

What should I tell my healthcare provider before taking GaviLyte-G?

Before you take GaviLyte-G, 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 a history of seizures
- are withdrawing from drinking alcohol
- have a low blood salt (sodium) level
- have kidney problems
- have any other medical conditions
- are pregnant. It is not known if GaviLyte-G 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 GaviLyte-G passes into your breast milk. You and your healthcare provider should decide if you will take GaviLyte-G while breastfeeding.

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

GaviLyte-G may affect how other medicines work. Do not take medicines by mouth within 1 hour of starting GaviLyte-G or after you start taking GaviLyte-G.

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
- starch-based thickeners. For patients who have trouble swallowing, do not mix GaviLyte-G with starch-based thickeners.

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 GaviLyte-G?

You must read, understand, and follow these instructions to take GaviLyte-G the right way.

- Take GaviLyte-G exactly as your healthcare provider tells you to take it.
- See the “Instructions for Use” on the bottle label for instructions on how to mix, take or give GaviLyte-G.
- **Do not take undissolved GaviLyte-G powder that has not been mixed with water (diluted). It may increase your risk of nausea, vomiting and fluid loss (dehydration).**
- Do not take other laxatives while taking GaviLyte-G.
- Drink reconstituted solution at a rate of 8 ounces (240 ml) every 10 minutes. Rapid drinking of each portion is better than drinking small amounts.
- **Do not eat or drink anything colored red or purple.**
- **Do not eat solid foods at least 2 hours before taking GaviLyte-G.** You may eat a light breakfast 2 hours before taking GaviLyte-G. For best results, do not consume solid food for 3 to 4 hours before drinking GaviLyte-G.
- Drink only water and clear liquids:
 - the day before your colonoscopy
 - while taking GaviLyte-G
 - after taking GaviLyte-G until 2 hours before your colonoscopy.
- Drink clear liquids before, during, and after you take GaviLyte-G to avoid fluid loss (dehydrated). Examples of clear liquids are:
 - water
 - clear broth
 - clear fruit juices without pulp including apple, white grape, or white cranberry
 - clear soda
 - strained limeade or lemonade
 - gelatin (without added fruit or topping)
 - coffee or tea (Do not use any dairy or non-dairy creamer)
- popsicles without pieces of fruit or fruit pulp
- You may experience some abdominal bloating and distention before the bowels start to move. If severe discomfort or distention occur, slow or temporarily stop (discontinue) drinking the solution and contact your healthcare provider.
- The first bowel movement should occur approximately one hour after you start drinking the solution.
- Continue drinking until the watery stool is clear and free of solid matter.

What are the possible side effects of GaviLyte-G?

GaviLyte-G can cause serious side effects, including:

- **See Section “What is the most important information I should know about GaviLyte-G?”**
- **changes in certain blood tests.** Your healthcare provider may do blood tests before and after you take GaviLyte-G 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 GaviLyte-G include:

- nausea
- stomach (abdominal) fullness
- bloating
- stomach (abdominal) cramps
- vomiting
- chest x-ray that shows water in the lungs (infiltrate) after vomiting or inhaling food or liquid (aspirate).
- anal irritation
- esophageal bleeding

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 GaviLyte-G. 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 GaviLyte-G?

- Store GaviLyte-G in a sealed container at room temperature, between 59°F to 86°F (15°C to 30°C).
- Store mixed (reconstituted) solution of GaviLyte-G at 36° to 46°F (2°C to 8°C). Do not freeze.
- Use mixed (reconstituted) solution of GaviLyte-G within 48 hours.
- After 48 hours, throw away (discard) any mixed (reconstituted) solution of GaviLyte-G that is not used.

Keep GaviLyte-G and all medicines out of the reach of children.

General information about the safe and effective use of GaviLyte-G.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use GaviLyte-G for a condition for which it was not prescribed. Do not give GaviLyte-G 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 GaviLyte-G. 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 call 1-866-403-7592.

What are the ingredients in GaviLyte-G?

GaviLyte-G comes in a 4-liter jug with GaviLyte-G powder.

Active ingredients: polyethylene glycol 3350, sodium sulfate, sodium bicarbonate, sodium chloride, and potassium chloride.

