



1. Identify Sucrase Deficiency Due to CSID
2. Look for Chronic Signs and Symptoms
3. Try a 4-Day Trial of **Sucraid®**

The **Sucraid® 4-Day Trial** offers eligible patients diagnosed with sucrase deficiency due to CSID a short therapeutic trial. The specialty pharmacy will contact patients to confirm response.*

Learn more about the only FDA-approved enzyme replacement therapy for the treatment of sucrase deficiency due to CSID and download the prescription form. (See QR code inside.)

IMPORTANT SAFETY INFORMATION FOR SUCRAID® (SACROSIDASE) ORAL SOLUTION

INDICATION

Sucraid® (sacrosidase) Oral Solution is indicated for the treatment of sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID), in adult and pediatric patients 5 months of age and older.

Contraindication

Sucraid® is contraindicated in patients known to be hypersensitive to yeast, yeast products, glycerin (glycerol), or papain.

Please see additional Important Safety Information on page 8.

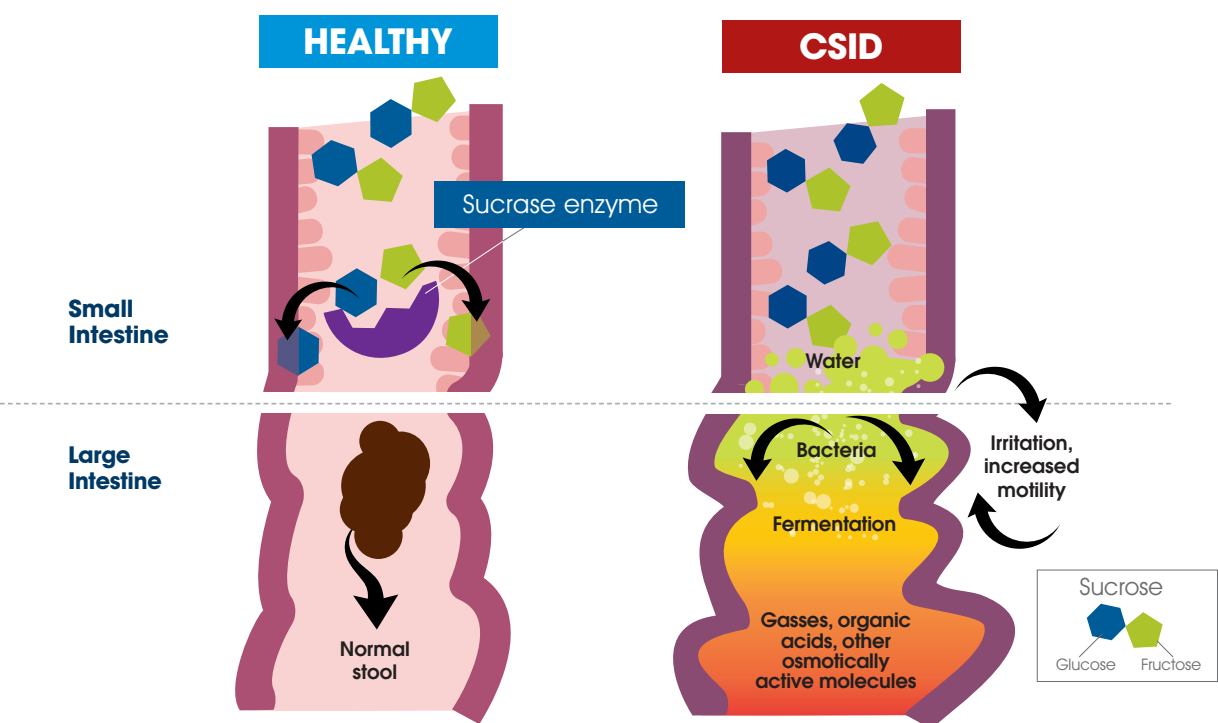
[Sucraid.com](https://www.sucraid.com)

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1. Identify CSID

What is CSID?

Congenital Sucrase-Isomaltase Deficiency (CSID) is a genetic disorder that affects a person's ability to digest sucrose. People with this condition lack sufficient sucrase activity in the small intestine to break down sucrose. Undigested sucrose passes through to the large intestine, causing diarrhea, bloating, abdominal pain, and other symptoms.



