Sucra.id® (isomaltase) Oral Solution

The purpose of your medicine:
Sucra.id is an enzyme preparation that replaces the isomaltase activity which is part of congenital sucrase-isomaltase deficiency (CSID). CSID is a condition where the body is unable to break down and absorb sucrose (table sugar) and other disaccharides.

Your doctor will tell you if you should take Sucra.id as your doctor has prescribed (see Figure 1). Do not use a kitchen teaspoon to measure the dosage. The dosage be taken at the beginning of each meal or snack.

Sucra.id may help improve the breakdown and absorption of starch (table sugar) from the food you eat, and thereby improve your symptoms of CSID.

Sucra.id should be given to children 1 year of age and older.

The recommended dosage is as follows:
The dosage of Sucra.id is determined according to age.

Side effects to watch for:

Over dosage with Sucra.id may be no effect seen. However, symptoms of overdose, if any, may include:
- Diarrhoea and abdominal pain
- Nausea and vomiting

Sucra.id is not expected to cause fetal harm when administered to a pregnant woman. However, Sucra.id should not be used during pregnancy.

To order, or for any questions, call 1-866-469-3773

www.sucraid.net

Distributed by: QOL Medical, LLC

Prescribing Information

CLINICAL PHARMACOLOGY

Sucra.id contains isomaltase, an enzyme that breaks down disaccharides from starch into monomer, dimer, tetramer, and octomer ranging from 100,000 g/mole to 800,000 g/mole.

Sucra.id is a pale yellow to colorless, clear solution with a pleasant sweet taste.

Sucra.id is a strict sucrose-free diet. Isomaltase breaks down disaccharides from starch into monomer, dimer, tetramer, and octomer ranging from 100,000 g/mole to 800,000 g/mole.

A generally accepted clinical definition of CSID is a condition characterized by the following:
- Absence or significant reductions of maltase activity, and normal lactase levels.
- Sucro-hydrolase activity of > 10 ppm when challenged with sucrose after fasting.
- Blood sugars and/or hydrogen output when they received sacrosidase in comparison with water or placebo.
- Glucose concentrations in the blood up to 2 hours after a meal.
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- Symptoms of malabsorption and malnutrition.

Adverse experiences with Sucra.id in clinical trials were generally minor and self-limiting.

DIAGNOSIS AND TESTING

Sucra.id is part of Congenital Sucrase-Isomaltase Deficiency (CSID).

The diagnosis of CSID is made based on symptoms, history of similar symptoms in family members, and the following tests:
- Blood sugar levels and/or hydrogen contents in the breath in response to the oral loading test (see Figure 1).
- Breath hydrogen test when challenged with sucrose after fasting.
- A single dose of Sacrosidase increases breath hydrogen when taken on an empty stomach (see Figure 1).

The purpose of your medicine:
Sucra.id is an enzyme replacement therapy for the deficiency of isomaltase, which is part of congenital sucrase-isomaltase deficiency (CSID). CSID is a condition where the body is unable to break down and absorb sucrose (table sugar) and other disaccharides.

Your doctor will tell you if your diet or diabetes needs to be adjusted when you begin to take Sucra.id.

Sucra.id can help improve the breakdown and absorption of starch (table sugar) from the food you eat, and thereby improve your symptoms of CSID.

Your doctor will tell you if you should restrict the amount of starch in your diet.

These sample menus are only suggestions to use when following a low-sucrose, low-starch diet. Collectively, the menus may not meet your nutrient needs; other foods should be added to the diet over time. Always consult your physician or dietitian for individualized diet recommendations.

Refer to the Diet Guides for Congenital Sucrase-Isomaltase Deficiency (CSID) for more information about a low-sucrose, low-starch diet.

Visit Sucra.id.COM for more information about CSID, including information on a low-sucrose, low-starch diet.

For further diet information, call the Registered Dietitian (RD) at 1-800-755-1662. The RD cannot provide medical advice.

Patient Package Insert

Sample Menus for a Low-Sucrose, Low-Starch Diet

![Sample Menus](image)

Figure 1. Measure dose with measuring spoon.

Figure 2. Mix dose in beverage or infant formula.

Sample Menus for a Low-Sucrose, Low-Starch Diet

1. Diabetic breakfast
- 1 egg
- 1 slice whole grain toast
- 1 cup orange juice
- 1 cup low-fat milk

2. Diabetic lunch
- 2 ounces grilled chicken breast
- 1 cup cooked vegetables
- 1 cup tomato soup
- 1 cup low-fat milk

3. Diabetic dinner
- 2 ounces baked salmon
- 1 cup cooked vegetables
- 1 cup low-fat milk

4. Dessert
- 1 cup fat-free frozen yogurt

![Sample Menus](image)
**Notes**

*All meals should be fresh, avoidfillers and sweetners. Meals cured with dextrose would be acceptable.*

**Choose a mayonnaise that does not contain sucrose or starch.**
- Take Sucraid® (Sacrosidase) Oral Solution as prescribed with all meals and snacks.
- If you do not drink milk’s milk, be sure to substantiate with Lactaid® milk or sugar-free, plain milk, or unflavored soy or almond milk.
- Always read food labels. Even if a food is labeled here, check the label to make sure it is in a safe ingredient is consistently changing.
- Dextrose can be purchased online from NOW® Foods (nowfoods.com) or from local breweries. Dextrose can be used in place of sugar.
- You can buy fructose at the grocery store on the aisle where other sugars are found. Proprietor can also be purchased online from NOW® Foods (nowfoods.com). Proprietor can be used in place of sugar.
- Take to your physician or dietitian about the overall completeness of your diet and take vitamin and mineral supplements as recommended.

**INDICATION**

Sucraid® (Sacrosidase) Oral Solution is an enzyme replacement therapy for the treatment of genetically determined sucrase deficiency, which is a result of Congenital Sucrase-Isomaltase Deficiency (CSID).

**IMPORTANT SAFETY INFORMATION FOR SUCRAID® (SACROSIDASE) ORAL SOLUTION**

**Sucraid® may cause serious allergic reactions.** 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 your diet or diabetes medicines need to be changed.
- **Sucraid may cause a change in your blood sugar levels.** If you have diabetes, 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.
- **Sucraid has not been tested to see if it works in patients with secondary (acquired) sucrase deficiency.**
- **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.
- **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 your diet or diabetes medicines need to be changed.
- **Never heat Sucraid or put it in warm or hot beverages or infant formula.** Do not mix Sucraid with fruit products, yogurt, or cream cheese.
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