

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

Recommended Feeding Guide for Infants with CSID

BIRTH - 4 MOS.

- Choose breast milk or standard infant formula that has lactose as the carbohydrate source (no sucrose or starch) to provide all the nutrients infants need for the first 6 months of life (refer to CSIDcares.org for more information about infant formula).
- Be aware of specialty formulas that contain corn syrup/solids, maltodextrin, modified cornstarch or tapioca starch, and/or sugar and may be hard for the infant with CSID to digest.

4-6 MOS.

- The American Academy of Pediatrics (AAP) recommends starting solid foods around 6 months of age.¹
- The American Academy of Allergies, Asthma, and Immunology (AAAAI) recommends adding only one single food (not mixtures) every 3-5 days to see how well the new food is tolerated.²
- Starting Sucraid® (sacrosidase) Oral Solution therapy may allow more variety when introducing solid foods. Begin by having your infant take Sucraid® with meals and snacks, as prescribed by your healthcare provider.
- Your healthcare provider may delay the introduction of infant cereals as the first food offered to your baby. Infant cereals have a high starch content and may contribute to gastrointestinal symptoms.
- Pureed fruits and vegetables that are low in sucrose and starch may be offered first (avocado, blueberries, papaya, or pears; green beans, spinach, yellow or zucchini squash).
- Strained meats may also be introduced, since they are a good source of iron.

6-9 MOS.

- Most babies begin weaning from breast or bottle feedings to a cup between 6 and 12 months of age.
- Your baby may be ready to advance to mashed fruits and vegetables that are low in sucrose and starch.
- Your baby may advance to very soft, plain, mashed meats with no breading.

9-10 MOS.

- Plain, unsweetened yogurt, cottage cheese, or pasteurized cheese may be added.
- Eggs (scrambled or hard-boiled and cut into small pieces) may be added.^a
- Your baby may be ready for more lumpy, textured foods or finger foods.^b

10-12 MOS.

- It may be time to advance to low-sucrose, low-starch table foods.^b

OVER 12 MOS.

- You may want to introduce whole cow's milk.^c
- Your baby may be ready for higher starch-containing foods like infant or iron fortified breakfast cereal, beans, peas, white or sweet potato, bread, pasta, or rice.^b

1. Meek JY, Noble L; Section on Breastfeeding. Policy statement: breastfeeding and the use of human milk. *Pediatrics*. 2022;150(1):e2022057988. doi:10.1542/peds.2022-057988

2. American Academy of Allergies, Asthma, and Immunology. Prevention of allergies and asthma in children. Last updated September 28, 2020. www.aaaaai.org/tools-for-the-public/conditions-library/allergies/prevention-of-allergies-and-asthma-in-children.

a. Unless there is a strong family history of allergies, the American Academy of Pediatrics now states there is no need to avoid peanut products, eggs, wheat, or fish until after one year of age. Consult with your baby's healthcare provider before offering these foods.

b. Foods should be mashed or cut into small bite sizes for safe chewing and swallowing.

c. If cow's milk is not tolerated due to lactase deficiency, Lactaid® milk may be substituted. A registered dietitian/nutritionist can offer other dairy alternatives as needed.

Additional Notes:

- **Added fats, oils, and acceptable sugars (dextrose, fructose) may be recommended to help meet calorie needs.**
- **If your baby is ever without Sucraid®, avoid foods high in sucrose.**
- **Check medication labels carefully since many liquid preparations contain sucrose. Talk to a pharmacist for assistance.**
- **Read food labels carefully for sucrose and starch content.**

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 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.

▶ 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 Infants

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



Sucraid®
(sacrosidase) Oral Solution
sucraid.com

What Is CSID?

If your baby 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 baby cannot digest **sucrose (table sugar)**. Without sufficient isomaltase that works, your baby 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 baby may need to restrict the amount of starch in their diet. Your doctor will tell you if you should restrict the amount of starch in your baby's 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 infants diagnosed with CSID who are 5 months of age or older.