► CSID is largely a clinical diagnosis

2. Look for Chronic Signs and Symptoms

Patients may present with signs and symptoms similar to those of other GI conditions especially after eating **sugar (sucrose)**. Any one of the following could indicate sucrase deficiency and potentially CSID



► Rule out organic conditions where CSID may not be the primary cause of symptoms.

3. Try a FREE 4-Day Trial of Sucraid® (sacrosidase) Oral Solution

The Sucraid® 4-Day Trial offers eligible patients a short therapeutic trial. The specialty pharmacy will contact patients to confirm response.*

Learn more about the only FDA-approved enzyme replacement therapy for the treatment of sucrase deficiency due to CSID and download the prescription form.



Sucraid® Rx Form

Several Testing Options Are Available to Assist a CSID Diagnosis

☐ Disaccharide Assay via EGD

☐ Sucrose Challenge Test

☐ Sucrose Breath Tests

☐ Genetic Test

Other factors can cause sucrose intolerance; a positive test may be something other than CSID. False positives and false negatives can occur.

About Sucraid®

Sucraid® is the only FDA-approved enzyme replacement therapy **indicated for the treatment of sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID)**, in adult and pediatric patients 5 months of age and older.

*This Program is not available for any patient who receives (or is eligible to receive) coverage or reimbursement (in full or in part) for medical treatment and/or prescription drugs through any federal, state, or other government health insurance program (including, but not limited to, Medicare, including Medicare Part D plans, Medicaid, Veterans Administration health coverage, TRICARE or other Department of Defense health coverage, or the Puerto Rico Government Health Insurance Plan). Product dispensed under the Sucraid® 4-Day Trial Program may not be resold, charged to patients, or submitted for reimbursement to any payer, either directly or indirectly. Neither healthcare provider nor patient are obligated in any way to prescribe or purchase Sucraid®.

Helpful Information

A. E-Prescribing and Specialty Pharmacy

B. Prior Authorization Information

A. E-Prescribing Sucraid®

Specialty Pharmacy Information:

Frontier Therapies - Optum
6425 Santa Margarita St. #110
Las Vegas, NV 89118
Phone: 1-833-800-0122
Fax: 1-866-850-9155

Step 1: Search for Frontier Therapies - Optum by name, city, zip, or MAIN phone number.

Frontier Therapies II - Optum 6425 Santa Margarita St. #110, Las Vegas, NV 89118	NABP: 788638 NPI: 1720364532 NCPDP: 2992750 Main Phone: 1-855-768-9727
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Step 2: Search and select the drug Sucraid® (sacrosidase) Oral Solution from the dropdown menu.

Step 3: Sucraid® recommended dosing, directions, dispense quantity, and refills.

- SINGLE-USE CONTAINER - for patients 33 pounds or less**
- + Take 1 mL by mouth with every meal or snack up to 8 times per day.
- Choose one:**
- + Dispense 120 single-use containers for a **30-day supply**.
 - + Dispense 360 single-use containers for a **90-day supply**.
- SINGLE-USE CONTAINER - for patients over 33 pounds**
- + Sucraid® Single-Use Containers, contain a single 2-mL dose
 - + Convenient for dosing when away from home, Sucraid® Single-Use Containers are stable for three days at room temperature (59°F to 77°F [15°C to 25°C])
- Choose one:**
- + Dispense 180 single-use containers for a **30-day supply**.
 - + Dispense 540 single-use containers for a **90-day supply**.

Step 4: Include the attestation statement (optional).**

A signed attestation statement gives the specialty pharmacy delegated authority to process and submit documentation for a prior authorization.

Include the following attestation statement in the directions text box:

"I authorize Frontier Therapies - Optum to initiate any de minimis authorization processes from applicable health plans, if needed, including the submission of any necessary forms to such health plans, to the extent not prohibited."

**Frontier Therapies - Optum cannot submit a prior authorization without the signed attestation statement.

Need help? Call Sucraid® Support
1-833-444-CSID (2743)

Please see Sucraid® (sacrosidase) Oral Solution Important Safety Information and full Prescribing Information attached to page 8 or at the end of this PDF download. Sucraid® may cause a serious allergic reaction.

