COULD IT BE CSID
CONGENITAL SUCRASE-ISOMALTASE DEFICIENCY

QOL Medical

Unresolved Gas, Bloating, Diarrhea…Could It Be CSID?

[Presenter Name, Title
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QOL Medical, LLC

Financial Disclosures

- [Disclose financial relationships with manufacturers and medical organizations here (e.g., QOL Medical, LLC, Speakers Bureau); if none, list "None."]

WHAT IS CSID?

CSID: Congenital Sucrase-Isomaltase Deficiency

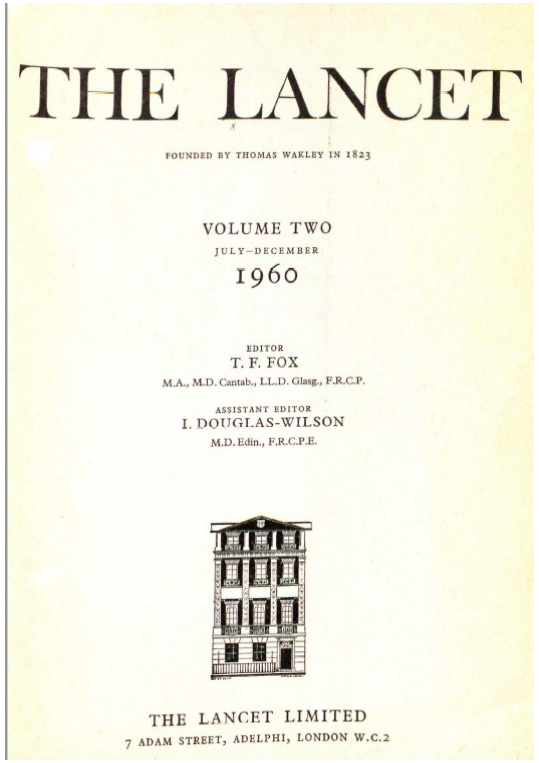
Sucrase-Isomaltase

- An enzyme that digests the majority of dietary carbohydrates
- Table sugar (sucrose) and many starches (e.g., potatoes, bread)
- Expressed in the microvilli of the brush border membrane
- Releases glucose and fructose from sucrose (sugar) so they can be absorbed into the bloodstream

Congenital Sucrase-Isomaltase Deficiency

The first report of an autosomal recessive Congenital Sucrase-Isomaltase Deficiency (CSID) was published in 1960.

Diarrhoea Caused by Deficiency of Sugar-Splitting Enzymes


THE LANCET

FOUNDED BY THOMAS WAKLEY IN 1823

VOLUME TWO
JULY–DECEMBER
1960

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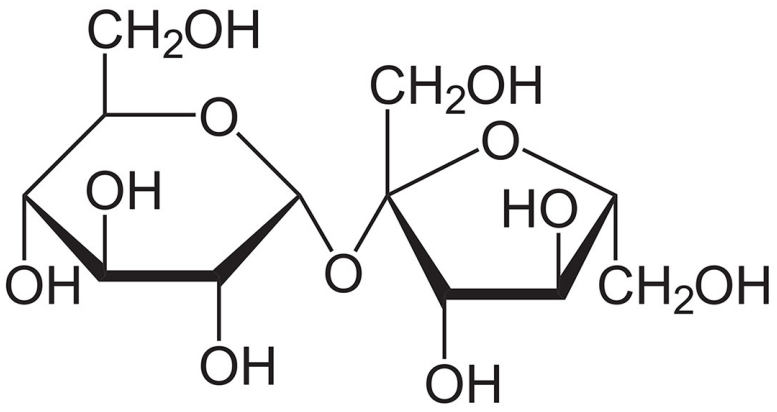
Weijers HA, Van De Kamer JH, Mossel DAA, Dicke WK. Diarrhoea Caused by Deficiency of Sugar-Splitting Enzymes. *Lancet*. 1960;276(7145):296-7.

