

Medication Guide

SUPREP[®] (Soo-prĕp) Bowel Prep Kit
(sodium sulfate, potassium sulfate and magnesium sulfate)
Oral Solution

Read this Medication Guide before you start taking SUPREP Bowel Prep Kit. 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 SUPREP Bowel Prep Kit?

SUPREP Bowel Prep Kit and other osmotic bowel preparations 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 chance of having fluid loss and changes in body salts with SUPREP Bowel Prep Kit is higher if you:

- have heart problems
- have kidney problems
- take water pills 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 SUPREP Bowel Prep Kit:

- 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 Section “What are the possible side effects of SUPREP Bowel Prep Kit?” for more information about side effects.

What is SUPREP Bowel Prep Kit?

SUPREP Bowel Prep Kit is a prescription medicine used by adults to clean the colon before a colonoscopy. SUPREP Bowel Prep Kit 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 SUPREP Bowel Prep Kit is safe and effective in children.

Who should not take SUPREP Bowel Prep Kit?

Do not take SUPREP Bowel Prep Kit if your healthcare provider has told you that you have:

- a blockage in your 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 (bowel)
- an allergy to any of the ingredients in SUPREP Bowel Prep Kit. See the end of this leaflet for a complete list of ingredients in SUPREP Bowel Prep Kit.

What should I tell my healthcare provider before taking SUPREP Bowel Prep Kit?

Before you take SUPREP Bowel Prep Kit, tell your healthcare provider if you:

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

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

SUPREP Bowel Prep Kit 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 SUPREP Bowel Prep Kit.

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 medicines
- laxatives

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 SUPREP Bowel Prep Kit?

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 SUPREP Bowel Prep Kit the right way.

- Take SUPREP Bowel Prep Kit exactly as your healthcare provider tells you to take it.
- **Do not drink SUPREP Bowel Prep Kit solution that has not been mixed with water (diluted), it may increase your risk of nausea, vomiting and fluid loss (dehydration).**
- Each bottle of SUPREP Bowel Prep Kit must be mixed with water (diluted) before drinking.
- It is important for you to drink the additional prescribed amount of water listed in the Instructions for Use to prevent fluid loss (dehydration).
- Do not take other laxatives while taking SUPREP Bowel Prep Kit.
- Do not eat solid foods while taking SUPREP Bowel Prep Kit. Only clear liquids are allowed while taking SUPREP Bowel Prep Kit.

What are the possible side effects of SUPREP Bowel Prep Kit?

SUPREP Bowel Prep Kit can cause serious side effects, including:

- **See Section “What is the most important information I should know about SUPREP Bowel Prep Kit?”**
- **changes in certain blood tests.** Your healthcare provider may do blood tests after you take SUPREP Bowel Prep Kit 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
- **heart problems. SUPREP Bowel Prep Kit may cause irregular heartbeats.**
- **seizures**
- **ulcers of the bowel or bowel problems**
- **worsening gout**

The most common side effects of SUPREP Bowel Prep Kit include:

- discomfort
- bloating
- stomach (abdominal) cramping
- nausea
- vomiting

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 SUPREP Bowel Prep Kit. 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 SUPREP Bowel Prep Kit?

- Store SUPREP Bowel Prep Kit at room temperature, between 59°F to 86°F (15°C to 30°C).

Keep SUPREP Bowel Prep Kit and all medicines out of the reach of children.

General information about the safe and effective use of SUPREP Bowel Prep Kit.

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

This Medication Guide summarizes important information about SUPREP Bowel Prep Kit. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information that is written for healthcare professionals.

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

What are the ingredients in SUPREP Bowel Prep Kit?

Active ingredients: sodium sulfate, potassium sulfate and magnesium sulfate

Inactive ingredients: sodium benzoate, sucralose, malic acid, citric acid, flavoring ingredients, purified water

Braintree Laboratories, Inc.
Braintree, MA 02185, USA

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