Sucraid.com

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B. Prior Authorization Checklist

1. Enter Patient Diagnosis Code (ICD-10)¹

Here is a list of possible ICD-10 codes that may apply to a CSID patient (may not be an all-inclusive list):

Sucrase-isomaltase deficiency	E74.31	Diarrhea, unspecified	R19.7
Other disorders of intestinal carbohydrate absorption	E74.39	Flatulence	R14.3
Malabsorption due to intolerance, not elsewhere classified	K90.49	Abdominal distension (gaseous)	R14.0
		Nausea	R11.0

2. Identify Patient Symptoms

Experiencing symptoms of sucrase deficiency due to Congenital Sucrase-Isomaltase Deficiency (CSID), including diarrhea, gas, bloating, abdominal cramping, nausea, or other

3. Detail Patient History

Prior treatment
Medical history
Dietary counseling
Other _____

4. Indicate Patient Tests and Results

- Evidence of deficient sucrase activity through one of the following recommended diagnostic tests:
- A. ¹³C-Sucrose Breath Test
 - B. Sucrose hydrogen-methane breath test
 - C. EGD biopsy and disaccharidase assay
 - ☐ 2 extra distal duodenal biopsy samples
 - ☐ Sent to specialty disaccharidase testing lab; results evaluated

Disaccharidase	Normal Range ²
Lactase	5 - 55 U/g protein
Sucrase	26 - 110 U/g protein
Maltase	105 - 380 U/g protein
Palatinase	9 - 32 U/g protein

Links to Prior Authorization Forms

Popular provider forms can be found at these links:

Aetna tinyurl.com/3vtmzb67	Cigna tinyurl.com/yp7kn3ma	Covermymeds Prime Therapeutics tinyurl.com/2ab56wjf	OptumRx tinyurl.com/2p85xhm
Anthem tinyurl.com/yc73d37h		Express Scripts tinyurl.com/yc3ma99b	

Reimbursement Disclaimer: This document is for informational purposes only and is not legal advice or official guidance from payors. It is not intended to increase or maximize reimbursement by any payor. Hospitals and physicians are solely responsible for being in compliance with Medicare and other payor rules and requirements for the information submitted with all claims and appeals. QOL Medical, LLC does not warrant or guarantee that the use of this information will result in coverage or payment for any particular therapy. Before any claims or appeals are submitted, hospitals and physicians should review official payor instructions and requirements, should confirm the accuracy of their coding or billing practices with these payors, and should use independent judgment when selecting codes that most appropriately describe the services or supplies provided to a patient.

1. Centers for Medicare & Medicaid Services. ICD-10. Last updated April 1, 2023. www.cms.gov/medicare/icd-10/2023-icd-10-cm
2. Hackenmueller SA, Grenache DG. Reference intervals for intestinal disaccharidase activities determined from a non-reference population. J Appl Lab Med. 2016;1(2):172-80. doi:10.1373/jalm.2016.020388

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WARNINGS, PRECAUTIONS, AND ADDITIONAL IMPORTANT SAFETY INFORMATION

■ Severe Hypersensitivity Reactions

Severe hypersensitivity reactions, including wheezing, difficulty breathing, rash, pruritis, and swelling of the face, lips, mouth, or tongue have been reported with administration of Sucraid®. Sucraid® contains papain, which is associated with hypersensitivity reactions.

■ Increased Blood Glucose Concentration in Patients With Diabetes Mellitus

Sucraid® enables the products of sucrose hydrolysis, glucose and fructose, to be absorbed and may increase blood glucose concentrations. Monitor blood glucose concentrations and adjust the diet accordingly for patients with diabetes mellitus.

■ Dietary Starch Restriction

Sucraid® does not replace isomaltase. Therefore, patients may still experience symptoms of CSID while taking Sucraid®. Consider dietary starch restriction in addition to Sucraid®, especially in patients in whom symptoms are not adequately controlled by Sucraid®.

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

■ 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; single-use containers can be removed from refrigeration and stored at 59°F-77°F (15°C-25°C) for up to 3 days (72 hours). Refer to Instructions for Use for full information on how to take Sucraid®.

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.



CALL: 1-800-705-1962 | SUCRAID.COM/HCP

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Sucraid® (sacrosidase) Oral Solution:

DESCRIPTION

Sacrosidase is an enzyme with the chemical name of 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 Da for the glycosylated monomer (range 66,000- 116,000 Da). Reports also suggest that the protein exists in solution as a monomer, dimer, tetramer, and octomer ranging from 100,000 Da to 800,000 Da. It has an isoelectric point (pI) of 4.5.