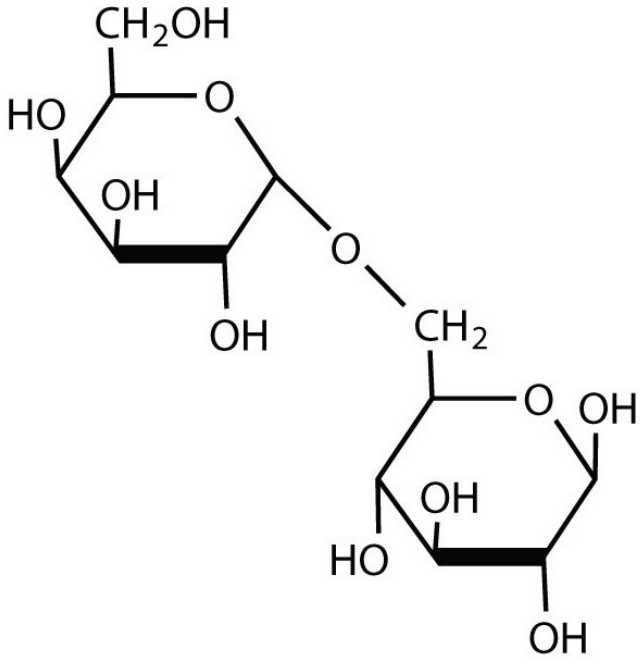
Sucrase-Isomaltase Substrates

Sucrose



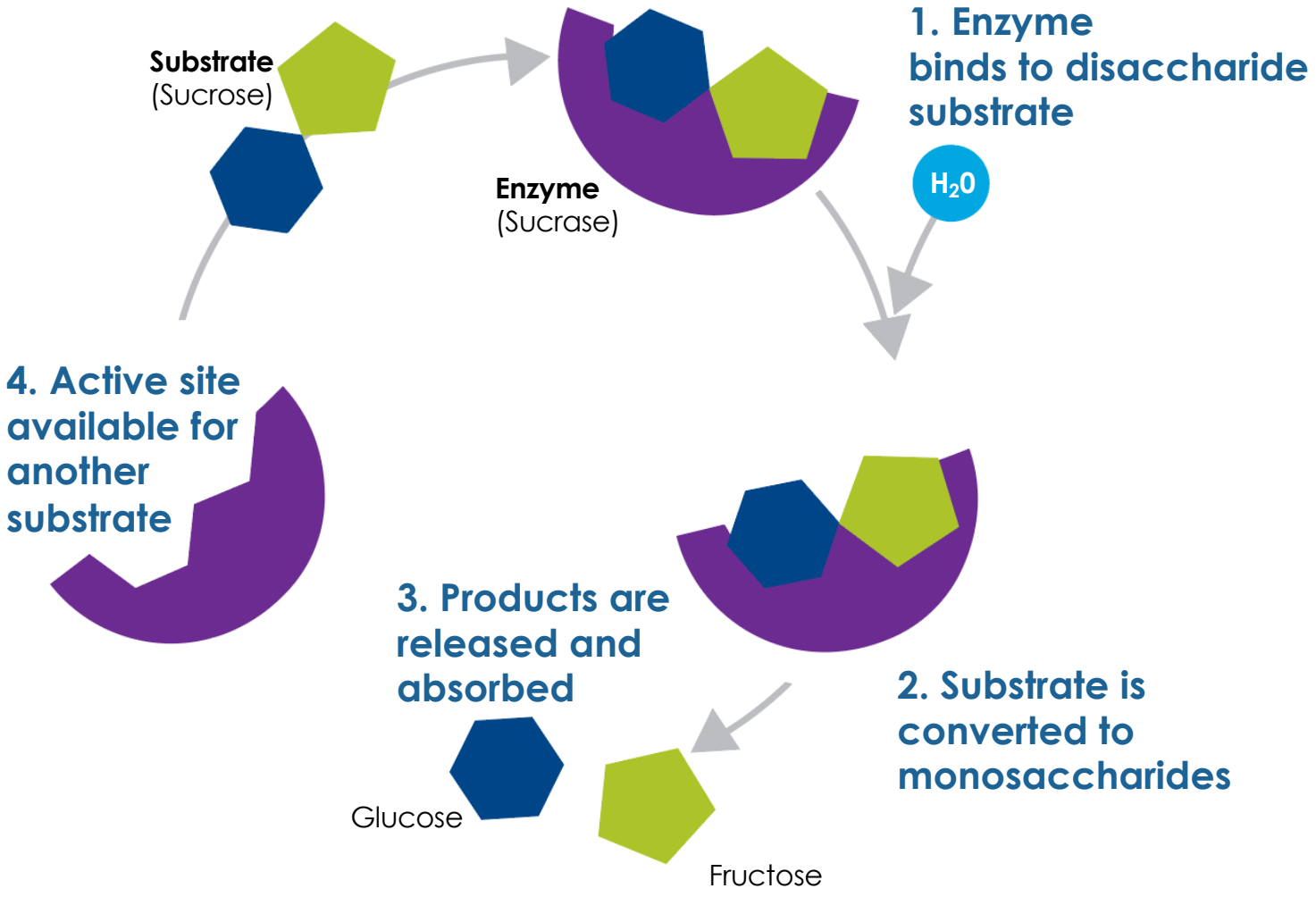
Glucose + Fructose
(α–1,2 glycosidic bond)

Isomaltose

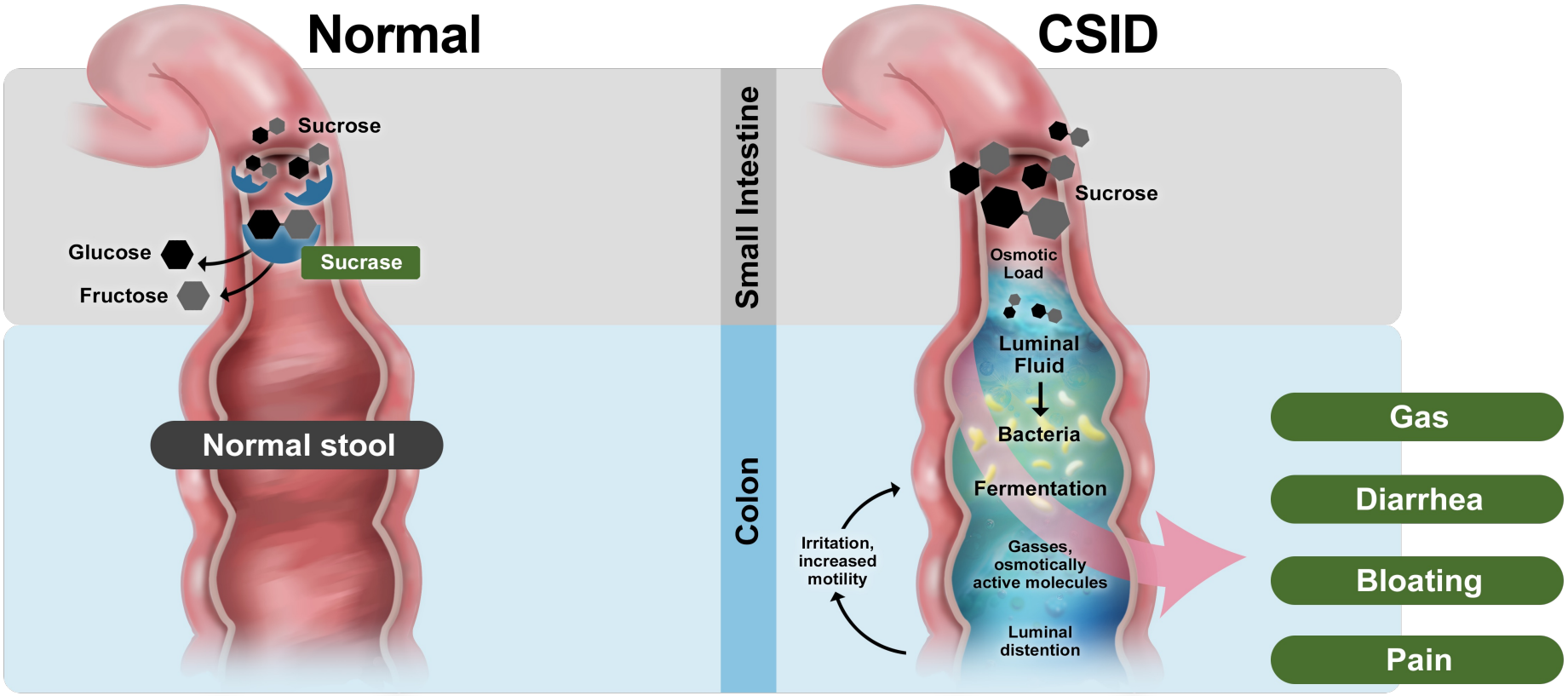


Glucose + Glucose
(α–1,6 glycosidic bond)

How Sucrase Works to Hydrolyze Sucrose



CSID Carb Maldigestion Pathophysiology



SI Gene

- Encodes a heterodimer with 2 active sites – sucrase and isomaltase
  - Located on chromosome 3[1]
  - Very large – approximately 100 kilobases[1]
  - 48 exons encoding 1827 amino acids[1]
- 2146 rare variants with 880 *SI* rare pathogenic variants (*SI*-RPVs)[2]
  - Sucrase-isomaltase protein transported and anchored to apical membrane of enterocytes to digest disaccharides in intestinal lumen[3]

1. Uhrich S, Wu Z, Huang JY, Scott CR. Four Mutations in the SI Gene Are Responsible for the Majority of Clinical Symptoms of CSID. *J Pediatr Gastroenterol Nutr.* 2012;55(suppl 2):S34-5.
2. Garcia-Etxebarria K, Zheng T, Bonfiglio F, et al. Increased Prevalence of Rare Sucrase-Isomaltase Pathogenic Variants in Irritable Bowel Syndrome Patients. *Clin Gastroenterol Hepatol.* 2018;16(10):1673-76.
3. Naim HY, Heine M, Zimmer KP. Congenital Sucrase-Isomaltase Deficiency: Heterogeneity of Inheritance, Trafficking, and Function of an Intestinal Enzyme Complex. *J Pediatr Gastroenterol Nutr.* 2012;55(suppl 2):S13-20.