Inactive ingredients: Lemon Flavored GaviLyte-G only (natural lemon flavor, maltodextrin, sodium saccharin)

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

Manufactured by:
Novel Laboratories, Inc.
Somerset, NJ 08873
Manufactured for:
Lupin Pharmaceuticals, Inc
Baltimore, MD 21202
SAP code: 275343
Rev: 01/2024

FILL TO THE LINE ON TOP OF THE BOTTLE	
Instructions for Use	
GaviLyte-G	
(PEG-3350 and Electrolytes)	
for oral solution	

Read this Instructions for Use and the Medication Guide before you start taking GaviLyte-G.

Important information

- **Do not take undissolved GaviLyte-G powder that has not been mixed with water (diluted).** It may increase your risk of nausea, vomiting and fluid loss (dehydration).
- **Do not eat solid foods at least 2 hours before taking GaviLyte-G.** For best results, do not consume solid food for 3 to 4 hours before drinking GaviLyte-G.

Prepare and take GaviLyte-G

1. This preparation can be used with or without the lemon flavor pack. The pharmacist will add the lemon flavor pack prior to dispensing (see packet instructions)
2. Add lukewarm drinking water to the fill mark (4 liters) on the jug. Do not add any other ingredients or flavors. Do not mix GaviLyte-G with starch-based thickeners.
3. Place the cap securely on the jug. Shake the jug very well (vigorously) several times to make sure that the ingredients are mixed well (dissolved).
4. Drink one 8-ounce (240 mL) cup of the mixed solution rapidly every 10 minutes. A loose watery bowel (stool) movement should result in approximately 1 hour. Continue drinking until you finish the entire contents (4-liters), your stools are clear, or as directed by your healthcare provider. If giving GaviLyte-G through the nasogastric (NG) tube, place GaviLyte-G into the NG tube at a rate of 20 to 30 ml per minute (1.2 or 1.8 liters per hour).
5. Throw away (discard) unused GaviLyte-G solution within 48 hours (2 days).

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HIGHLIGHTS OF PRESCRIBING INFORMATION	
These highlights do not include all the information needed to use GAVILYTE-G safely and effectively. See full prescribing information for GAVILYTE-G.	
GAVILYTE™-G (PEG-3350 (236 g) and Electrolytes for Oral Solution, USP) Initial U.S. Approval: 1984	
RECENT MAJOR CHANGES	05/2021
Warnings and Precautions, Aspiration: (5.7)	
INDICATIONS AND USAGE	
GaviLyte-G is a combination of PEG 3350, an osmotic laxative, and electrolytes indicated for cleansing of the colon in preparation for colonoscopy and barium enema X-ray examination in adults (1)	
DOSAGE AND ADMINISTRATION	
Preparation and Administration (2.1): <ul style="list-style-type: none">• Correct fluid and electrolyte abnormalities before treatment with GaviLyte-G.• Reconstitute GaviLyte-G with water prior to ingestion.• Do not take oral medications within 1 hour before the start or during administration of GaviLyte-G. (2.1)• Do not take other laxatives while taking GaviLyte-G.	

• Consume only clear liquids; avoid red and purple liquids.	
• Consume water or other clear liquids up until 2 hours before the time of the colonoscopy.	
• Do not consume solid food within 2 hours before starting GaviLyte-G.	
Adult Dosing Regimen (2.2):	
• On day prior to colonoscopy, instruct patients to consume a light breakfast at least 2 hours before starting GaviLyte-G.	
• Begin the recommended dosage regimen for GaviLyte-G early in the evening on the day before colonoscopy	
• Drink reconstituted solution at a rate of 8 ounces every 10 minutes, until 4 liters are consumed, or rectal effluent is clear.	
• For complete information on dosing, preparation and administration, see the full prescribing information. (2.1, 2.2)	
DOSAGE FORMS AND STRENGTHS	
For Oral Solution: 236 g polyethylene glycol 3350, 22.74 g sodium sulfate (anhydrous), 6.74 g sodium bicarbonate, 5.86 g sodium chloride, 2.97 g potassium chloride and 2 g favoring agent supplied in one 4 liter disposable jug. (3)	

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