Sucraid®(sacrosidase) Oral Solution is an oral enzyme replacement therapy.

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.

Sucraid may contain small amounts of papain (see WARNINGS). 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 glycerin, water, citric acid, and sodium hydroxide 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 (see DOSAGE AND ADMINISTRATION, Administration Instructions).

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 sucrose activity, a very marked reduction in isomaltase activity, and a moderate decrease in maltase activity.

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, diarrhea, 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.

CLINICAL STUDIES

A two-phase (dose response preceded by a breath hydrogen phase) double-blind, multi-site, crossover trial was conducted in 28 pediatric patients (approximately 5 months to 12 years of age) 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 pediatric patients up to 3 years of age, 86% became asymptomatic. In pediatric patients over 3 years of age, 77% became asymptomatic. Thus, the therapeutic response did not differ significantly according to pediatric 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, pediatric patients showed a marked decrease in breath hydrogen output when they received sacrosidase in comparison to placebo.

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

INDICATIONS AND USAGE

Sucraid®(sacrosidase) Oral Solution is indicated for the treatment of sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID), in adult and pediatric patients 5 months of age and older.

CONTRAINDICATIONS

Sucraid is contraindicated in patients known to be hypersensitive to yeast, yeast products, glycerin (glycerol), or papain (see WARNINGS).

WARNINGS

Severe Hypersensitivity Reactions

Severe hypersensitivity reactions, including wheezing, rash, and pruritis, have been reported with administration of Sucraid. Sucraid contains papain, which is associated with hypersensitivity reactions (see DESCRIPTION).

A pediatric patient in the clinical trials experienced a hypersensitivity reaction of severe wheezing that required hospitalization. Postmarketing cases of cutaneous hypersensitivity reactions have also been reported.

Instruct patients or caregivers to stop Sucraid and seek medical attention if symptoms suggestive of a hypersensitivity reaction occur. Sucraid is contraindicated in patients who have had a known hypersensitivity reaction (see CONTRAINDICATIONS).

PRECAUTIONS

Increased Blood Glucose Concentrations in Patients with Diabetes Mellitus

Sucraid enables the products of sucrose hydrolysis, glucose and fructose, to be absorbed and may increase blood glucose concentrations. Monitor blood glucose concentrations and adjust the diet accordingly for patients with diabetes mellitus.

Dietary Starch Restriction

Sucraid does not replace isomaltase. Therefore, patients may still experience symptoms of CSID while taking Sucraid. Consider dietary starch restriction in addition to Sucraid, especially in patients in whom symptoms are not adequately controlled by Sucraid.

Information for Patients

See Patient Package Insert and the Instructions for Use.

Drug Interactions

Fruit Juice

The acidity in fruit juice may reduce the enzyme activity in Sucraid. Administration of Sucraid with liquids other than water, milk, or infant formula has not been studied and is not recommended (see DOSAGE AND ADMINISTRATION, Administration Instructions).

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

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

The safety and effectiveness of Sucraid for the treatment of sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID), have been established in pediatric patients aged 5 months and older. Use of Sucraid for this indication is supported by evidence from adequate and well-controlled studies in pediatric patients (see CLINICAL STUDIES AND ADVERSE REACTIONS).

Geriatric Use

Clinical trials of Sucraid did not include patients 65 years of age and older to determine if they respond differently from younger adult patients.

ADVERSE REACTIONS

The following adverse reactions associated with the use of sacrosidase were identified in clinical studies or postmarketing reports. Because some of these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

In clinical studies of up to 54 months duration, a total of 52 patients were treated with Sucraid. The reported adverse reactions (number of patients) were as follows: abdominal pain (4), vomiting (3), nausea (2), diarrhea (2), constipation (2), insomnia (1), headache (1), nervousness (1), and dehydration (1).

Hypersensitivity reactions (wheezing, rash, and pruritis) have been reported (see WARNINGS).

DOSAGE AND ADMINISTRATION

Important Administration Information

- Administer Sucraid with each meal or snack.
- Mix Sucraid with cold or room temperature water, milk or infant formula prior to administration. Administration of Sucraid in liquids other than water, milk, or infant formula has not been studied and is not recommended. Do not mix or consume Sucraid with fruit juice.
- Do not warm or heat the water, milk, or infant formula before or after addition of Sucraid.
- Administer half of the dose at the beginning of the meal or snack and the other half of the dose during the meal or snack.