Role of *SI* Gene

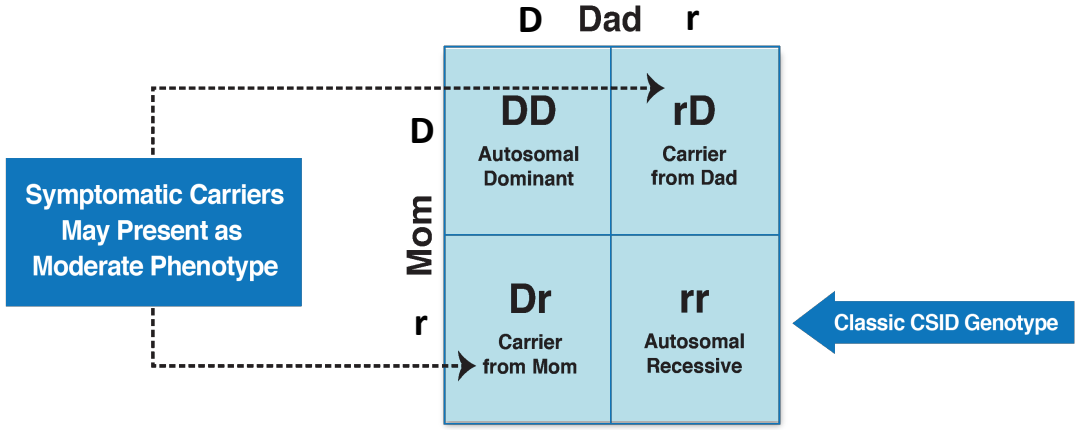
- CSID – hypomorphic variants result in lack of active protein at the cell surface causing reduced digestion, malabsorption, and colonic fermentation of carbs[1]

CSID Genotypes

- In 31 biopsy-diagnosed CSID patients, at least 1 of the 4 most common CSID variants was present in approximately 60% of the patients' alleles[2]
  - Genotypes include homozygous, compound heterozygous, and simple heterozygous

1. Naim HY, Heine M, Zimmer KP. Congenital Sucrase-Isomaltase Deficiency: Heterogeneity of Inheritance, Trafficking, and Function of an Intestinal Enzyme Complex. *J Pediatr Gastroenterol Nutr.* 2012;55(suppl 2):S13-20.
2. Uhrich S, Wu Z, Huang JY, Scott CR. Four Mutations in the SI Gene are Responsible for the Majority of Clinical Symptoms of CSID. *J Pediatr Gastroenterol Nutr.* 2012;55(suppl 2):S34-5.

CSID Genotypes and Phenotypes



- **CSID originally assumed to be an autosomal recessive disease[1]**
  - Sucrase activity is very low (<15 µM/min/g); most severe symptoms
- **Recent studies also found symptomatic disease in heterozygotes[2]**
  - Sucrase activity low (<25 µM/min/g)
  - Correlations between CSID phenotype and heterozygous genotype

1. Chumpitazi BP, Robayo-Torres CC, Opekun AR, Nichols BL Jr, Naim HY. Congenital Sucrase-Isomaltase Deficiency: Summary of an Evaluation in One Family. *J Pediatr Gastroenterol Nutr.* 2012;55(suppl 2):S36.
2. Uhrich S, Wu Z, Huang JY, Scott CR. Four Mutations in the SI Gene are Responsible for the Majority of Clinical Symptoms of CSID. *J Pediatr Gastroenterol Nutr.* 2012;55(suppl 2):S34-5.

HOW DO CSID PATIENTS PRESENT?

CSID Has Three Different Presentations in Pediatrics

- Infants
- Toddlers
- Adolescents

CSID Signs and Symptoms in Infants

- Usually a more clinically-significant phenotype
- Asymptomatic for the first 4 to 6 months
- Non-bloody, non-mucus diarrhea develops after weaning
- Bloating usually present
- Crampy abdominal pain and colic

CSID Signs and Symptoms in Infants

- Significant diaper rash present due to acidic diarrhea
- Symptoms better when baby is fasting
- Poor weight gain or failure to thrive

CSID Signs and Symptoms in Toddlers

- Intermittent diarrhea (malabsorption)
- Crampy abdominal pain
- Bloating and flatulence
- Aversion to fruits and sweets
- Better if fasting

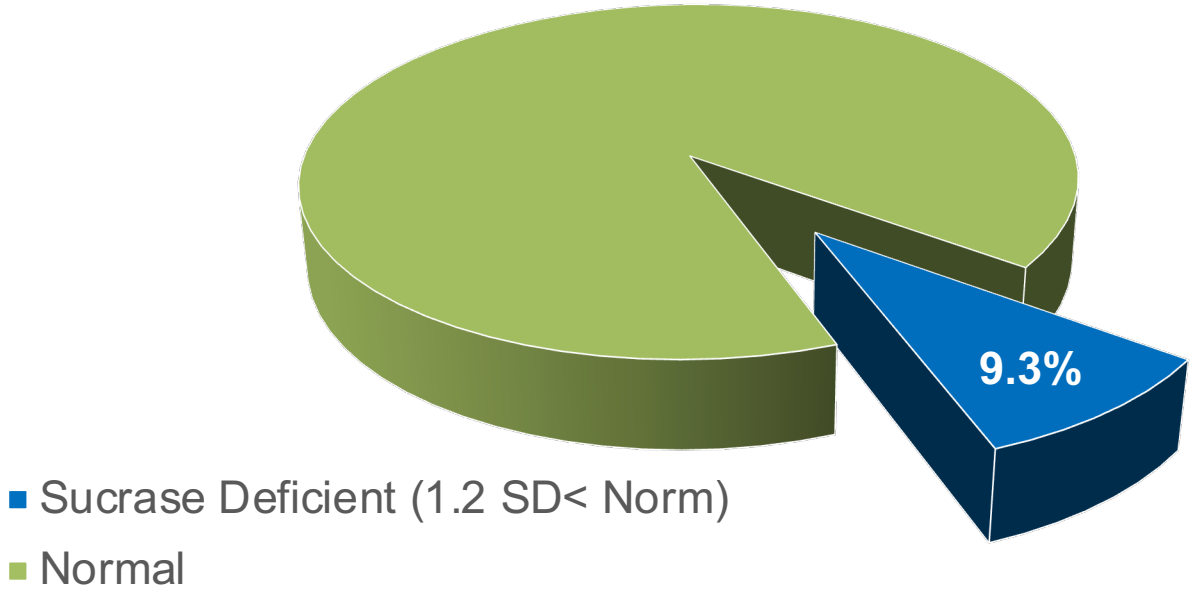
CSID Signs and Symptoms in Adolescents

- Mild cases may present with only bloating or flatulence
- More severe cases may present with IBS-D-like symptoms
- What happens if you have constipation and CSID at the same time?
- Increased prevalence of rare *SI* genetic variants in irritable bowel syndrome patients suggests some of these patients may have been misdiagnosed[1]

1. Garcia-Etxebarria K, Zheng T, Bonfiglio F, et al. Increased Prevalence of Rare Sucrase-isomaltase Pathogenic Variants in Irritable Bowel Syndrome Patients. *Clin Gastroenterol Hepatol.* 2018;16(10):1673-76.

How Common Is Sucrase Deficiency?

