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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.

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Manufactured by:
Novel Laboratories, Inc.
Somerset, NJ 08873

Manufactured for:
Lupin Pharmaceuticals, Inc
Naples, FL 34108

SAP code: 276390

Rev: 11/2024

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).

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

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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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
Warnings and Precautions, Aspiration: (5.7) 05/2021

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):
- 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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Rev: 1

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CONTRAINDICATIONS

- Gastrointestinal (GI) obstruction (4, 5.6)
- Bowel perforation (4, 5.6)
- Toxic colitis or toxic megacolon (4)
- Gastric retention (4)
- Ileus (4)
- Hypersensitivity to components of Gavilyte-G (4, 5.8)

WARNINGS AND PRECAUTIONS

- Risk of fluid and electrolyte abnormalities: Encourage adequate hydration, assess concurrent medications, and consider laboratory assessments prior to and after use. (5.1, 5.2, 7.1)
- Cardiac arrhythmias: Consider pre-dose and post-colonoscopy ECGs in patients at increased risk of serious cardiac arrhythmias. (5.2)
- Seizures: Use caution in patients with a history of seizures and patients at increased risk of seizure, including medications that lower the seizure threshold. (5.3, 7.1)
- Patients with renal impairment or taking concomitant medications that affect renal function: Use caution, ensure adequate hydration and consider testing. (5.4, 7.1, 8.6)
- Mucosal ulcerations: Consider potential for mucosal ulcerations when interpreting colonoscopy findings in patients with known or suspected inflammatory bowel disease. (5.5, 7.3)
- Patients at risk for aspiration: Observe during administration. (5.7)
- Hypersensitivity reactions including anaphylaxis: Inform patients to seek immediate medical care if symptoms occur. (5.8)

ADVERSE REACTIONS

Most common adverse reactions are: nausea, abdominal fullness, bloating, abdominal cramps, vomiting and anal irritation (6)

To report SUSPECTED ADVERSE REACTIONS, contact Lupin Pharmaceuticals, Inc. at 1-866-403-7592 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

DRUG INTERACTIONS

Some drugs increase risks due to fluid and electrolyte changes (7.1)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 11/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

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2 DOSAGE AND ADMINISTRATION
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*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

GaviLyte-G is indicated for bowel cleansing prior to colonoscopy and barium enema X-ray examination in adults.

2 DOSAGE AND ADMINISTRATION

2.1 Important Preparation and Administration Instructions

- Correct fluid and electrolyte abnormalities before treatment with Gavilyte-G *[see Warnings and Precautions (5.1)]*.
- Reconstitute Gavilyte-G with water prior to ingestion, do not take undissolved Gavilyte-G *[see Dosage and Administration (2.2)]*. Do not reconstitute with other liquids and/or add starch-based thickeners to the mixing container *[see Warnings and Precautions (5.7)]*.
- Do not take oral medications within 1 hour before the start of or during administration of Gavilyte-G *[see Drug Interactions (7.2)]*.
- Do not take other laxatives while taking Gavilyte-G *[see Drug Interactions (7.3)]*.
- Consume only clear liquids, avoid red and purple liquids.
- Patients may consume water or other clear liquids during the bowel preparation and after completion of the bowel preparation up until 2 hours before the time of the colonoscopy.
- The solution is more palatable if chilled prior to administration.
- Do not consume solid food within 2 hours before starting Gavilyte-G. For the best results, do not consume solid food for 3 to 4 hours before drinking the solution.
- If severe bloating, distention or abdominal pain occurs, slow or temporarily discontinue Gavilyte-G until the symptoms abate.

2.2 Dosage Regimen

Instruct adult patients that on the day before the colonoscopy procedure, they may consume a light breakfast at least 2 hours before starting Gavilyte-G. Begin the recommended dosage regiment for Gavilyte-G early in the evening on the day before colonoscopy.

Instruct patients to take Gavilyte-G in conjunction with clear liquids as follows:

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)

4 Liter Jug

- Fill the supplied container containing the Gavilyte-G powder with lukewarm drinking water to the 4-liter fill line
  - Do not add any other ingredients, flavors, etc.
- After capping the container, shake vigorously several times to ensure that the ingredients are dissolved.
- Drink at a rate of 8 ounces every 10 minutes until the entire contents are consumed or the rectal effluent is clear. A loose watery bowel movement should result in approximately one hour.
- After reconstitution, keep solution refrigerated 2° to 8°C (36° to 46°F). Do not freeze. Use within 48 hours, discard unused portion.

