

NOTICE TO PHYSICIAN

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(Sample) Letter of Medical Necessity

Insurer

(Address)

Re: (Patient's name)

Date of Birth:

Policy Number: (Patient's ID number)

Dear (Insurer's contact's name and title):

I am writing to request prior authorization to initiate Sucraid® (sacrosidase) Oral Solution for (Name of patient). This letter provides evidence that this enzyme replacement therapy is medically necessary for (his/her) care and that it is an accepted treatment for Congenital Sucrase-Isomaltase Deficiency (CSID). CSID is a rare genetic disorder that affects a patient's ability to digest certain sugars due to absent or low levels of two digestive enzymes, sucrase and isomaltase. These enzymes are involved in the digestion of sugar and starch. Untreated patients with CSID experience gastrointestinal symptoms such as diarrhea, excessive gas, bloating, abdominal cramps, and, in infants and young children, malnutrition.^{1,2}

The following sections provide detailed information about the patient's medical history, a description of the treatment, and the reasons for using Sucraid® in this case.

Patient History and Diagnosis

On (Date), I diagnosed (Patient name) with CSID. (Include complete information on diagnosis and methods used in the determination of diagnosis, such as evaluation of the patient's case history, a disaccharidase assay test using a small bowel biopsy taken during an esophagogastroduodenoscopy [EGD] procedure, or a sucrose breath test [hydrogen methane or ¹³C]. *<Include proof of response to therapy (e.g., describe symptoms improved, quality of life, etc. Also list previous therapies that have been tried and failed (e.g., nutritional counseling, dietary adjustments) and what factors led to the discontinuation of these therapies.>*

In my clinical judgment, all diagnostic assays have limitations. A disaccharidase assay test using a small bowel biopsy taken during an esophagogastroduodenoscopy (EGD) is no exception. The fact that treatment with Sucraid® alleviated symptoms of this patient, suggests this patient benefited from Sucraid®.

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Treatment Description and Rationale

Sucraid® is approved by the U.S. Food and Drug Administration 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. Please see Attachments 1 and 2.

I have chosen to treat **(Patient's name)** with Sucraid® based on the history previously stated, and because it is the indicated medical treatment for CSID. I believe the patient's prognosis without Sucraid is _____. However, with Sucraid®, the prognosis is _____. In summary, Sucraid® is medically necessary in this case and should be covered and/or reimbursed. Please feel free to contact me if you require additional information.

Sincerely,
(Physician's name)

***Do not submit the sample letters verbatim. The sample letter is intended to be a guide only. Letters should be drafted using your own words. Be specific and thorough with patient data, treatment rationale and expected outcomes. Attach as much supporting documentation as possible and reference it in the body of the letter.**

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

²Treem WR. Clinical aspects and treatment of congenital sucrase-isomaltase deficiency; *J Pediatr Gastroenterol Nutr.* 2012;55(suppl2):S7-S13. doi:10.1097/01.mpg.0000421401.57633.90

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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.

Important Safety Information for Sucraid® (sacrosidase) Oral Solution

- Do not prescribe Sucraid® to patients known to be hypersensitive to yeast, yeast products, papain, or glycerin (glycerol).
- Sucraid® may cause a serious allergic reaction. Patients should stop taking Sucraid® and get emergency help immediately if any of the following side effects occur: difficulty breathing, wheezing, or swelling of the face. Care should be taken when administering initial doses of Sucraid® to observe any signs of acute hypersensitivity reaction.
- Although Sucraid® provides replacement therapy for the deficient sucrase, it does not provide specific replacement therapy for the deficient isomaltase.
- Adverse reactions as a result of taking Sucraid® may include worse abdominal pain, vomiting, nausea, diarrhea, constipation, difficulty sleeping, headache, nervousness, and dehydration.
- Before prescribing Sucraid® to diabetic patients, the physician should consider that Sucraid® will enable sucrose hydrolysis and the absorption of those hydrolysis products, glucose and fructose.
- The effects of Sucraid® have not been evaluated in patients with secondary (acquired) disaccharidase deficiency.
- **DO NOT HEAT SOLUTIONS CONTAINING SUCRAID®.** Do not put Sucraid® in warm or hot fluids. Do not reconstitute or consume Sucraid® with fruit juice since the acidity of the juice may reduce the enzyme activity of Sucraid®. Half of the reconstituted Sucraid® should be taken at the beginning of the meal or snack and the other half during the meal or snack.
- Sucraid® should be refrigerated at 36°F-46°F (2°C-8°C) and should be protected from heat and light; 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®.



QL60103

Prescribing Information

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 sucrase 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.

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).

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

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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:

- 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.
- Stir to mix well.
- 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.
- Do not save any of the mixed Sucraid solution for later use.
- Rinse the measuring scoop with water.

Single-Use Container:

- Empty the entire contents of the single-use container (2 mL) in 120 mL of cold or room temperature water, milk, or infant formula.
- Stir to mix well.
- 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.
- 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:

- 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.
- Stir to mix well.
- 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.
- Do not save any of the mixed Sucraid solution for later use.
- Rinse the measuring scoop with water.

Single-Use Container:

- Empty the entire contents of the single-use container (2 mL) in 120 mL of cold or room temperature water, milk, or infant formula.
- Stir to mix well.
- 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).
- 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>

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.

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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

Patient Information

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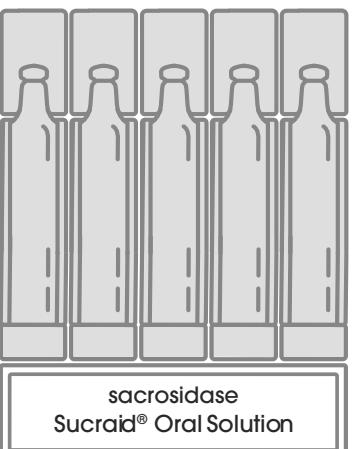
For more information, go to www.sucraid.com or call 1-866-469-3773.

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)

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.

Manufactured by:
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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.

Revised: July 2024

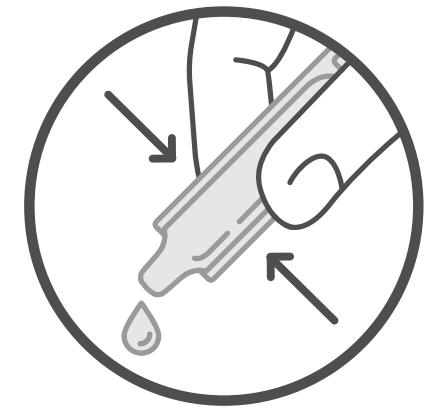


Figure 2