Study of Idiopathic Sucrase Deficiency[1]
N = 27,875



1. Nichols BL Jr, Adams B, Roach CM, Ma CX, Baker SS. Frequency of Sucrase Deficiency in Mucosal Biopsies. *J Pediatr Gastroenterol Nutr*. 2012;55 (suppl 2):S28-30.

Incidence of Sucrase-Isomaltase Rare Pathogenic Variants (*SI*-RPV) in GI Patients

	Chronic Diarrhea[1]	IBS-D[2]
Subjects (N)	**308**	**952**
Known CSID Variants (n)	**14**	**40**
Incidence	**4.5%**	**4.2%**

- *SI*-RPV does not always cause CSID, but highly correlated
- Data suggests a portion of CSID patients might be misdiagnosed with IBS-D
- IBS-D symptoms are very similar to CSID symptoms
- Consider CSID in your diagnostic algorithm *especially* if patient is unresponsive to low-FODMAP diet/IBS-D treatments

1. QOL Medical, LLC. Data on file.
2. Garcia-Etxebarria K, Zheng T, Bonfiglio F, et al. Increased Prevalence of Rare Sucrase-Isomaltase Pathogenic Variants in Irritable Bowel Syndrome Patients. *Clin Gastroenterol Hepatol.* 2018;16(10):1673-76.

HOW IS CSID DIAGNOSED?

Long-Term GI Symptoms, Combined With:

- Evidence of deficient sucrase activity
  - Determined by EGD biopsy and disaccharidase assay
    - 2 to 4 extra distal duodenal biopsy samples
    - Sent to specialty disaccharidase testing lab
- Other tests that aid in diagnosing sucrase deficiency include:
  - ^{13}C-sucrose breath test
  - Sucrose hydrogen-methane breath test
  - Sucrose challenge symptoms test
  - Short therapeutic trial of Sucraid® (sacrosidase) Oral Solution for patients where CSID is suspected

EGD = esophagogastroduodenoscopy

Please see Sucraid® (sacrosidase) Oral Solution Important Safety Information within this presentation and full Prescribing Information provided with this presentation. Sucraid® may cause a serious allergic reaction.

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**. Patients should stop taking Sucraid® and get emergency help immediately if any of the following side effects occur: difficulty breathing, wheezing, or swelling of the face. Care should be taken when administering initial doses of Sucraid® to observe any signs of acute hypersensitivity reaction.
- Do not use Sucraid® with patients known to be hypersensitive to yeast, yeast products, papain, or glycerin (glycerol).
- Although Sucraid® provides replacement therapy for the deficient sucrase, it does not provide specific replacement therapy for the deficient isomaltase.

Please see additional Important Safety Information in this presentation.

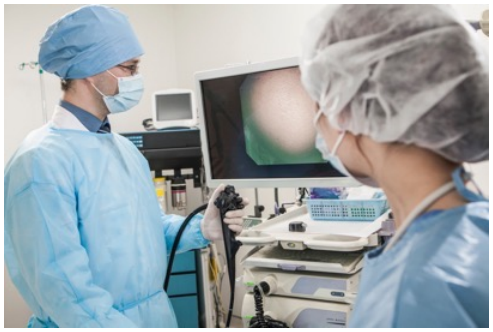
Important Safety Information for Sucraid® (sacrosidase) Oral Solution (continued)

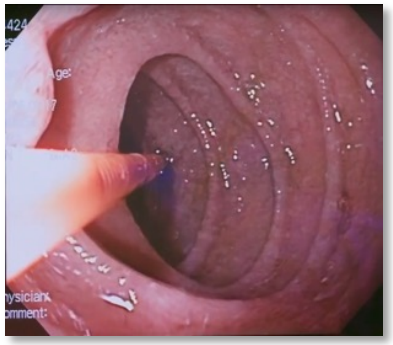
- Adverse reactions as a result of taking Sucraid® may include worse abdominal pain, vomiting, nausea, diarrhea, constipation, difficulty sleeping, headache, nervousness, and dehydration.
- Before prescribing Sucraid® to diabetic patients, the physician should consider that Sucraid® will enable sucrose hydrolysis and the absorption of those hydrolysis products, glucose and fructose.
- The effects of Sucraid® have not been evaluated in patients with secondary (acquired) disaccharidase deficiency.
- DO NOT HEAT SOLUTIONS CONTAINING SUCRAID®. Do not put Sucraid® in warm or hot fluids. Do not reconstitute or consume Sucraid® with fruit juice since the acidity of the juice may reduce the enzyme activity of Sucraid®. Half of the reconstituted Sucraid® should be taken at the beginning of the meal or snack and the other half 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.

Full Prescribing Information was provided prior to this presentation, can be accessed online at sucraid.com/pi.pdf, and is available at this presentation.

Disaccharidase Assay – The Gold Standard

- Disaccharidase assays
  - Able to measure activity of 4 enzymes, depending on substrate used: lactase, sucrase, maltase, palatinase (isomaltase)
  - 2-4 extra distal duodenal biopsies (best near ampulla of Vater)
  - Freeze and dry ice ship to specialty lab (not path lab)
- Upper GI endoscopy (EGD) can be broadly helpful to:
  - Help rule in/out celiac disease or lactose intolerance
  - Assess small bowel health





Disaccharidase Assay Reference Intervals

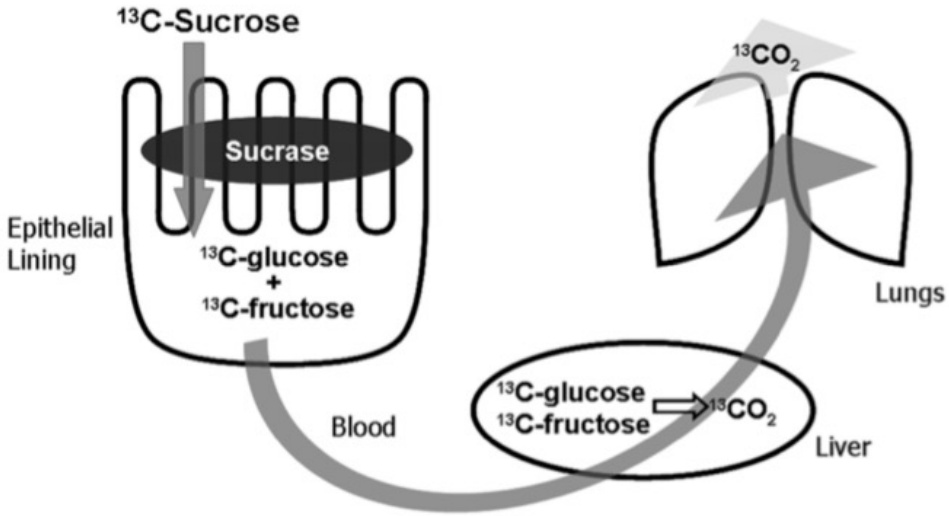
Disaccharidase	Normal Range*
Lactase	15 – 46 U/min/g protein
Sucrase	25 – 70 U/min/g protein
Maltase	100 – 224 U/min/g protein
Palatinase	5 – 26 U/min/g protein

*Subject to change following normal range studies conducted by the lab

Hackenmueller SA and Grenache DG. Reference Intervals for Intestinal Disaccharidase Activities Determined from a Non-Reference Population. *J Appl Lab Med*. 2016;1(2):172-80.