Administration via a Nasogastric Tube For patients with a nasogastric tube, administer the reconstituted Gavilyte-G solution at a rate of 20 to 30 mL per minute (1.2 to 1.8 liters per hour).

3 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 and 2.97 g potassium chloride as a white to off-white powder. When reconstituted with water to a volume of 4 liters, the solution contains 59 g/L PEG-3350, 5.69 g/L sodium sulfate, 1.69 g/L sodium bicarbonate, 1.47 g/L sodium chloride and 0.743 g/L potassium chloride.

4 CONTRAINDICATIONS

GaviLyte-G is contraindicated in the following conditions:

- Gastrointestinal (GI) obstruction *[see Warnings and Precautions (5.6)]*
- Bowel perforation *[see Warnings and Precautions (5.6)]*
- Toxic colitis or toxic megacolon
- Gastric retention
- Ileus
- Hypersensitivity to any component of Gavilyte-G *[see Warnings and Precautions (5.8)]*

5 WARNINGS AND PRECAUTIONS

5.1 Serious Fluid and Serum Chemistry Abnormalities

Advise patients to hydrate adequately before, during, and after the use of GaviLyte-G. Use caution in patients with congestive heart failure when replacing fluids. If a patient develops significant vomiting or signs of dehydration including signs of orthostatic hypotension after taking GaviLyte-G, consider performing post-colonoscopy lab tests (electrolytes, creatinine, and BUN) and treat accordingly. Fluid and electrolyte disturbances can lead to serious adverse events including cardiac arrhythmias, seizures and renal impairment. Correct fluid and electrolyte abnormalities before treatment with GaviLyte-G.

In addition, use caution when prescribing GaviLyte-G for patients who have conditions, or who are using medications, that increase the risk for fluid and electrolyte disturbances or may increase the risk of adverse events of seizure, arrhythmias, and renal impairment [*see Drug Interactions (7.1)*]

5.2 Cardiac Arrhythmias

There have been rare reports of serious arrhythmias associated with the use of ionic osmotic laxative products for bowel preparation. Use caution when prescribing GaviLyte-G for patients at increased risk of arrhythmias (e.g., patients with a history of prolonged QT, uncontrolled arrhythmias, recent myocardial infarction, unstable angina, congestive heart failure, or cardiomyopathy). Consider pre-dose and post-colonoscopy ECGs in patients at increased risk of serious cardiac arrhythmias.

5.3 Seizures

There have been reports of generalized tonic-clonic seizures and/or loss of consciousness associated with use of bowel preparation products in patients with no prior history of seizures. The seizure cases were associated with electrolyte abnormalities (e.g., hyponatremia, hypokalemia, hypocalcemia, and hypomagnesemia) and low serum osmolality. The neurologic abnormalities resolved with correction of fluid and electrolyte abnormalities.

Use caution when prescribing GaviLyte-G for patients with a history of seizures and in patients at increased risk of seizure, such as patients taking medications that lower the seizure threshold (e.g., tricyclic antidepressants), patients withdrawing from alcohol or benzodiazepines, or patients with known or suspected hyponatremia *[see Drug Interactions (7.1)]*.

5.4 Renal Impairment

Use caution when prescribing GaviLyte-G for patients with impaired renal function or patients taking concomitant medications that may affect renal function (such as diuretics, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, or non-steroidal anti-inflammatory drugs) *[see Drug Interactions (7.1)]*. Advise these patients of the importance of adequate hydration, and consider performing baseline and post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN) in these patients *[see Use is Specific Populations (8.6)]*.

5.5 Colonic Mucosal Ulcerations and Ischemic Colitis

Administration of osmotic laxative products may produce colonic mucosal aphthous ulcerations, and there have been reports of more serious cases of ischemic colitis requiring hospitalization. Concurrent use of stimulant laxatives and GaviLyte-G may increase this risk *[see Drug Interactions (7.3)]*. Consider the potential for mucosal ulcerations resulting from the bowel preparation when interpreting colonoscopy findings in patients with known or suspect inflammatory bowel disease (IBD).

