**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).

**INDICATIONS AND USAGE**
Sucraid® (sacrosidase) Oral Solution is indicated as oral replacement therapy for the genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID).

**CONTRAINdications**
Patients known to be hypersensitive to yeast, yeast products, glycyrrhizin (gynostemma), or puerarin.

**WARNINGS**
Sucraid® (sacrosidase) Oral Solution is contraindicated in patients with a known deficiency of sucrase.

**PRECAUTIONS**
General
Adverse reactions or side effects may be seen in some people taking Sucraid.

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

**OVERDOSAGE**
Sucraid® (sacrosidase) Oral Solution has not been studied in overdose situations. In the event of accidental overdose, the patient should be observed and treated for other possible causes of symptoms such as nausea, vomiting, diarrhea, or abdominal pain.

**Llaboratory Tests**
The definitive test for diagnosis of CSID is the measurement of intestinal disaccharidases following small bowel biopsy. Other tests used to define abnormalities include the breath hydrogen test (high incidence of abdominal pain in patients with CSID) and small intestinal biopsy which shows good agreement with small intestinal biopsy for diagnosis of CSID.

**DIAGNOSTIC TESTS**

**Sucrase Activity Assay**
Sucrase activity is naturally produced in the brush border of the small intestine, which is involved in the absorption of monosaccharides from disaccharides. In the absence of endogenous human sucrase, as in CSID, sucrose is not completely absorbed from the intestine and the presence in the ileal luminal content may lead to increased stool output associated with osmotic retention of water. This may result in loose stools.

**CLINICAL STUDIES**
Long-term studies in animals with Sucraid have not been performed. In a double-blind, placebo-controlled study, patients with CSID on sucrose or on a diet that excluded sucrose for at least 4 weeks were administered Sucraid and placebo in a ratio of 1:1. The Sucraid single-use container may be stored between 59°F to 77°F (20°C to 25°C) for up to 2 days (72 hours).

**CONCLUSION**
Sucraid has been used in patients as young as 5 months of age. Evidence from small intestinal biopsy for diagnosis of CSID. The definitive test for diagnosis of CSID is the measurement of intestinal disaccharidases following small bowel biopsy.

**LABORATORY TESTS**

**Drug Interactions**
Sucraid does not break down some sugars found in foods that have functional disaccharidase deficiencies. The effects of Sucraid have not been evaluated in patients with secondary disaccharidase deficiencies.

**DOSAGE AND ADMINISTRATION**
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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.

**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.

**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.

**Step 8:** Discard the Sucraid multiple-dose bottle after use. The Sucraid single-use container may be stored between 59°F to 77°F (15°C to 25°C) for up to 3 days.

**Step 9:** Do not warm or heat the mixed solution before taking or giving Sucraid.

**Step 10:** 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.

**Step 11:** Throw away expired or empty Sucraid containers in your household trash.

**Step 12:** Do not change the dose of Sucraid without talking to your healthcare provider.

**Step 13:** Do not give or take Sucraid with fruit juice.

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