Sucrose Breath Test

- Test is noninvasive, short in duration, and may be administered by patient in the office or at home
- Patients with CSID may experience GI symptoms from the sucrose taken for the test
- For more information, or to order a test, call 1-800-705-1962



Principle of ^{13}C Breath Test

Metabolic Solutions. Posted April 2014. www.metsol.com/wp-content/uploads/2014/04/Sucrose-Breath-Test.pdf

TREATMENT

Dietary Changes: Low-Sucrose Diet

Sucrose Content

Category	Food	Portion	Sucrose (grams)
Juice	Orange juice	4 oz	5.0
	Grape juice	4 oz	0.1
Fruit	Peaches, canned	½ cup	4.5
	Watermelon	1 cup	1.8
	Mandarin orange, canned	½ cup	1.7
	Banana	½ banana	1.4
	Apple sauce	½ cup	1.2
	Pears, canned	½ cup	0.7
Vegetables	Corn, canned	½ cup	3.2
	Sweet potato, mashed	½ cup	2.9
	Carrots, raw	½ cup	2.2
	Broccoli, cooked	½ cup	0.2

Regents of the University of Minnesota. 2023 NCC Food and Nutrient Database. Subscription-based website. www.ncc.umn.edu/products/nutrients-nutrient-ratios-and-other-food-components/

Starch Content

Category	Food	Portion	Starch (grams)
Vegetables	White potato, mashed	½ cup	17.9
	Black beans, canned	½ cup	13.2
	Chickpeas, canned	½ cup	11.3
	Sweet potato, mashed	½ cup	9.0
Grains	Brown rice	½ cup	25.0
	White rice	½ cup	18.2
	Quinoa	½ cup	16.0
	Oatmeal	½ cup	12.7

Regents of the University of Minnesota. 2023 NCC Food and Nutrient Database. Subscription-based website. www.ncc.umn.edu/products/nutrients-nutrient-ratios-and-other-food-components/

COULD IT BE
CSID
CONGENITAL SUCRASE-ISOMALTASE DEFICIENCY

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FODMAP & CSID

Are your patients on a low-FODMAP diet still experiencing discomfort? Have you considered **Sucrose Intolerance due to CSID (Congenital Sucrase-Isomaltase Deficiency)?** Below is a list of foods that are allowed on a low-FODMAP diet. The **highlighted foods** are high in sucrose and/or starch and may be causing continued GI symptoms.

Fruit

Banana
Blueberry
Boysenberry
Cantaloupe
Cranberry
Grapes
Grapefruit
Honeydew melon
Kiwi
Lemon
Lime
Mandarin
Orange
Passionfruit
Pineapple
Raspberry
Rhubarb
Strawberry
Tangelo

1-888-871-1589
info@sucroseintolerance.com
sucroseintolerance.com

Vegetables

Alfalfa
Bamboo shoots
Bean shoots
Beans (green)
Bok choy
Carrot
Celery
Chives
Cucumber
Endive
Ginger
Lettuce
Olives
Parsnip
Parsley
Potato
Pumpkin
Red capsicum (bell pepper)
Silverbeet
Spring onion (green section)
Spinach
Squash (this may be troublesome for some; check individual tolerance)
Sweet potato
Taro
Tomato
Turnip
Yam
Zucchini

Grain Foods

Cereals
Gluten-free bread or cereal products

Bread
100% spelt bread

Rice

Oats

Polenta

Other
Arrowroot
Millet
Psyllium
Quinoa
Sorghum
Tapioca

Milk Products

Milk
Lactose-free milk*
Oat milk*
Rice milk*
Soy milk*
*check for additives

Cheeses

Hard cheeses
Brie
Camembert

Yogurt
Lactose-free varieties

Ice Cream Substitutes
Gelati
Sorbet

Butter Substitutes
Olive oil

Other

Tofu

Sweetener
Artificial sweeteners not ending in '-ol'
Glucose
Sugar* (sucrose)

Honey Substitutes
Golden syrup†
Maple syrup†
Molasses
†small quantities

This list of foods is not a "diet." The purpose of the list is to demonstrate that a low-FODMAP diet is not low in sucrose or starch. Therefore, a low-FODMAP diet would not be appropriate for someone diagnosed with CSID. **It is NOT intended for patient distribution.**

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SUC21.3069.

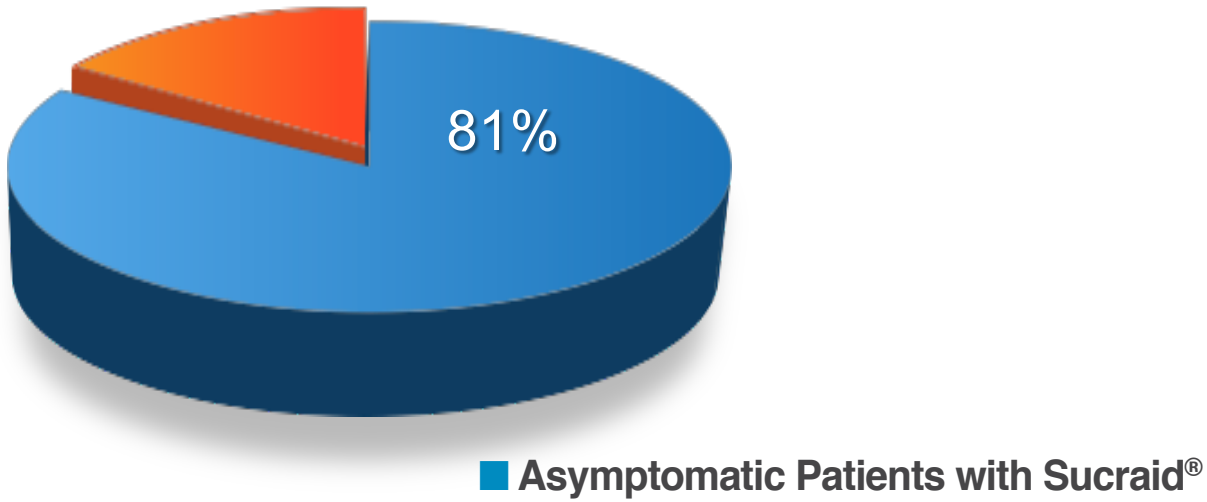
QOL Medical, LLC

Sucraid® (sacrosidase) Oral Solution, manufactured by QOL Medical, LLC, is an enzyme replacement therapy to relieve the symptoms of Congenital Sucrase-Isomaltase Deficiency (CSID)

Please see Sucraid® (sacrosidase) Oral Solution Important Safety Information within this presentation and full Prescribing Information provided with this presentation.
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).
Sucraid® may cause a serious allergic reaction. Sucraid® shouldn't be used by patients who are known to be hypersensitive to yeast, yeast products, papain, or glycerin (glycerol).

Sucraid® Overall Symptomatic Response

81% of patients became asymptomatic* with Sucraid® in a 10-day clinical trial
N = 28



*Asymptomatic defined as symptom-free for at least 7 of the 10 study days.

Please see Sucraid® (sacrosidase) Oral Solution Important Safety Information within this presentation and full Prescribing Information provided with this presentation. Sucraid® may cause a serious allergic reaction.

