

# Sucraid<sup>®</sup>

(sacrosidase) Oral Solution

## Letter of Medical Necessity for School/Work

Date: \_\_\_\_\_

To Whom It May Concern:

Patient Name: \_\_\_\_\_

Patient DOB: \_\_\_\_\_

The patient named above is under my medical care. This patient is prescribed to take Sucraid<sup>®</sup> (sacrosidase) Oral Solution with meals and snacks as indicated below.

Mix \_\_\_\_\_ mL of Sucraid<sup>®</sup> with 2-4 ounces of cool-to-room temperature water, milk, or infant formula. Drink half the mixture before eating each meal or snack and drink the remaining half while eating each meal or snack.

NEVER HEAT SUCRAID<sup>®</sup> OR PUT IT IN WARM OR HOT BEVERAGES OR INFANT FORMULA. Do not mix Sucraid<sup>®</sup> with fruit juice or take it with fruit juice. Take Sucraid<sup>®</sup> as prescribed by your doctor.

Sucraid<sup>®</sup> should be refrigerated at 36°F-46°F (2°C-8°C) and should be protected from heat and light.

Thank you,

\_\_\_\_\_  
Healthcare Provider Signature

## 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.
- 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® does not break down some sugars that come from the digestion of starch. You may need to restrict the amount of starch in your diet. Your doctor will tell you if you should restrict starch in your diet.
- Tell your doctor if you have diabetes, as your blood glucose levels may change if you begin taking Sucraid®. Your doctor will tell you if your diet or diabetes medicines need to be changed.
- Some patients treated with Sucraid® may have worse abdominal pain, vomiting, nausea, or diarrhea. Constipation, difficulty sleeping, headache, nervousness, and dehydration have also occurred in patients treated with Sucraid®. Check with your doctor if you notice these or other side effects.
- Sucraid® has not been tested to see if it works in patients with secondary (acquired) sucrase deficiency.
- **NEVER HEAT SUCRAID® OR PUT IT IN WARM OR HOT BEVERAGES OR INFANT FORMULA.** Do not mix Sucraid® with fruit juice or take it with fruit juice. Take Sucraid® as prescribed by your doctor. Normally, half of the dose of Sucraid® is taken before a meal or snack and the other half is taken during the meal or snack.
- Sucraid® should be refrigerated at 36°F-46°F (2°C-8°C) and should be protected from heat and light.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.FDA.gov/medwatch](http://www.FDA.gov/medwatch) or call 1-800-FDA-1088.**

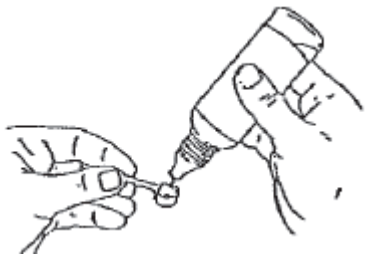


Write down the date the sealed bottle is first opened in the space provided on the bottle label. Always throw away the bottle four weeks after first opening it because Sucraid contains no preservatives. For the same reason, you should rinse the measuring scoop with water after each time you finish using it.

To get the full benefits of this medicine, it is very important to take Sucraid as your doctor has prescribed. The usual dosage is 1 to 2 milliliters (mL) with each meal or snack: 1 mL = 1 full measuring scoop (28 drops from the bottle tip) and 2 mL = 2 full measuring scoops (56 drops from the bottle tip).

Measure your dose with the measuring scoop provided (see Figure 1). Do not use a kitchen teaspoon or other measuring device since it will not measure an accurate dose.

**Figure 1. Measure dose with measuring scoop.**



Mix your dose in 2 to 4 ounces of water, milk, or infant formula (see Figure 2). Sucraid should not be dissolved in or taken with fruit juice.

**NEVER HEAT SUCRAID OR PUT IT IN WARM OR HOT BEVERAGES OR INFANT FORMULA.** Heating Sucraid causes it to lose its effectiveness. The beverage or infant formula should be taken cold or at room temperature.

**Figure 2. Mix dose in beverage or infant formula.**



It is recommended that approximately half of your dosage be taken at the beginning of each meal or snack and the remainder of your dosage be taken during the meal or snack.

### Storing your medicine:

Sucraid is available in 4 fluid ounce (118 mL) see-through plastic bottles, packaged two bottles per box. A 1 mL measuring scoop is provided with each bottle. Always store Sucraid in a refrigerator at 36°F - 46°F (2°C - 8°C). Protect Sucraid from heat and light.

If your bottle of Sucraid has expired (the expiration date is printed on the bottle label), throw it away.