Sucraid® Dosing			
WEIGHT:	DOSE:	MIX WITH:	TAKE:
Less than 33 pounds	1 milliliter (mL) Sucraid® with meals and snacks	2-4 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 SucraidASSIST™ at 1-800-705-1962.

Do I Need to Change My Baby's Diet?†

Before making any diet changes, speak with your baby's healthcare provider, especially if your baby is underweight or not gaining weight as expected. Working with a registered dietitian/nutritionist is recommended to ensure your baby is meeting their nutrient needs for normal growth and development. The addition of vitamins, minerals, and other supplements may be needed to complete the diet.

† See **"Recommended Feeding Guide for Infants with CSID"**

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

GOAL	The goal with Sucraid® therapy is to eat as normal and as healthy a diet as possible!
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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 an enzyme replacement therapy for the treatment of genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID).

IMPORTANT SAFETY INFORMATION FOR SUCRAID® (SACROSIDASE) ORAL SOLUTION

- Sucraid® may cause a serious allergic reaction. If you notice any swelling or have difficulty breathing, get emergency help right away.
- 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 are allergic to, have ever had a reaction to, or have ever had difficulty taking yeast, yeast products, papain, or glycerin (glycerol).
- Tell your doctor if you have diabetes, 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 *Recommended Feeding Guide for Infants with CSID* page and in enclosed full Prescribing 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.

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

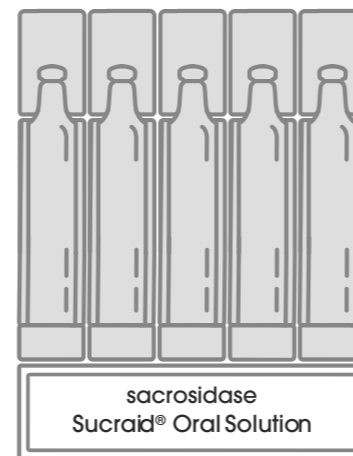
For more information, go to www.Sucraid.com or call 1-866-469-3773.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.
Revised: May 2023

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 a child and adult more than 33 pounds (15 kg).
- 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**.

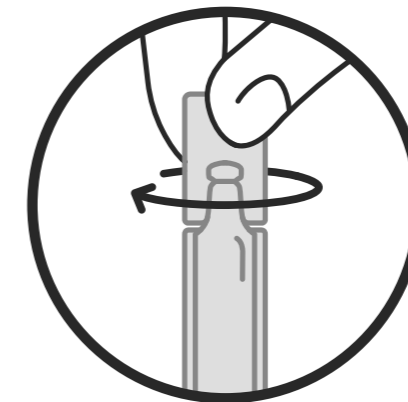


Figure 1

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**.

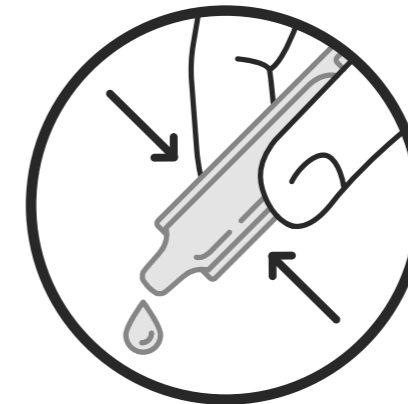


Figure 2

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**.

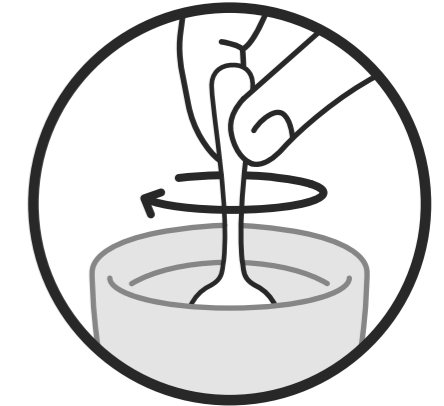


Figure 3

Step 5: 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.

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.

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