Treem WR, McAdams L, Stanford L, et al. Sacrosidase Therapy for Congenital Sucrase-Isomaltase Deficiency. *J Pediatr Gastroenterol Nutr.* 1999;28(2):137-42.

COULD IT BE
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CONGENITAL SUCRASE-ISOMALTASE DEFICIENCY

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HOW TO TAKE SUCRAID® (sacrosidase) ORAL SOLUTION

Administering Sucraid® - Bottle

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

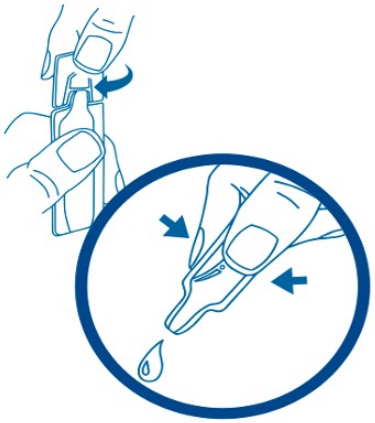
Mix dose in 2 to 4 ounces of water, milk, or infant formula. Sucraid® should not be dissolved in or taken with fruit juice.

Half of your Sucraid® dosage should be taken at the beginning of each meal or snack and the remainder of your dosage should be taken during the meal or snack.

Sucraid® (Sacrosidase) Oral Solution dosing: Patients < 33 lbs – 1 mL and patients > 33 lbs – 2 mL. It should not be mixed with hot beverages, fruit juice, or other acidic beverages as this may reduce the efficacy of Sucraid®.

Please see Sucraid® (sacrosidase) Oral Solution Important Safety Information within this presentation and full Prescribing Information provided with this presentation. Sucraid® may cause a serious allergic reaction.

Administering Sucraid® Single-Use



Twist cap off single-use container. **Squeeze** contents into 4 oz of water, milk, or infant formula.

Mix your dose. Sucraid® should not be dissolved in or taken with fruit juice.

Half of your Sucraid® dosage should be taken at the beginning of each meal or snack and the remainder of your dosage should be taken during the meal or snack.

Sucraid® (Sacrosidase) Oral Solution Single-Use dose is indicated for patients > 33 lbs. It should not be mixed with hot beverages, fruit juice, or other acidic beverages as this may reduce the efficacy of Sucraid®.

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CLINICAL VIGNETTES

Case 1: Nicholas, Michelin Man No More…

- Nicholas was born FT, 7 pounds and 12 ounces, uncomplicated labor and delivery*
- Exclusively breastfed; yellow, seedy stools
- Weight by 5 months: 17 pounds
- Solids started, cereals, followed by veggies and fruits
- Stools turned loose and green

*This is a real patient case study.

Case 1: Nicholas, Michelin Man No More…

- Initial visit with pediatrician: viral gastroenteritis
- Support measures initiated, food stopped, and symptoms improved
- 6 months of age: solids restarted, diarrhea reappears
- PE: fussy infant, with mildly bloated abdomen, and burned perianal area
- Multiple stool samples collected, negative
- *Saccharomyces boulardii* probiotic started, some improvement noticed
- Symptoms keep on recurring

Case 1: Nicholas, Michelin Man No More…

- Referral to ped gastro done by 7 months, barely any weight gain
- CBC, CMP, celiac panel negative
- Stool DNA probe for bacteria and parasites negative
- Mom noticed worsening of symptoms with fruit
- EGD with biopsy and disaccharidases ordered

Case 1: Nicholas, Michelin Man No More…

- Endoscopy is visually normal
- Biopsies showed nonspecific duodenitis with no villous blunting
- Disaccharidase analyses showed:
  - Lactase 6 (15-45)
  - Sucrase 15 (25-70)
  - Maltase normal
  - Palatinase normal

Case 1: Nicholas, Michelin Man No More…

- Why are both lactase and sucrase low?
- Why did he have mild improvement on *Saccharomyces boulardii*?
- What is your next step in treatment?
- Besides sucrose, which other foods can trigger symptoms?

Case 1: Nicholas, Michelin Man No More…

- Nicholas was diagnosed with CSID, treatment started ASAP
  - Sucraid® (sacrosidase) Oral Solution – 8,500 units = 1 mL = 28 drops
  - Mixed in 2 oz of water or room temperature formula with each meal or snack
  - Why not warm? Why not juice?
- Reduced sucrose/maltose diet
- Immediate resolution of diarrhea. Nicholas started thriving again!*

*Results may vary.

Please see Sucraid® (sacrosidase) Oral Solution Important Safety Information within this presentation and full Prescribing Information provided with this presentation. Sucraid® may cause a serious allergic reaction.

Case 2: Christina, the Ballerina

- Christina is a beautiful 10-year-old girl previously healthy*
- Brought directly to pediatric GI due to vague abdominal pains
- Symptoms (bloating, abdominal pain, distension, and increased flatulence) on and off for "too long" according to mom
- PE shows a normal to thin child
- Profile view shows no rib cage drop

*This is a real patient case study.

Case 2: Christina, the Ballerina

Further questioning:

- Mom mentions she is embarrassed some days to wear her ballet bodice due to distension
- Somewhat increased flatulence noticed
- Most abdominal pain occurs after meals

Case 2: Christina, the Ballerina

- CBC, CMP, sed rate, CRP, celiac panel normal
- Stools for ova and parasite, *Giardia* antigen, negative
- KUB: non-obstructive bowel gas pattern
- Increased intestinal air

Case 2: Christina, the Ballerina

Sucrose breath test:

- Baseline…… 4 ppm H_2
- 30 minutes……. 7 ppm H_2
- 60 minutes…….18 ppm H_2
- 90 minutes……. 45 ppm H_2

Case 2: Christina, the Ballerina

- Would you recommend EGD with biopsy/disaccharidases?
- How reliable is breath testing?
- Hydrogen breath test vs. ^{13}C-sucrose breath test?
- How would you treat her at this point?

Case 2: Christina, the Ballerina

- Christina was diagnosed with CSID and started on Sucraid® (sacrosidase) Oral Solution
  - Meals: 17,000 units = 2 mL = 56 drops
  - Snacks: 8,500 units = 1 mL = 28 drops
- Reduced sucrose diet
- Christina's abdomen was significantly less bloated, she had no more abdominal pains, and she was very happy!*
- She tolerates starches well, with no symptoms with maltose-containing foods (pancakes, bread, cereals)
  - Why? Because there are four different maltase enzymes, so complete maltose intolerance is extremely rare.

*Results may vary.

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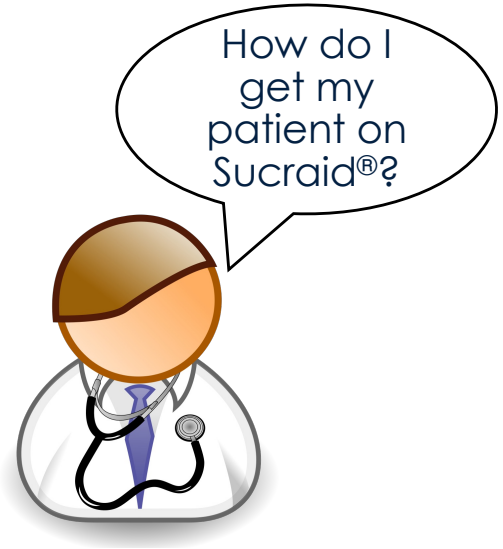
PRESCRIBE SUCRAID® (sacrosidase) ORAL SOLUTION

A Positive CSID Patient: What Now?