Recommended Dosage

The recommended dosage is:

- *Patients weighing 15 kg and less:* 8,500 International Units (1 mL) administered orally with each meal or snack.
- *Patients weighing more than 15 kg:* 17,000 International Units (2 mL) administered orally with each meal or snack.

Preparation and Administration Instructions for Patients Weighing 15 kg or Less

Multiple-Dose Bottle:

1. Using the measuring scoop provided, add 1 scoop of Sucraid (1 mL) to 60 mL of cold or room temperature water, milk, or infant formula.
2. Stir to mix well.
3. Administer half of the mixed Sucraid solution (30 mL) at the beginning of the meal or snack and the other half of the mixed solution (30 mL) during the meal or snack.
4. Do not save any of the mixed Sucraid solution for later use.
5. Rinse the measuring scoop with water.

Single-Use Container:

1. Empty the entire contents of the single-use container (2 mL) in 120 mL of cold or room temperature water, milk, or infant formula.
2. Stir to mix well.
3. Divide the mixed Sucraid solution into two separate 60 mL portions. The first portion (60 mL) is for immediate use.
 - Administer half of the first portion (30 mL) of the mixed Sucraid solution at the beginning of the meal or snack and the other half of the first portion (30 mL) of the mixed Sucraid solution during the meal or snack.
4. Store the second portion of the mixed Sucraid solution (60 mL) at 2°C to 8°C (36°F to 46°F) for up to 24 hours for administration with the next meal or snack.
 - Discard the mixed Sucraid solution if not used within 24 hours.

Preparation and Administration Instructions for Patients Weighing More than 15 kg

Multiple-Dose Bottle:

1. Using the measuring scoop provided, add 2 scoops of Sucraid (2 mL) to 120 mL of cold or room temperature water, milk, or infant formula.
2. Stir to mix well.
3. Administer half of the mixed Sucraid solution (60 mL) at the beginning of the meal or snack and the other half of the mixed Sucraid solution (60 mL) during the meal or snack.
4. Do not save any of the mixed Sucraid solution for later use.
5. Rinse the measuring scoop with water.

Single-Use Container:

1. Empty the entire contents of the single-use container (2 mL) in 120 mL of cold or room temperature water, milk, or infant formula.
2. Stir to mix well.
3. Administer half of the mixed Sucraid solution (60 mL) at the beginning of the meal or snack and the other half of the mixed solution during the meal or snack (60 mL).
4. Do not save any of the mixed Sucraid solution for later use.

HOW SUPPLIED

118 mL Multiple-Dose Bottle

Sucraid (sacrosidase) Oral Solution is available in 118 mL (4 fluid ounces) multiple-dose translucent plastic bottles, packaged two bottles per carton. Each mL of solution contains 8,500 International Units of sacrosidase. A 1 mL measuring scoop is provided with each bottle. A full measuring scoop is 1 mL.

NDC# 67871-111-04 (2 x 118 mL multiple-dose bottles)

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

2 mL Single-Use Container

Sucraid (sacrosidase) Oral Solution is available in 2 mL, single-use containers that are packaged into a foil pouch. Each 2 mL single-use container contains 17,000 International Units of sacrosidase. Each foil pouch holds a card of 5 containers. Five pouches are then packaged in a box (25 containers). Six boxes are further packaged in a carton (150 containers).

NDC# 67871-111-07 (150 x 2 mL single-use containers)

Store under refrigeration, 2°C to 8°C (36°F to 46°F). Protect from light. Single-use container can be removed from refrigeration and stored at 15°C to 25°C (59°F to 77°F) for up to 3 days (72 hours).

Manufactured by:
QOL Medical, LLC Vero Beach, FL 32963
U.S. License No. 2195

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

Rev <08/24>

Patient Information

SUCRAID® (Su-kreid) (sacrosidase) Oral Solution

What is SUCRAID?

SUCRAID is a prescription medicine for the treatment of people who were born with a lack of (deficiency) sucrase, which is part of congenital sucrose-isomaltase deficiency (CSID). It is not known if SUCRAID is safe and effective in children under 5 months of age.