5.6 Use in Patients with Significant Gastrointestinal Disease

If gastrointestinal obstruction or perforation is suspected, perform appropriate diagnostic studies to rule out these conditions before administering GaviLyte-G *[see Contraindications (4)]*.

Use with caution in patients with severe active ulcerative colitis

5.7 Aspiration

Use with caution in patients with impaired gag reflex, unconscious, or semiconscious patients, and patients prone to regurgitation or aspiration. Observe these patients during administration of GaviLyte-G, especially if it is administered via nasogastric tube.

Do not combine GaviLyte-G with starch-based thickeners *[see Dosage and Administration (2.1)]*. Polyethylene glycol (PEG), a component of GaviLyte-G, when mixed with starch-thickened liquids reduces the viscosity of the starch-thickened liquid. When a PEG-based product used for another indication was mixed in starch-based pre-thickened liquids used in patients with dysphagia, thinning of the liquid occurred and cases of chocking and potential aspiration were reported.

5.8 Hypersensitivity Reactions

Gavilyte-G contains PEG and may cause serious hypersensitivity reactions including anaphylaxis, angioedema, rash, urticaria, and pruritus *[see Adverse Reactions (6)]*. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should signs and symptoms occur.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Renal impairment *[see Warnings and Precautions (5.4)]*
- Colonic mucosal ulcerations and ischemic colitis *[see Warnings and Precautions (5.5)]*
- Patients with significant gastrointestinal disease *[see Warnings and Precautions (5.6)]*
- Aspiration *[see Warnings and Precautions (5.7)]*

The following adverse reactions associated with the use of Gavilyte-G were identified in clinical trials or post marketing reports. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency, reliably, or establish a causal relationship to drug exposure.

- *Cardiovascular:* arrhythmia, atrial fibrillation, peripheral edema, asystole, and acute pulmonary edema after aspiration *[see Warnings and Precautions (5.2)]*.
- *Nervous system:* tremor, seizure *[see Warnings and Precautions (5.3)]*
- *Hypersensitivity:* Urticaria/rash, pruritus, dermatitis, rhinorrhea, dyspnea, chest and throat tightness, fever, angioedema, anaphylaxis and anaphylactic shock *[see Contraindications (4), Warnings and Precautions (5.8)]*
- *Gastrointestinal:* Nausea, abdominal fullness and bloating are the most common adverse reactions (occurred in up to 50% of patients). Other less common adverse reactions include: abdominal cramps, vomiting, "butterfly-like" infiltrates on chest X-ray after vomiting and aspirating PEG, anal irritation, and upper GI bleeding from Mallory-Weiss Tear, esophageal perforation [usually with gastroesophageal reflux disease (GERD)].

7 DRUG INTERACTIONS

7.1 Drugs that May Increase Risks Due to Fluid and Electrolyte Abnormalities

Use caution when prescribing GaviLyte-G for patients with conditions and/or who are using medications that increase the risk for fluid and electrolyte disturbances or may increase the risk of renal impairment, seizure, arrhythmias, and prolonged QT in the setting of fluid and electrolyte abnormalities *[see Warnings and Precautions (5.1, 5.2, 5.3, 5.4)]*. Consider additional patient evaluations as appropriate.

7.2 Potential for Reduced Drug Absorption

Gavilyte-G can reduce the absorption of other administered drugs. Administer oral medications within one hour before the start of administration of Gavilyte-G *[see Dosage and Administration (2.1)]*.

7.3 Stimulant Laxatives

Concurrent use of stimulant laxatives and GaviLyte-G may increase the risk of mucosal ulceration or ischemic colitis. Avoid use of stimulant laxatives (e.g., bisacodyl, sodium picosulfate) while taking Gavilyte-G *[see Warnings and Precautions (5.5)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Animal reproduction studies have not been conducted with GaviLyte-G. It is also not known whether GaviLyte-G can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. GaviLyte-G should be given to a pregnant woman only if clearly needed.

8.3 Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when GaviLyte-G is administered to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness of GaviLyte-G in pediatric patients have not been established.

8.5 Geriatric Use

Clinical studies of GaviLyte-G did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

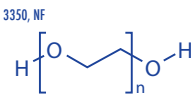
8.6 Renal Impairment

Use Gavilyte-G with caution in patients with renal impairment or patients taking concomitant medications that may affect renal function *[see Drug Interactions (7.1)]*. These patients may be at risk for renal injury. Advise these patients of the importance of adequate hydration before, during and after use of Gavilyte-G and consider performing baseline and post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN) in these patients *[see Warnings and Precautions (5.4)]*.

