Helpful Information for Patients

Sucraid®
(sacrosidase) Oral Solution

Information about **Sucraid®** can be found at **Sucraid.com**

Specialty Pharmacy

For drug delivery information, contact the specialty pharmacy at
Phone: 1-833-800-0122
Fax: 1-866-850-9155

CSID

For information on Congenital Sucrase-Isomaltase Deficiency (CSID) and Sucraid® visit **Sucraid.com**

For general information, visit sucraid.com

Getting Started

WEEK 1
- Start by having your child take Sucraid® (sacrosidase) Oral Solution with meals and snacks as prescribed by your healthcare provider.
- During the next four weeks, keep a journal of what your child eats and any gastrointestinal (GI) symptoms experienced.
- You may continue your child's usual diet or speak with a registered dietitian/nutritionist (RDN) to help plan a healthy diet that is right for your child.

WEEK 2
- If your child's symptoms are better, no further changes are needed.
- If your child is still having some GI symptoms, cut back on the amount of starch eaten and monitor GI symptoms for a week. **See *Foods High in Starch* highlighted below.**
  Tip: Limit starch intake to one serving (a quarter to a half cup) per meal or half the amount usually eaten.

WEEK 3
- If your child's symptoms are better, you can begin to gradually add some high-starch foods back into your child's diet, to determine the types and amounts of starch your child is able to tolerate per meal and per day.
  Tip: In general, add only one new food every three days to be sure it is well-tolerated.

WEEK 4
- If your child continues to experience any lingering GI symptoms or if your child's symptoms return at any point, contact your child's healthcare provider to review their food intake.
  Note: If your child is ever without Sucraid®, he/she should avoid foods high in sucrose. **See *Red Flag Foods* below.**

Foods High in Starch

STARCHY VEGETABLES
- Beans (black, kidney, lima)
- Corn
- Peas (black-eyed, green)
- Potatoes (white, red, golden)
- Sweet potatoes
- Yams

WHOLE GRAINS
- Brown rice
- Bran cereal, oats
- Popcorn
- Quinoa
- Whole grain bread, cereal, crackers, pasta

REFINED STARCH
- Cakes
- Cookies
- Cereal, granola bars
- Chips (corn, potato, tortilla)
- Muffins, pastries
- Pancakes, waffles
- Pasta
- Refined cereal
- Saltine crackers
- White bread
- White rice

Created with Nutrition Data System for Research© (Regents of the University of Minnesota, 2017). High starch defined as > 2.5 g starch per 100 g food or > 2.5 g starch

Red Flag Foods (Foods High in Sucrose)

FRUIT
- Apples
- **Apricots**
- Bananas
- **Cantaloupe**
- Clementine
- **Dates**
- Grapefruit
- Guava
- Honeydew melon
- Mandarin oranges
- **Mango**
- **Nectarine**
- **Oranges**
- Passion fruit
- **Peaches**
- Persimmon
- **Pineapple**
- Plums
- **Tangelos**
- **Tangerines**
- Watermelon

VEGETABLES
- **Beets**
- **Carrots**
- Cassava (yucca)
- **Chickpeas (garbanzo beans)**
- **Coleslaw**
- **Corn**
- Edamame
- **Green peas**
- Jicama
- Kidney beans
- Lima beans
- Okra
- Onion
- **Parsnips**
- Pumpkin
- Snow peas
- Split peas
- Sweet pickles
- **Sweet potatoes, yams**

DAIRY
- Flavored milks containing sucrose (chocolate milk)*
- Milk shakes sweetened with condensed milk, malted milk*
- Yogurt*
- Yogurt containing fruits from the high-fructose fruits listed above

BAKED AND PROCESSED FOODS*
- **Breakfast cereals**
- **Granola bars**
- Muffins
- Pancakes, **pastries**, and waffles
- Sweets and desserts: cake, pie, cookies
- **Candy**
- Ice cream
- Popsicles
- **Pudding**
- **Pie**
- Sherbet
- Sorbet
- **Brownies**
- Chocolate

SWEETENERS AND INGREDIENTS
- **Sucrose (table sugar)**
- **Brown sugar**
- **Granulated sugar**
- **Powdered and raw sugar**
- **Beet sugar**
- **Cane sugar/syrup**
- **Cane juice**
- **Coconut sugar**
- **Date sugar**
- **Maple syrup/sugar**
- **Molasses**
- **Syrup**
- **Jelly, jam**

** Sweetened with sucrose.* **Bold is especially high in sucrose**

Created with Nutrition Data System for Research© (Regents of the University of Minnesota, 2017). High sucrose defined as ≥1 g sucrose per 100 g food

NOTE: This information is provided for educational purposes only and is not a substitute for talking with your child's doctor. You should consult with your child's healthcare provider if you have questions or concerns about your child's diet and/or the use of Sucraid®.

