

MEDICATION GUIDE

GaviLyte™-G (GAV-ee-LITE-G)

(PEG-3350 (235 g) and Electrolytes for Oral Solution, USP)

Read this Medication Guide before you start taking GaviLyte-G. 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 GaviLyte-G?

GaviLyte-G 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 GaviLyte-G 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 GaviLyte-G:

- vomiting that prevents you from keeping down the solution
- dizziness
- urinating less often than normal
- headache

See Section "what are the possible side effects of GaviLyte-G?" for more information about side effects.

What is GaviLyte-G?

GaviLyte-G is a prescription medicine used by adults to clean the colon before a colonoscopy or barium enema X-ray examination. GaviLyte-G 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 GaviLyte-G is safe and effective in children.

Who should not take GaviLyte-G?

Do not take GaviLyte-G 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 (toxic megacolon)
- an allergy to any of the ingredients in GaviLyte-G. See the end of this leaflet for a complete list of ingredients in GaviLyte-G.

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
- 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 non-prescription medicines, vitamins, and herbal supplements.

GaviLyte-G may affect how other medicines work. Medicines taken by mouth may not be absorbed properly when taken within 1 hour before the start of 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

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.
- Drink 240 mL (8 oz.) every 10 minutes. Rapid drinking of each portion is better than drinking small amounts.
- The first bowel movement should occur approximately one hour after you start drinking the solution.
- You may experience some abdominal bloating and distention before the bowels start to move. If severe discomfort or distention occur, stop drinking temporarily or drink each portion at longer intervals until the discomfort goes away.
- Continue drinking until the watery stool is clear and free of solid matter. This usually requires 3 liters and it is best to drink all of the solution.
- **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).**
- Each jug of GaviLyte-G must be reconstituted with water (diluted) to 4 liters total volume before drinking.
- Do not take other laxatives while taking GaviLyte-G.
- **Do not eat solid foods on the day before your colonoscopy and until after your colonoscopy.** Drink only clear liquids:
 - the day before your colonoscopy
 - while taking GaviLyte-G

- after taking GaviLyte-G 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 GaviLyte-G 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 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 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
- **heart problems. GaviLyte-G may cause irregular heartbeats.**
- **seizures**
- **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
- anal irritation

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 at room temperature, between 59°F to 86°F (15°C to 30°C).

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?

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.

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Novel Laboratories, Inc.

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GAVIS Pharmaceuticals, LLC.

Somerset, NJ 08873

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