11 DESCRIPTION

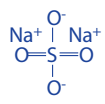
Gavilyte-G is a combination of polyethylene glycol 3350, an osmotic laxative, and electrolytes (sodium sulfate, sodium chloride, sodium bicarbonate and potassium chloride) for oral solution supplied in a 4 liter disposable jug containing 236 g polyethylene glycol 3350, 22.74 g sodium sulfate (anhydrous), 6.74 g sodium bicarbonate, 5.86 g sodium chloride, and 2.97 g potassium chloride as a white to off-white powder.

Polyethylene Glycol 3350, NF



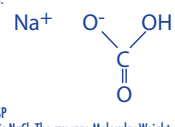
Sodium Sulfate, USP

The chemical name is Na_2SO_4. The average Molecular Weight is 142.04. The structural formula is:



Sodium Bicarbonate, USP

The chemical name is $NaHCO_3$. The average Molecular Weight is 84.01. The structural formula is:



Sodium Chloride, USP

The chemical name is NaCl. The average Molecular Weight: 58.44. The structural formula is:

$Na^+ Cl^-$

Potassium Chloride, USP

The chemical name is KCl. The average Molecular Weight: 74.55. The structural formula is:

K-Cl

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The primary mode of action is thought to be through the osmotic effect of polyethylene glycol 3350 which causes water to be retained in the colon and produces a watery stool.

12.2 Pharmacodynamics

GaviLyte-G induces as diarrhea which rapidly cleanses the bowel, usually within four hours.

12.3 Pharmacokinetics

The pharmacokinetics of PEG 3350 following administration of GaviLyte-G were not assessed. Available pharmacokinetic information for oral PEG 3350 suggests that it is poorly absorbed.

16 HOW SUPPLIED/STORAGE AND HANDLING

Gavilyte-G (polyethylene glycol 3350 and electrolytes for oral solution) is supplied in a 4-liter disposable jug containing 236 g polyethylene glycol 3350, 22.74 g sodium sulfate (anhydrous), 6.74 g sodium bicarbonate, 5.86 g sodium chloride and 2.97 g potassium chloride as a white to off white powder.

- When reconstituted with water to a volume of 4 liters, the solution contains 59 g/L PEG3350, 5.69 g/L sodium sulfate, 1.69 g/L sodium bicarbonate, 1.47 g/L sodium chloride and 0.743 g/L potassium chloride.

Gavilyte-G 4 Liter Disposable Jug NDC 43386-090-19

Storage

Store in sealed container at 15° to 30°C (59° to 86°F). Store reconstituted solution of Gavilyte-G at 2° to 8°C (36° to 46°F). Do not freeze *[see Dosage and Administration (2.1)]*.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-Approved Patient Labeling (Medication Guide and Instructions for Use).

Instruct patients:

- To reconstitute Gavilyte-G with water prior to ingestion.
- Not to take other laxatives while they are taking Gavilyte-G.
- Not to take oral medications within 1 hour before the start or during the administration of Gavilyte-G.
- To take only clear liquids but avoid red and purple liquids.
- To consume water or other clear liquids during the bowel preparation and after completion of the bowel preparation up until 2 hours before the time of the colonoscopy.
- To follow the directions in the *Instructions for Use* on how to prepare and administer the product.
- If they experience severe bloating, distention or abdominal pain, to slow or temporarily discontinue drinking the solution and to contact their healthcare provider.
- To contact their healthcare provider if they develop signs and symptoms of dehydration or if they experience altered consciousness or seizures. *[see Warnings and Precautions (5.1, 5.2, 5.3, 5.4)]*.
- To discontinue administration of the solution and contact their healthcare provider if they develop symptoms of a hypersensitivity reaction *[see Warnings and Precautions (5.8)]*.

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Medication Guide

GaviLyte™-G (GAV-ee-LITE-G)

(PEG-3350 (236 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 (arrhythmias) 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 (loose stools). 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).
- problems with food and fluid emptying from your stomach (gastric retention).
- a problem with food moving too slowly through your intestines (ileus).
  - an allergy to any of the ingredients in GaviLyte-G. See the end of this Medication Guide for a complete list of ingredients in GaviLyte-G.

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