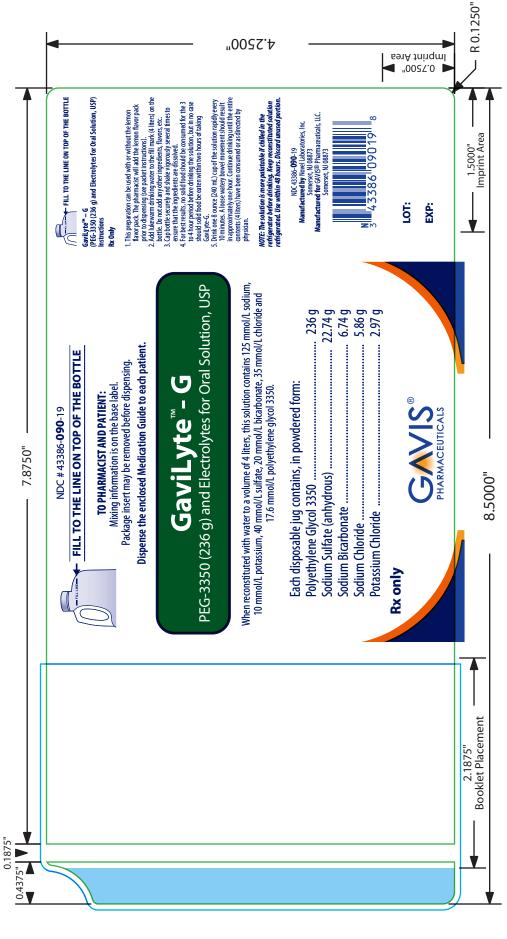


GRAND PRAIRIE, TX 75050 (469)733-1506 920 AVENUE R BLDG. #200

Novel Pharmaceuticals GaviLyte<sup>TM</sup> - G (PEG-3350)

# Base Label



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# Front

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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:

o heart problems. GaviLyte-G may cause

 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

The most common side effects of GaviLyte-G

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

Call your doctor for medical advice about side

effects. You may report side effects to FDA at

O Store GaviLyte-G at room temperature, between

Keep GaviLyte-G and all medicines out of the

General information about the safe and

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

This Medication Guide summarizes important

more information, talk-with your-healthcare

provider. You can ask your pharmacist or

For more information call 1-866-403-7592.

What are the ingredients in GaviLyte-G?

sodium sulfate, sodium bicarbonate, sodium chloride, and potassium chloride.

**Inactive ingredients:** Lemon Flavored GaviLyte-G only (natural lemon flavor,

maltodextrin, sodium saccharin)

Manufactured by:

Novel Laboratories, Inc.

**GAVIS Pharmaceuticals, LLC.** 

Somerset, NJ 08873

Manufactured for:

Somerset, NJ 08873

GLB-090-4L-02

Rev: 02/2016

U.S.-Food and Drug Administration.-

Active ingredients: polyethylene glycol 3350,

This Medication Guide has been approved by the

for healthcare professionals.

information about GaviLyte-G. If you would like

healthcare provider for information that is written

procedure you are. It may harm them.

healthcare provider or pharmacist.

How should I store GaviLyte-G?

-59°F to-86°F-(15°C to 30°C).-

effective use of GaviLyte-G.

stomach (abdominal) fullness

o stomach (abdominal) cramps

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irregular heartbeats.

o seizures

include:

o nausea

bloating

vomiting

o anal irritation

1-800-FDA-1088

reach of children

- have heart problems
- have stomach or bowel problems
- o have ulcerative colitis
- have problems with swallowing or gastric
- o have a history of seizures
- o are withdrawing from drinking alcohol
- have a low blood salt (sodium) level
- have kidney problems
- o any other medical conditions o 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 o 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

- o medicines for blood pressure or heart problems
- o medicines for kidney problems o medicines for seizures
- water pills (diuretics)

-laxatives

- o non-steroidal anti-inflammatory medicines (NSAID) pain medicines
- 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. \_a 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. O 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. O 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
- 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
- \_ O\_ while taking\_GaviLyte-G \_
- o after taking GaviLyte-G until 2 hours before your colonoscopy

# Do not eat or drink anything 2 hours before your colonoscopy. O Drink clear liquids before, during, and after you

- take GaviLyte-G to avoid fluid loss (dehydrated). Examples of clear liquids are:
- 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?'
- o 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:
  - 0 vomiting
  - nausea 0
  - 0 bloating 0 dizziness
- stomach (abdominal) cramping
- headache
- urinate less than usual 0
- trouble drinking clear liquid

CONTRAINDICATIONS

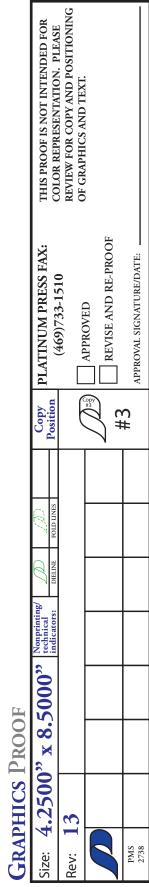
Gastrointestinal (GI) obstruction, ileus, or gastric retention (4, 5.6)
Bowel perforation (4, 5.6)
Toxic colitis or toxic megarcolon (4)
Known allergy or hypersensitivity to components of Gavillyte-6 (4, 11)

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<sup>TM</sup>-G (PEG-3350 (236 g) and Electrolytes for Oral Solution, USP) Initial U.S. Approval: 1984

--- RECENT MAJOR CHANGES Warnings and Precautions (5)

INDICATIONS AND USAGE
Grillyte-G is a combination of PEG 3350, on somotic loxative, and electrolytes indicated for cleansing of the colon in preparation for colonoscopy and barium enemo X-ray examination in adults (1)

