

(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® (sacrosidase) Oral Solution with meals and snacks as indicated below.

Instructions for Use: Sucraid® Single-Use Containers*

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

Step 2: Twist the cap to the left to remove it from the container.

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

Step 4: Mix your or your child's prescribed dose in 4 ounces of cold or room temperature water, milk, or infant formula. For patients 15 kg (33 lbs) or less, divide into two 2-ounce portions (one portion per meal or snack. The second portion should be refrigerated and discarded if not used within 24 hours).

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.

* The Sucraid® single-use container may be stored between 59°F to 77°F (15° to 25°C) for up to 3 days.

Thank you,

Healthcare Provider Signature

Important Safety Information for Sucraid® (sacrosidase) Oral Solution

Indication

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

Contraindication

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

Warnings, Precautions, and Additional Important Safety Information

- **Severe Hypersensitivity Reactions**

Sucraid® may cause a severe hypersensitivity reaction (a serious allergic reaction). If you notice any swelling of your face, lips, mouth, or tongue, or have difficulty breathing, experience wheezing, rash, or itchiness, get emergency help right away. Sucraid® contains papain, which is associated with hypersensitivity reactions.

- 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).

- **Increased Blood Glucose Levels in Patients With Diabetes Mellitus**

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.

- **Restricting Starch in Your Diet**

Sucraid® does not break down some sugars that come from the digestion of starch so you may still experience symptoms of CSID while taking Sucraid®. 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.

- 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®.

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.