

Medication Guide

Suclear™ (Soo-kleer)

(sodium sulfate, potassium sulfate and magnesium sulfate oral solution; and PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution)

Read this Medication Guide before you start taking Suclear. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about Suclear?

Suclear can cause serious side effects, including:

Serious loss of body fluid (dehydration) and changes in blood salts (electrolytes) in your blood. These changes can cause:

- **abnormal heartbeats that can cause death**
- **seizures.** This can happen even if you have never had a seizure.
- **kidney problems**

Your risk of having fluid loss and changes in blood salts with Suclear is higher if you:

- have heart problems
- have kidney problems
- take water pills (diuretics) or non-steroidal anti-inflammatory drugs (NSAIDS)

Tell your healthcare provider right away if you have any of these symptoms of a loss of too much body fluid (dehydration) while taking Suclear:

- vomiting that prevents you from keeping down the additional prescribed amount of water listed in the Instructions for Use in the "Patient Instructions for Use" booklet
- dizziness
- urinating less often than normal
- headache

See "What are the possible side effects of Suclear?" for more information about side effects.

What is Suclear?

Suclear is a prescription medicine used by adults to clean the colon before a colonoscopy. Suclear cleans your colon by causing you to have diarrhea. Cleaning your colon helps your healthcare provider see the inside of your colon more clearly during your colonoscopy.

It is not known if Suclear is safe and effective in children.

Who should not take Suclear?

Do not take Suclear if your healthcare provider has told you that you have:

- a blockage in your intestine (bowel obstruction)
- an opening in the wall of your stomach or intestine (bowel perforation)
- problems with food and fluid emptying from your stomach (gastric retention)
- a very dilated intestine (toxic megacolon)
- an allergy to any of the ingredients in Suclear. See the end of this leaflet for a complete list of ingredients in Suclear.

What should I tell my healthcare provider before taking Suclear?

Before you take Suclear, tell your healthcare provider if you:

- have heart problems
- have a history of seizures
- have kidney problems
- have ulcerative colitis
- have stomach or bowel problems
- have problems with swallowing or gastric reflux
- have gout
- are withdrawing from drinking alcohol
- have a low blood salt (sodium) level
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if Suclear will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Suclear passes into your breast milk. You and your healthcare provider should decide if you will take Suclear while breastfeeding.

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

Suclear may affect how other medicines work. Medicines taken by mouth may not be absorbed properly when taken within 1 hour before the start of each dose of Suclear.

Especially tell your healthcare provider if you take:

- medicines for blood pressure or heart problems
- medicines for kidney problems
- medicines for seizures
- water pills (diuretics)
- non-steroidal anti-inflammatory medicines (NSAID) pain medicine s
- laxatives
- medicines for depression or mental health problems

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure if you are taking any of the medicines listed above.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take Suclear?

See the Instructions for Use in the “Patient Instructions for Use” booklet for dosing instructions. You must read, understand, and follow these instructions to take Suclear the right way.

- **Take Suclear exactly as your healthcare provider tells you to take it.** Your healthcare provider will prescribe the Split-Dosing option or the Day-Before Dosing option, depending on the scheduling of your colonoscopy.
- Suclear comes in a kit. The contents of each bottle in the Suclear Kit must be mixed with water (diluted) before drinking. **Do not take Suclear oral solution or powder that has not been mixed with water, it may increase your risk of nausea, vomiting, and fluid loss (dehydration).** It is important for you to drink the additional prescribed amount of water listed in the Instructions for Use to help prevent fluid loss (dehydration).
- Do not take other laxatives while taking Suclear.
- **Do not eat solid foods or drink milk or alcohol on the day before your colonoscopy and until after your colonoscopy.** Drink only clear liquids:
 - the day before your colonoscopy
 - while taking Suclear
 - after taking Suclear until 2 hours before your colonoscopy.**Do not eat or drink anything 2 hours before your colonoscopy.**
- Drink clear liquids before, during, and after you take Suclear to avoid fluid loss (dehydrated). Examples of clear liquids are:
 - water
 - clear fruit juices without pulp including apple, white grape, or white cranberry
 - strained limeade or lemonade
 - coffee or tea (Do not use any dairy or non-dairy creamer)
 - clear broth
 - clear soda
 - gelatin (without added fruit or topping)
 - popsicles without pieces of fruit or fruit pulp

Do not eat or drink anything colored red or purple.

What are the possible side effects of Suclear?

Suclear can cause serious side effects, including:

- See **“What is the most important information I should know about Suclear?”**

- **changes in certain blood tests.** Your healthcare provider may do blood tests after you take Suclear to check your blood for changes. Tell your healthcare provider if you have any symptoms of too much fluid loss, including:
 - vomiting
 - nausea
 - bloating
 - dizziness
 - stomach (abdominal) cramping
 - headache
 - urinate less than usual
 - trouble drinking clear liquid
- **ulcers of the bowel or bowel problems (ischemic colitis).** Tell your healthcare provider right away if you have severe stomach-area (abdomen) pain or rectal bleeding.

The most common side effects of Suclear include:

- discomfort
- stomach-area (abdomen) bloating, pain, and tenderness
- nausea
- vomiting
- headache

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Suclear. For more information, ask your healthcare provider or pharmacist.

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 Suclear?

- Store Suclear at room temperature, between 68°F to 77°F (20°C to 25°C).

Keep Suclear and all medicines out of the reach of children.

General information about the safe and effective use of Suclear.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Suclear for a condition for which it was not prescribed. Do not give Suclear to other people, even if they are going to have the same procedure you are. It may harm them.

This Medication Guide summarizes the most important information about Suclear. If you would like more information, talk with your healthcare provider. You can ask

your pharmacist or healthcare provider for information about Suclear that is written for health professionals.

For more information, go to www.braintreelabs.com or call 1-800-874-6756.

What are the ingredients in Suclear?

Active ingredients:

Oral solution: sodium sulfate, potassium sulfate, and magnesium sulfate.

Powder for solution: polyethylene glycol 3350, sodium chloride, sodium bicarbonate, potassium chloride.

Inactive ingredients:

Oral solution: sodium benzoate, sucralose, malic acid, citric acid, flavoring ingredients, purified water.

Powder for solution: Cherry, Lemon-Lime, Orange and Pineapple flavor packs.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Braintree Laboratories, Inc.
Braintree, MA 02185, USA

Issued: 01/2013