- Frontier Therapies – Optum is the exclusive distributing specialty pharmacy for Sucraid® (sacrosidase) Oral Solution
- To prescribe Sucraid® and minimize treatment delays, prescribing healthcare providers should submit the following:
  - Valid prescription
  - Patient's pharmacy insurance information
  - Diagnostic test results
  - Supporting clinical documentation
    - ✓ ICD-10 diagnosis code
    - ✓ Progress notes
    - ✓ Tried and failed therapies
    - ✓ Diet modifications



Please see Sucraid® (sacrosidase) Oral Solution Important Safety Information within this presentation and full Prescribing Information provided with this presentation. Sucraid® may cause a serious allergic reaction.

How Do I Send in the Prescription?

Phone: 1-833-800-0122 Fax: 1-866-850-9155

COULD IT BE
CSID
CONGENITAL SUCRASE-ISOMALTASE DEFICIENCY

QOL Medical

HOW TO GET SUCRAID® (sacrosidase) ORAL SOLUTION

Sucraid® must be kept cold and is only available from one specialty pharmacy, Frontier Therapies – Optum. It cannot be ordered from retail pharmacies.

Please see Sucraid® (sacrosidase) Oral Solution Important Safety Information within this presentation and full Prescribing Information provided with this presentation. Sucraid® may cause a serious allergic reaction.

Helpful Information

For Product Information:

Frontier Therapies – Optum, Specialty Pharmacy
Phone: 1(833) 800-0122
Fax: 1(866) 850-9155

Sucraid.com

Please see Sucraid® (sacrosidase) Oral Solution Important Safety Information within this presentation and full Prescribing Information provided with this presentation. Sucraid® may cause a serious allergic reaction.

QUESTIONS?

THANK YOU

[Presenter Name, Title
Email@QOLMed.com]

QOL Medical, LLC

QL60102

Prescribing Information

Sucraid® (sacrosidase) Oral Solution:

DESCRIPTION

Sacrosidase is an enzyme with the chemical name of β,D-fructofuranoside fructohydrolase. The enzyme is derived from baker's yeast (Saccharomyces cerevisiae). It has been reported that the primary amino acid structure of this protein consists of 513 amino acids with an apparent molecular weight of 100,000 Da for the glycosylated monomer (range 66,000- 116,000 Da). Reports also suggest that the protein exists in solution as a monomer, dimer, tetramer, and octomer ranging from 100,000 Da to 800,000 Da. It has an isoelectric point (pI) of 4.5.

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).

Sucraid is a pale yellow to colorless, clear solution with a pleasant, sweet taste. Each milliliter (mL) of Sucraid contains 8,500 International Units (IU) of the enzyme sacrosidase, the active ingredient.

Sucraid may contain small amounts of papain. Papain is known to cause allergic reactions in some people. Papain is a protein-cleaving enzyme that is introduced in the manufacturing process to digest the cell wall of the yeast and may not be completely removed during subsequent process steps. Sucraid contains sacrosidase in a vehicle comprised of glycerin, water, citric acid, and sodium hydroxide to maintain the pH at 4.0 to 4.7. Glycerol (glycerin) in the amount consumed in the recommended doses of Sucraid has no expected toxicity.

This enzyme preparation is fully soluble with water, milk, and infant formula. DO NOT HEAT SOLUTIONS CONTAINING Sucraid. Do not put Sucraid in warm or hot liquids (see DOSAGE AND ADMINISTRATION, Administration Instructions).

CLINICAL PHARMACOLOGY

Congenital sucrase-isomaltase deficiency (CSID) is a chronic, autosomal recessive, inherited, phenotypically heterogeneous disease with very variable enzyme activity. CSID is usually characterized by a complete or almost complete lack of endogenous sucrase activity, a very marked reduction in isomaltase activity, a moderate decrease in maltase activity, and normal lactase levels.

Sucrase is naturally produced in the brush border of the small intestine, primarily the distal duodenum and jejunum. Sucrase hydrolyzes the disaccharide sucrose into its component monosaccharides, glucose and fructose. Isomaltase breaks down disaccharides from starch into simple sugars. Sucraid does not contain isomaltase.

In the absence of endogenous human sucrase, as in CSID, sucrose is not metabolized. Unhydrolyzed sucrose and starch are not absorbed from the intestine and their presence in the intestinal lumen may lead to osmotic retention of water. This may result in loose stools.

Unabsorbed sucrose in the colon is fermented by bacterial flora to produce increased amounts of hydrogen, methane, and water. As a consequence, excessive gas, bloating, abdominal cramps, nausea, and vomiting may occur.

Chronic malabsorption of disaccharides may result in malnutrition. Undiagnosed/untreated CSID patients often fail to thrive and fall behind in their expected growth and development curves. Previously, the treatment of CSID has required the continual use of a strict sucrose-free diet.

CSID is often difficult to diagnose. Approximately 4% to 10% of pediatric patients with chronic diarrhea of unknown origin have CSID. Measurement of expired breath hydrogen under controlled conditions following a sucrose challenge (a measurement of excess hydrogen excreted in exhalation) in CSID patients has shown levels as great as 6 times that in normal subjects.

A generally accepted clinical definition of CSID is a condition characterized by the following: stool pH < 6, an increase in breath hydrogen of > 10 ppm when challenged with sucrose after fasting and a negative lactose breath test. However, because of the difficulties in diagnosing CSID, it may be warranted to conduct a short therapeutic trial (e.g., one week) to assess response in patients suspected of having CSID.

CLINICAL STUDIES

A two-phase (dose response preceded by a breath hydrogen phase) double-blind, multi-site, crossover trial was conducted in 28 patients (aged 4 months to 11.5 years) with confirmed CSID. During the dose-response phase, the patients were challenged with an ordinary sucrose-containing diet while receiving each of four doses of sacrosidase: full strength (9000 IU/mL) and three dilutions (1:10 [900 IU/mL], 1:100 [90 IU/mL], and 1:1000 [9 IU/mL]) in random order for a period of 10 days. Patients who weighed no more than 15 kg received 1 mL per meal; those weighing more than 15 kg received 2 mL per meal. The dose did not vary with age or sucrose intake. A dose-response relationship was shown between the two higher and the two lower doses. The two higher doses of sacrosidase were associated with significantly fewer total stools and higher proportions of patients having lower total symptom scores, the primary efficacy end-points. In addition, higher doses of sacrosidase were associated with a significantly greater number of hard and formed stools as well as with fewer watery and soft stools, the secondary efficacy end-points.

Analysis of the overall symptomatic response as a function of age indicated that in CSID patients up to 3 years of age, 86% became asymptomatic. In patients over 3 years of age, 77% became asymptomatic. Thus, the therapeutic response did not differ significantly according to age.

A second study of similar design and execution as the first used 4 different dilutions of sacrosidase: 1:100 (90 IU/mL), 1:1000 (9 IU/mL), 1:10,000 (0.9 IU/mL), and 1:100,000 (0.09 IU/mL). There were inconsistent results with regards to the primary efficacy parameters.