Keep this medicine in a safe place in your refrigerator where children cannot reach it.

QOL Medical, LLC  
Vero Beach, FL 32963

[www.sucraid.com](http://www.sucraid.com)

For questions call 1-866-469-3773

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wheezing after oral sacrosidase.

### GENERAL

Although Sucraid provides replacement therapy for the deficient sucrose, it does not provide specific replacement therapy for the deficient isomaltase. Therefore, restricting starch in the diet may still be necessary to reduce symptoms as much as possible. The need for dietary starch restriction for patients using Sucraid should be evaluated in each patient.

It may sometimes be clinically inappropriate, difficult, or inconvenient to perform a small bowel biopsy or breath hydrogen test to make a definitive diagnosis of CSID. If the diagnosis is in doubt, it may be warranted to conduct a short therapeutic trial (e.g., one week) with Sucraid to assess response in a patient suspected of sucrose deficiency.

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

### INFORMATION FOR PATIENTS

See Patient Package Insert. Patients should be instructed to discard bottles of Sucraid 4 weeks after opening due to the potential for bacterial growth. For the same reason, patients should be advised to rinse the measuring scoop with water after each use.

Sucraid is fully soluble with water, milk, and infant formula, but it is important to note that this product is **sensitive to heat**. Sucraid should not be reconstituted or consumed with fruit juice, since its acidity may reduce the enzyme activity.

### USE IN DIABETICS

The use of Sucraid will enable the products of sucrose hydrolysis, glucose and fructose, to be absorbed. This fact must be carefully considered in planning the diet of diabetic CSID patients using Sucraid.

### LABORATORY TESTS

The definitive test for diagnosis of CSID is the measurement of intestinal disaccharidases following small bowel biopsy.

Other tests used alone may be inaccurate: for example, the breaths hydrogen test (high incidence of false negatives) or oral sucrose tolerance test (high incidence of false positives). Differential urinary disaccharide testing has been reported to show good agreement with small intestinal biopsy for diagnosis of CSID.

### DRUG INTERACTIONS

Neither drug-drug nor drug-food interactions are expected or have been reported with the use of Sucraid. However, Sucraid should not be reconstituted or consumed with fruit juice, since its acidity may reduce the enzyme activity.

### 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. Pregnancy Category C. 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

Sucraid has been used in patients as young as 5 months of age. Evidence in one controlled trial in pri-

marily pediatric patients shows that Sucraid is safe and effective for the treatment of the genetically acquired sucrose deficiency, which is part of CSID.

### ADVERSE REACTIONS

Adverse experiences with Sucraid in clinical trials were generally minor and were frequently associated with the underlying disease.

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

Note: diarrhea and abdominal pain can be a part of the clinical presentation of the **genetically determined sucrose deficiency**, which is part of congenital sucrose-isomaltase deficiency (CSID).

One asthmatic child experienced a serious hypersensitivity reaction (wheezing) probably related to sacrosidase (see Warnings). The event resulted in withdrawal of the patient from the trial but resolved with no sequelae.

### OVERDOSAGE

Overdosage with Sucraid has not been reported.

### DOSAGE AND ADMINISTRATION

The recommended dosage is 1 or 2 mL (8.500 to 17.000 I.U.) or 1 or 2 full measuring scoops (each full measuring scoop equals 1 mL; 28 drops from the Sucraid container tip equals 1 mL) taken orally with each meal or snack diluted with 2 to 4 ounces (60 to 120 mL) of water, milk, or infant formula. The beverage or infant formula should be served cold or at room temperature. The beverage or infant formula should not be warmed or heated before or after addition of Sucraid because heating is likely to decrease potency. Sucraid should not be reconstituted or consumed with fruit juice since its acidity may reduce the enzyme activity.

It is recommended that approximately half of the dosage be taken at the beginning of the meal or snack and the remainder be taken during the meal or snack.

The recommended dosage is as follows:

1 mL (8,500 I.U.) (one full measuring scoop or 28 drops) per meal or snack for patients up to 15 kg in body weight.

2 mL (17,000 I.U.) (two full measuring scoops or 56 drops) per meal or snack for patients over 15 kg in body weight.

Dosage may be measured with the 1 mL measuring scoop (provided) or by drop count method (1 mL equals 28 drops from the Sucraid container tip).

### HOW SUPPLIED

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

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

Rx only.

Distributed by:  
QOL Medical, LLC  
Vero Beach, FL 32963

To order, or for any questions, call 1-866-469-3773  
[www.sucraid.com](http://www.sucraid.com)

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