Do not take or give your child SUCRAID if you or your child:

- are allergic to yeast, yeast products, glycerin (glycerol), or papain. See the end of this Patient Information leaflet for a complete list of ingredients in SUCRAID.
- Before you take or give your child SUCRAID, tell your healthcare provider about all of your medical conditions, including if you or your child:
 - have diabetes. SUCRAID can interact with the food in your diet and may change your blood sugar levels. Your healthcare provider will tell you if your diet or diabetes medicines need to be changed.
 - are pregnant or plan to become pregnant. It is not known if SUCRAID will harm your unborn baby.
 - are breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you will take SUCRAID while breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take or give SUCRAID?

- **See the detailed Instructions for Use that come with this Patient Information leaflet for instructions about the right way to take or give SUCRAID.**
- SUCRAID should be taken or given exactly as prescribed by your healthcare provider.Do not change the dose of SUCRAID without talking to your healthcare provider.
- SUCRAID comes in a 118-mL multiple-dose bottle or a 2-mL single-use container.Your healthcare provider will decide which type of SUCRAID is best for you to use.
- The dose of SUCRAID depends on body weight.Your healthcare provider will tell you how much SUCRAID you should take or give your child.
 - The dose for a child 33 pounds (15 kg) or less is 1 mL or 28 drops of SUCRAID in 2 ounces of water, milk, or infant formula.
 - The dose for a child or adult more than 33 pounds (15 kg) is 2 mL or 56 drops of SUCRAID in 4 ounces of water, milk, or infant formula.
- SUCRAID can only be dissolved in cold or room temperature water, milk, or infant formula. **Do not** put SUCRAID in warm or hot liquids.
 - **Do not** mix SUCRAID with fruit juice. **Do not** take or give SUCRAID with fruit juice.
 - **Do not** warm or heat the mixed solution before taking or giving SUCRAID.
- Measure your dose or your child's dose of SUCRAID using the measuring scoop that comes with the SUCRAID bottle.**Do not** use a kitchen teaspoon or other measuring device.
- SUCRAID should be taken or given with each meal or snack. Half of the SUCRAID dose should be taken at the beginning of each meal or snack. Take or give the remaining SUCRAID dose during the meal or snack.
- Rinse the measuring scoop with water after each use.
- SUCRAID does not break down some sugars found in foods that have starch, such as wheat, rice, and potatoes. Your healthcare provider may tell you to avoid eating foods with starch.

What are the possible side effects of SUCRAID?

- **SUCRAID may cause serious side effects, including:**
- **severe allergic reactions.** Severe allergic reactions have happened in some people taking SUCRAID. Tell your healthcare provider right away or go to the nearest emergency room if you have any of the following symptoms:
 - difficulty breathing
 - wheezing
 - rash
 - swelling of the face, lips, mouth, or tongue

Your healthcare provider may need to monitor you or your child carefully when first starting treatment with SUCRAID.

The most common side effects of SUCRAID include:

- stomach (abdominal) pain
- vomiting
- nausea
- diarrhea
- constipation
- problems sleeping
- headache
- nervousness
- dehydration

These are not all of the possible side effects of SUCRAID. **Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

How should I store SUCRAID?

- **SUCRAID 118 mL multiple-dose bottle**
 - Store in the refrigerator between 36°F to 46°F (2°C to 8°C).
 - Throw away after 4 weeks of first opening the multiple-dose bottle.
 - Protect from heat and light.
- **SUCRAID 2-mL single-use container**
 - Store in the refrigerator between 36°F to 46°F (2°C to 8°C)
 - After removing from the refrigerator, the 2-mL single-use container can be stored between 59°F to 77°F (15°C to 25°C) for up to 3 days (72 hours).
 - Protect from heat and light.
- **Keep SUCRAID and all medicines out of the reach of children.**

General information about the safe and effective use of SUCRAID.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. **Do not** use SUCRAID for a condition for which it was not prescribed. **Do not** give SUCRAID to other people, even if they have the same symptoms that you have. It may harm them.You can ask your pharmacist or healthcare provider for information about SUCRAID that is written for health professionals.

What are the ingredients in SUCRAID?

Active ingredient: sacrosidase

Inactive ingredients: Citric acid, glycerol, sodium hydroxide, and water.

Manufactured by:
QOL Medical, LLC Vero Beach, FL 32963
U.S. License No. 2195
For more information, go to www.Sucraid.com or call 1-866-469-3773.

This Patient Package Insert has been approved by the U.S. Food and Drug Administration

Revised: August 2024

Instructions for Use

SUCRAID® (Su-kreid) (sacrosidase) oral solution:
118 mL Multiple-Dose Bottle

Read this Instructions for Use before you start taking or giving SUCRAID to a child, and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your or your child's medical condition or treatment.