ADDITIONAL IMPORTANT SAFETY INFORMATION

- 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 just 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; 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®.

Please see additional Important Safety Information on *What Is CSID?* page and in enclosed full Prescribing Information. 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® and Diet Therapy for Children

This Guide is Intended for **Children** with Congenital Sucrase-Isomaltase Deficiency (CSID)

Sucraid®
(sacrosidase) Oral Solution
sucraid.com

What Is CSID?

If your child has been diagnosed with **Congenital Sucrase-Isomaltase Deficiency (CSID),** his/her body is not making enough of the digestive enzymes, **sucrase** or **isomaltase** that work. Without sufficient sucrase that works, your child cannot digest **sucrose (table sugar)**. Without sufficient isomaltose that works, your child may have trouble digesting **starch.*** When sucrose and starch are not well digested, they can cause gastrointestinal (GI) symptoms like diarrhea, abdominal pain, gas, and bloating, and over time, may lead to poor weight gain, weight loss, and/or malnutrition.[1] Other reported symptoms have included reflux and constipation.

*Sucraid® does not break down some sugars resulting from the digestion of starch. Therefore, your child may need to restrict the amount of starch in their diet. Your doctor will tell you if your child should restrict the amount of starch in their diet.

Tell Me About Sucraid®

Sucraid® (sacrosidase) Oral Solution is an FDA-approved enzyme replacement for sucrase to aid in the digestion of sucrose in patients with diagnosed CSID.

Sucraid® Dosing

WEIGHT:	DOSE:	MIX WITH:	TAKE:
Less than or equal to 33 pounds	1 milliliter (mL) Sucraid® with meals and snacks	4 ounces of water, milk, or sucrose-free, starch-free infant formula	Drink half of the mixture before meals and snacks; drink the remaining half mid-way through the meal or snack
More than 33 pounds	2 milliliters (mL) Sucraid® with meals and snacks		

Sucraid® must be kept refrigerated. Do not mix Sucraid® in anything other than water, milk, or infant formula. Do not heat Sucraid® or mix in hot beverages. For more information about Sucraid®, call Sucraid*ASSIST*™ at 1-800-705-1962.

Do I Need to Change My Child's Diet?†

- Before making any changes to your child's diet, it is important to speak with your child's healthcare provider, especially if your child is underweight or not gaining weight as expected.
- Diet is specific to each child and depends on many factors, such as:
  - How much sucrose and starch your child is currently eating
  - If your child is meeting age-level growth milestones
  - If your child has any other health issues that require a special diet
  - If your child has developed any feeding aversions, is on a supplemental formula, or has a feeding tube
  - How well your child's digestive enzymes and gastrointestinal (GI) tract are working
- Some children may be able to continue their current diet when starting Sucraid® therapy.
- Other children may need to cut back on foods high in starch for a period of time.
- Other children may need to eliminate sucrose and starch from their diet initially and then gradually add foods back to the diet to determine which foods are tolerated and which foods cause GI symptoms. This type of diet plan should only be undertaken under the guidance of your child's healthcare provider or a registered dietitian/nutritionist.
- Vitamins, minerals, and additional supplements may be needed to meet all of your child's nutritional needs.

† See "Getting Started"

1 Gericke B, Amiri M, Naim HY. The multiple roles of sucrase-isomaltase in the intestinal physiology. *Mol Cell Pediatr.* 2016;3(1):2. doi:10.1186/s40348-016-0033-y

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

- 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).
- Sucraid® may cause a serious allergic reaction. If you notice any swelling or have difficulty breathing, get emergency help right away.
- 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.

Please see additional Important Safety Information on *Getting Started* page and in enclosed full Prescribing Information.

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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.

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 sucrase-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.

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 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.**

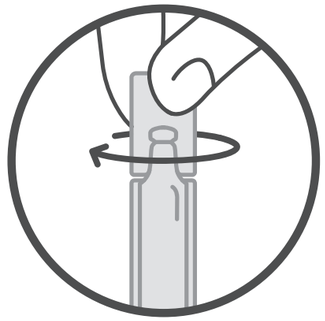

Figure 1

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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