

Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution 17.5 g/3.13 g/1.6 g per 6 ounces

Your doctor has recommended split-dose Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution. Below you will see step-by-step instructions and tips to help you properly prep your bowels using Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution. Although this guide is intended to be used as a helpful reference, please refer to the Full Prescribing Information for complete details.

Package contents: Two 6-ounce bottles of oral solution | One 19-ounce mixing container with a 16-ounce fill line.



The Split-Dose (2-Day) Bowel Prep Regimen

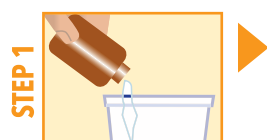
+ Both 6-ounce bottles are required for a complete prep.

☾ On the evening before your procedure (or when your healthcare provider instructs you to begin) complete steps 1 through 4 below using one 6-ounce bottle before going to bed.

☀ On the morning of your procedure, repeat steps 1 through 4 using the other 6-ounce bottle.

2 HRS You **must** finish drinking the final glass of water from step 4 at **least 2 hours** before your procedure, or as directed by your healthcare provider.

You must dilute the concentrate as directed prior to use.



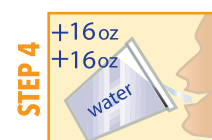
Pour **ONE** (1) 6-ounce bottle of the Oral Solution into the mixing container.



Add cool drinking water to the 16-ounce **LINE** on the container and mix.



Drink **ALL** the liquid in the container.



You **MUST** drink two (2) more 16-ounce containers of water over the next 1 hour.

HELPFUL HINTS

Care for Yourself

Bowel prep is a laxative, so you'll be spending a lot of time in the restroom while following this two-step dosing regimen. To keep yourself comfortable while the preparation does its work, here are some tips:

- Stay home or somewhere you feel comfortable that has a private restroom. This process is not something you would want to undergo while traveling or in public with limited restroom access.
- Keep a smartphone, book, magazine, tablet, or e-reader close by to help you pass the time as you go in and out of the restroom.
- Consider using moistened wipes to soothe any discomfort from repeated wiping with toilet paper.
- Keep your healthcare provider's number close at hand or saved on your phone. If you experience significant discomfort or feel something isn't right, call them right away.

Set Yourself Up for Success

Following simple rules on the day before your procedure can help you get the preparation process right the first time:

- You may have a light breakfast or have clear liquids ONLY.
- Clear liquids you can drink include water, limeade/lemonade, chicken broth, gelatin desserts without fruit or topping (NO RED OR PURPLE), coffee/tea, and strained fruit juices without pulp including apple, orange, white grape, or white cranberry.
- Do not eat dinner, drink milk, eat or drink anything colored red or purple, or drink alcoholic beverages.

Don't Improvise

It's important to take the bowel preparation solution and required water exactly as your healthcare provider instructs you. Here's why:

- This regimen is designed to prepare your bowels so that your colonoscopy provider can see clearly when performing the procedure.
- If your colon is not properly prepared and your provider is not able to perform the procedure, or cannot get a good picture, they may ask you to go through the whole process again.

IMPORTANT SAFETY INFORMATION

INDICATION

Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution is an osmotic laxative indicated for cleansing of the colon as a preparation for colonoscopy in adults.

CONTRAINDICATIONS

Patients with gastrointestinal (GI) obstruction, bowel perforation, gastric retention, ileus, toxic colitis or toxic megacolon or known allergies to components of the kit should not take Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution.

DOSAGE AND ADMINISTRATION

Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution should be taken as a split-dose oral regimen. The dose for colon cleansing requires administration of two bottles of Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution. Each bottle is administered as 16 ounces of diluted Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution with an additional 1 quart of water taken orally. All Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution and required water should be completed at least two hours prior to colonoscopy or as directed by physician.

WARNINGS AND PRECAUTIONS

Risk of fluid and electrolyte abnormalities:

Adequate hydration is advised before, during and after use. Fluid and electrolyte disturbances can lead to serious adverse events including cardiac arrhythmias, seizures, and renal impairment; **Cardiac arrhythmias:** Use caution in patients at increased risk of arrhythmia and consider pre-dose and post-colonoscopy ECGs for

at-risk patients; **Seizures:** Use caution in patients with a history of seizures or at increased risk for seizures, including medications that lower the seizure threshold, patients withdrawing from alcohol or benzodiazepines, or patients with known or suspected hyponatremia; **Renal impairment:** Use caution in patients with impaired renal function or taking medication that can impact renal function and consider baseline and post-colonoscopy laboratory testing; **Colonic mucosal ulcerations and ischemic colitis:** Concurrent use of stimulant laxatives and Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution increase risk of ulcerations and colitis; **Use in patients with significant gastrointestinal disease:** Perform appropriate diagnostic studies to rule out suspected gastrointestinal obstruction or perforation before administering Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution. Use with caution in patients with severe ulcerative colitis; **Aspiration:** Use with caution in patients with impaired gag reflex and monitor patients at risk of aspiration during administration of Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution.

ADVERSE REACTIONS

The most common adverse reactions seen in >2% of patients after administration of Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution were overall discomfort, abdominal distention, abdominal pain, nausea, vomiting, and headache.

See full Prescribing Information for complete dosing and administration instructions.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.