

OVERDOSAGE
Overdose with Sucraid has not been reported.

DOSE AND ADMINISTRATION
The recommended dosage is 1 or 2 mL (0.50 to 1.00 mL) of 2 full measuring scoops (each full measuring scoop equals 1 mL) once daily or divided equally for two meals. The dosage may be increased gradually to a maximum of 4 mL (2 full measuring scoops) 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® (sucrase) Oral Solution is available in 118 mL, 4 fluid ounce (120 mL) translucent plastic bottles, packaged two bottles per box. Each mL of solution contains 0.930 international units (IU) of sucrase. A 1 mL measuring scoop is provided with each bottle. A full measuring scoop is 1 mL.

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

Distributed by:
QOL Medical, LLC
Vero Beach, FL 32963
To order, or for any questions, call 1-888-469-3773
www.sucraid.net
NDC# 67871-111-04

Although Sucraid provides replacement therapy for the deficient sucrase, X does not provide specific replacement therapy for the deficient sucrase. 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
Use 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. It is important to note that this product is sensitive to heat. Sucraid should not be reconstituted or rewarmed with fruit juice, since its acidity may reduce the enzyme activity.

USE IN DIABETES
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 disaccharidase deficiencies 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 breath 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 to be of clinical significance. The use of Sucraid together with other agents used to treat the underlying disease may cause additive effects, and patients should be carefully monitored for signs of such effects.

Although Sucraid provides replacement therapy for the genetically acquired sucrase deficiency, it is effective for the treatment of the genetically acquired sucrase deficiency, which is part of CSID.