In both trials, however, patients showed a marked decrease in breath hydrogen output when they received sacrosidase in comparison to placebo.

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

Patients known to be hypersensitive to yeast, yeast products, glycerin (glycerol), or papain.

WARNINGS

Severe wheezing 90 minutes after a second dose of sacrosidase necessitated admission into the ICU for a 4-year-old boy. The wheezing was probably caused by sacrosidase. He had asthma and was being treated with steroids. A skin test for sacrosidase was positive.

Other serious events have not been linked to Sucraid.

PRECAUTIONS

Care should be taken to administer initial doses of Sucraid near (within a few minutes of travel) a facility where acute hypersensitivity reactions can be adequately treated. Alternatively, the patient may be tested for hypersensitivity to Sucraid through skin abrasion testing. Should symptoms of hypersensitivity appear, discontinue medication and initiate symptomatic and supportive therapy.

Skin testing as a rechallenge has been used to verify hypersensitivity in one asthmatic child who displayed wheezing after oral sacrosidase.

GENERAL

Although Sucraid provides replacement therapy for the deficient sucrase, 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 sucrase deficiency.

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

INFORMATION FOR PATIENTS

See Patient Package Insert. Instruct patients 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.

Administer Sucraid with water, milk, or infant formula. Do not warm or heat the beverage or infant formula before or after addition of Sucraid. Do not mix or consume Sucraid with fruit juice.

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 breath 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.

Do not mix or consume Sucraid with fruit juice, since 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

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 primarily pediatric patients shows that Sucraid is safe and effective for the treatment of the genetically acquired sucrase 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 sucrase deficiency, which is part of congenital sucrase-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

Dosage

- *Patients weighing 15 kg and less*: The recommended dosage is 1 mL (8,500 International Units) administered orally with each meal or snack.
- *Patients weighing more than 15 kg*: The recommended dosage is 2 mL (17,000 International Units) administered orally with each meal or snack.

Preparation Instructions

1 mL (8,500 International Units) dose for patients weighing 15 kg or less:

- Multiple-Dose Bottle: Measure 1 scoop (provided) or 28 drops using the multiple-dose bottle in 60 mL of water, milk, or infant formula and mix well. Rinse the measuring scoop with water after each use.

2 mL (17,000 International Units) dose for patients weighing more than 15 kg:

- Multiple-Dose Bottle: Measure 2 scoops (provided) or 56 drops using the multiple-dose bottle in 120 mL of water, milk, or infant formula and mix well. Rinse the measuring scoop with water after each use.
- Single-Use Container: Empty the entire contents of the 2-mL single-use container in 120 mL of water, milk, or infant formula and mix well.

Administration Instructions

- Administer half of the mixed solution at the beginning of the meal or snack and the other half during the meal or snack.
- Serve the beverage or infant formula cold or at room temperature. Do not warm or heat the beverage or infant formula before or after addition of Sucraid.
- Administration of Sucraid with liquids other than water, milk, or infant formula has not been studied and is not recommended. Do not mix or consume Sucraid with fruit juice.

HOW SUPPLIED

118-mL Multiple-Dose Bottle

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

NDC# 67871-111-04 (2 x 118-mL multiple-dose bottles)

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

2-mL Single-Use Container

Sucraid (sacrosidase) Oral Solution is available in 2-mL single-use containers that are packaged into a foil pouch. Each 2-mL single-use container contains 17,000 International Units of sacrosidase.

Each foil pouch holds a card of 5 containers. Five pouches are then packaged in a box (25 containers). Six boxes are further packaged in a carton (150 containers).

NDC# 67871-111-07 (150 x 2-mL single-use containers)

Store under refrigeration, 2°C to 8°C (36°F to 46°F). Protect from light. Single-use container can be removed from refrigeration and stored at 15°C to 25°C (59°F to 77°F) for up to 3 days (72 hours).

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

www.Sucraid.com
For questions, call 1-866-469-3773
Revised: May 2023

Patient Information

Sucraid® (Su-kreid) (sacrosidase) Oral Solution:

What is Sucraid?

Sucraid is an oral replacement therapy for people who were born with a sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID). People with this condition cannot digest certain sugars.

It is not known if Sucraid is safe and effective in children under 5 months of age.

Do not take or give your child Sucraid if you or your child:

- are allergic to yeast, yeast products, glycerin (glycerol), or papain. See the end of this Patient Information leaflet for a complete list of ingredients in Sucraid.
- have had a positive skin test for sacrosidase.

Before you take or give your child Sucraid, tell your healthcare provider about all of your medical conditions, including if you or your child:

- have diabetes. Sucraid can interact with the food in your diet and may change your blood sugar levels. Your healthcare provider will tell you if your diet or diabetes medicines need to be changed.
- are pregnant or plan to become pregnant. It is not known if Sucraid will harm your unborn baby.
- are breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you will take Sucraid while breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take or give Sucraid?

- See the detailed Instructions for Use that come with this Patient Information leaflet for instructions about the right way to take or give Sucraid.
- Sucraid should be taken or given exactly as prescribed by your healthcare provider. Do not change the dose of Sucraid without talking to your healthcare provider.
- Sucraid comes in a 118-mL multiple-dose bottle or a 2-mL single-use container. Your healthcare provider will decide which type of Sucraid is best for you to use.
- 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 in 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 at the beginning of each meal or snack. Take or give the remaining Sucraid dose during the meal or snack.
- Rinse the measuring scoop with water after each use.
- Sucraid does not break down some sugars found in foods that have starch, such as wheat, rice, and potatoes. Your healthcare provider may tell you to avoid eating foods with starch.

What are the possible side effects of Sucraid?

Sucraid may cause serious side effects, including:

- **Severe allergic reaction** can happen in some people taking Sucraid.

  Symptoms of a severe allergic reaction include:
  - difficulty breathing
  - wheezing
  - swelling of the face, lips, mouth, or tongue

Your healthcare provider may need to monitor you or your child carefully when first starting treatment with Sucraid. Get medical help right away and tell your healthcare provider as soon as possible if you or your child have any of the symptoms listed above.

Other side effects of Sucraid may include:

- stomach (abdominal) pain
- vomiting
- nausea
- diarrhea
- constipation
- difficulty sleeping
- headache
- nervousness
- dehydration

These are not all of the possible side effects of Sucraid.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Sucraid?

- Store the Sucraid multiple-dose bottle and 2-mL 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.

General information about the safe and effective use of Sucraid

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Sucraid for a condition for which it was not prescribed. Do not give Sucraid to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about Sucraid that is written for healthcare professionals.

What are the ingredients in Sucraid?

Active ingredient: sacrosidase

Inactive ingredients: Citric acid, glycerol, sodium hydroxide, and water.

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 Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: May 2023

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.**

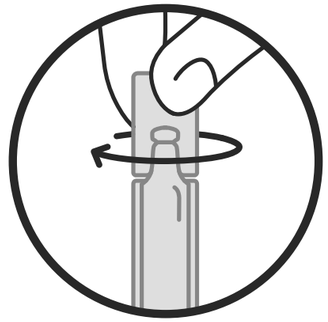


Figure 1

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.

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