Important information you need to know before taking or giving SUCRAID:

- Your healthcare provider will decide the right dose of SUCRAID for you or your child. **Do not** change the dose of SUCRAID without talking to your healthcare provider.
- The dose of SUCRAID depends on body weight. Your healthcare provider will tell you how much SUCRAID you should take or give your child.
 - The dose for a child 33 pounds (15 kg) or less is 1 mL or 28 drops of SUCRAID in 2 ounces of water, milk, or infant formula.
 - The dose for a child or adult more than 33 pounds (15 kg) is 2 mL or 56 drops of SUCRAID in 4 ounces of water, milk, or infant formula.
- SUCRAID can only be dissolved with cold or room temperature water, milk, or infant formula. **Do not** put SUCRAID in warm or hot liquids. **Do not** dissolve SUCRAID with fruit juice. **Do not** take or give SUCRAID with fruit juice.
- **Do not** warm or heat the mixed solution before taking or giving SUCRAID.
- Measure your dose or your child's dose of SUCRAID using the measuring scoop that comes with the SUCRAID bottle. **Do not** use a kitchen teaspoon or other measuring device.
- SUCRAID should be taken or given with each meal or snack. Half of the SUCRAID dose should be taken or given at the beginning of each meal or snack. Take or give the remaining SUCRAID dose during the meal or snack.
- **Do not** use the SUCRAID multiple-dose bottle if the seal has been damaged. Contact your pharmacist or healthcare provider if you cannot use the SUCRAID multiple-dose bottle.

Supplies needed to take or give SUCRAID:

- SUCRAID 118 mL multiple-dose bottle
- 1 measuring scoop (included in SUCRAID carton)
- 2 to 4 ounces of cold or room temperature water, milk, or infant formula (not included)
- Meal or snack (not included)

How to take or give SUCRAID:

Step 1: Check the expiration date on the SUCRAID bottle. **Do not** use SUCRAID after the expiration date on the bottle has passed.

Step 2: Write down the date the bottle is first opened in the space provided on the bottle label.

Step 3: Each bottle of SUCRAID has a plastic screw cap that covers a dropper dispensing tip. Remove the plastic screw cap by twisting it to the left.

Step 4: Use the measuring scoop that comes in your SUCRAID carton to measure your or your child's prescribed dose. See **Figure 1**. Reseal the bottle after each use by replacing and twisting the plastic screw cap to the right until tight.



Figure 1

Step 5: Mix your or your child's prescribed dose in 2 ounces or 4 ounces of cold or room temperature water, milk, or infant formula as instructed by your healthcare provider. See **Figure 2**.



Figure 2

Step 6: Take or give half of the mixed solution at the beginning of each meal or snack. Take or give the remaining mixed solution during the meal or snack.

Step 7: Rinse the measuring scoop with water after each use.

Throwing away (disposal of) SUCRAID:

- Throw away (discard) the SUCRAID multiple-dose bottle and any remaining medicine in your household trash 4 weeks after first opening.

How should I store SUCRAID?

- Store the SUCRAID multiple-dose bottle in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Protect SUCRAID from heat and light.

Keep SUCRAID and all medicines out of the reach of children.

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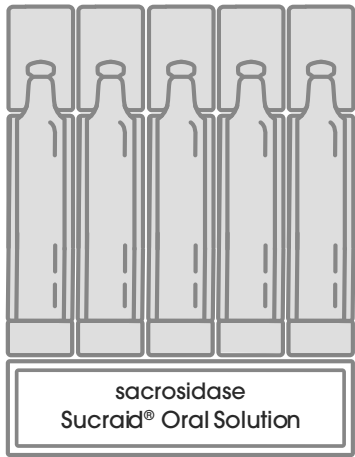
For more information, go to www.sucraid.com or call 1-866-469-3773.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.
Issued: May 2022

Instructions for Use

Sucraid® (Su-kreid) (sacrosidase) Oral Solution:
2-mL Single-Use Container

Read this Instructions for Use before you start taking or giving Sucraid to a child, and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your or your child's medical condition or treatment.



Important information you need to know before taking or giving Sucraid:

- The 2-mL single-use container is for children and adults.
- Sucraid is supplied in 2-mL single-use containers in a foil pouch. Each foil pouch holds 5 single-use containers. **Each container is one 2 mL Sucraid dose.**
- Your healthcare provider will decide the right dose of Sucraid for you or your child. **Do not** change the dose of Sucraid without talking to your healthcare provider.
- Sucraid can only be dissolved with cold or room temperature water, milk, or infant formula. **Do not** put Sucraid in warm or hot liquids. **Do not** dissolve Sucraid with fruit juice. **Do not** give or take Sucraid with fruit juice.

- **Do not** warm or heat the mixed solution before taking or giving Sucraid.
- Sucraid should be taken or given with each meal or snack. Half of the Sucraid dose should be taken at the beginning of each meal or snack. Take or give the remaining Sucraid dose during the meal or snack.
- **Do not** use the Sucraid single-use container if the seal has been damaged. Contact your pharmacist or healthcare provider if you cannot use the Sucraid single-use container.

Supplies needed to take or give Sucraid:

- 1 Sucraid 2-mL container
- 4 ounces of cold or room temperature water, milk, or infant formula (not included)
- Meal or snack (not included)
- Spoon to mix (not included)

How to take or give Sucraid:

Step 1: Check the expiration date on the Sucraid foil pouch. **Do not** use Sucraid if it is past the expiration date. Remove 1 Sucraid 2-mL container from a foil pouch.

Step 2: Twist the cap to the left to remove it from the container. See **Figure 1**.

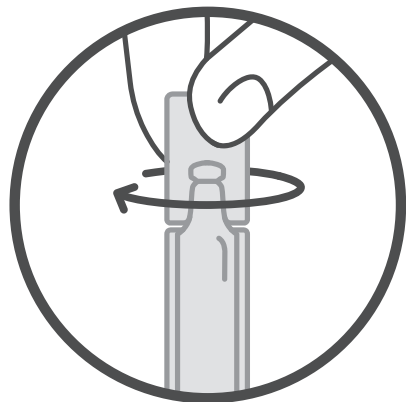


Figure 1

Step 3: Squeeze all the Sucraid solution in the container into 4 ounces of cold or room temperature water, milk, or infant formula. See **Figure 2**.



Figure 2

Step 4: Mix your or your child's prescribed dose in 4 ounces of cold or room temperature water, milk, or infant formula. See **Figure 3**.

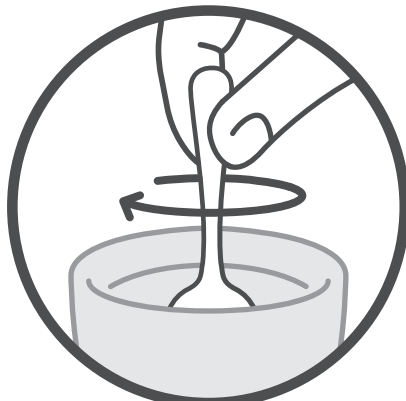


Figure 3

Step 5: For patients weighing more than 33 pounds (15 kilograms):

- The entire 4 ounces of mixed solution will be taken or given during each meal or snack. Take or give half of the mixed solution (2 ounces) at the beginning of the meal or snack and take or give the other half of the mixed solution (2 ounces) during the meal or snack.

For patients weighing 33 pounds (15 kilograms) or less:

- Divide the 4-ounce mixed solution into two separate 2-ounce portions.
- Take or give half of the first portion (1 ounce) at the beginning of the meal or snack and take or give the other half of the first portion (1 ounce) during the meal or snack.
- Store the second portion (2 ounces) in the refrigerator at 36°F to 46°F (2°C to 8°C) for the next meal or snack. Take or give half of the second portion (1 ounce) at the beginning of the next meal or snack and take or give the other half of the second portion (1 ounce) during the meal or snack.
- Throw away the second portion (2 ounces) if you do not use it within 24 hours.

Throwing away (disposal of) Sucraid:

- Throw away expired or empty Sucraid containers in your household trash.

How should I store Sucraid?

- Store the Sucraid single-use container in the refrigerator between 36°F to 46°F (2°C to 8°C).
- The Sucraid single-use container may be stored between 59°F to 77°F (15°C to 25°C) for up to 3 days.
- Protect Sucraid from heat and light.

Keep Sucraid and all medicines out of the reach of children.

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For more information, go to www.Sucraid.com or call 1-866-469-3773.

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