- DOSAGE AND ADMINISTRATION
- Gavilyte-6, supplied as a powder, must be reconstituted with water before its use [2.1, 5.8]
   On day prior to colonoscopy, instruct patients to:
- Ear to light breakfast or have clear liquids (avoid red and purple liquids) [2.2]
   Early in the evening prior to colonoscopy, fill container containing Gavilyte-G powder with lukewarm water to 4 liter fill line (2.2)



(Does not print, 1.9375" Page #19 1.9375" 2.0000" After capping container, shake vigorously several times. Instruct patients to consume water or clear liquids during and after bowel preparation up until 2 hours before time of colonoscopy (2.3). Adults: Drink at a rate of 240 mt [8 az.] every 10 minutes, until 4 liters are consumed or rectal effluent is clear. For nasogastric tube (NGT), rate is 1.2 to 1.8 DOSAGE FORMS AND STRENGTHS

— DOSAGE FORMS AND STRENGTHS

For oral solution: polyethylene glycol 3350 236 grams, sodium sulfate (anhydrous)
22.74 grams, sodium bictononale 6.74 grams, sodium halorido 5.86 grams,
potassium chloride 2.97 grams, and flavoring ingredients 2 gram; supplied in one
4 liter disposable [ug. (3) Cover (Page #1)

920 AVENUE R BLDG. #200

GRAND PRAIRIE, TX 75050 (469)733-1506

- Risk of fluid and electrolyte abnormalities, arrhythmias, seizures and renal impairment assess concurrent medications and consider testing in some patients (5.1, 5.2, 5.3, 5.4)
- Patients with renal insufficiency— use caution, ensure adequate hydration and consider testing (5.4)

  • Suspected GI obstruction ruction or perforation – rule out the diagnosis before
- Suspected to distriction of periodition Tole but the languages below administration (4, 5.6)
   Patients at risk for aspiration observe during administration (5.7)
   Not for direct ingestion dilute and take with additional water (5.8)

Most common adverse reactions (≥3%) are: nousea, abdominal fullness and bloating. Abdominal cramps, vomiting and anal irritation occur less frequently (6)

To report SUSPECTED ADVERSE REACTIONS, contact GAVIS Pharmaceuticals, LLC. 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) Oral medication taken within 1 hour of start of each dose might not be absorbed

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide

# FULL PRESCRIBING INFORMATION: CONTENTS

- INDICATIONS AND USAGE DOSAGE AND ADMINISTRATION
- Dosage Overview Administration Instructions Prior to Dosage
- 2.3 Dosage DOSAGE FORMS AND STRENGTHS
- CONTRAINDICATIONS WARNINGS AND PRECAUTIONS
- Serious Fluid and Serum Chemistry Abnormalities
- Cardiac Arrhythmias
- Renal Impairment
- Colonic Mucosal Ulcerations and Ischemic Colitis Use in Patients with Significant Gastrointestinal Disease
- Not for Direct Ingestion ADVERSE REACTIONS DRUG INTERACTIONS
- Drugs that May Lead to Fluid and Electrolyte Abnormalities Potential for Altered Drug Absorption
- -/.3. Stimulent-Loxatives. — .

  USE IN SPECIFIC POPULATIONS

  8.1 Pregnancy

  8.3 Nursing Mothers

  8.4 Pediatric Use

  8.5 Geriatric Use

- USE IN SPECIFIC POPULATION
  3.1 Pregnancy
  8.3 Nursing Mothers
  8.4 Pediatric Use
  8.5 Geriatric Use
  DESCRIPTION
  CLINICAL PHARMACOLOGY
  12.1 Machanism of Action
  12.2 Pharmacodynamics
  12.3 Pharmacokinetics
  NONCLINICAL TOXICOLOGY
  3.1 (arxinogenesis, Mutagenesis, Mutagenesis, Mutagenesis, Marganesis, Mutagenesis, Marganesis, Marganesis, Mutagenesis, Mutagenesis,
- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
  HOW SUPPLIED/STORAGE AND HANDLING
  PATIENT COUNSELING INFORMATION
- \*Sections or subsections omitted from the full prescribing information are not listed

## **FULL PRESCRIBING INFORMATION** 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 Dosage Overview
Growlyte-6, supplied as a powder, must be reconstituted with water before its use; it
is not for direct ingestion [see Dosage and Administration (2.2), Warnings and
Precautions (5.8)]. The 4 liter reconstituted Govilyte-6 solution contains: 236 grams
of polyethylene glycol (PEG) 3350, 22.74 grams sodium sulfate (anhydrous), 6.74
grams of sodium bicarbonate, 5.86 grams of sodium chloride, and 2.97 grams of
potassium chloride. Govilyte-6 is supplied with lemon flavor pack.

2.2 Administration Instructions Prior to Dosage
On the day prior to the colonoscopy, instruct patients to:
a) Take only dear liquids, but avoid red and purple liquids. Patients may consume
a light breakfast.

a light breaktest.

b) Early in the evening prior to colonoscopy, fill the supplied container containing the Govilyte-G powder with lukewarm water (to facilitate dissolution) to the 4 liter fill line. The solution is clear and colorless when reconstituted to a final

volume of 4 liters.

c) After capping the container, shake vigorously several times to ensure that the ingredients are dissolved. When reconstituted use within 48 hours.

2.3 Dosage
The following is the recommended dose of reconstituted Gavityte-G solution for odults. Instruct patients they may consume water or 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.

• Adults: Instruct patients to drink a total of 4 liters at a rate of 240 mL (8 oz.)

every 10 minutes, until 4 liters are consumed or the rectal effluent is clear.

Rapid drinking of each portion is preferred to drinking small amounts

continuously. For NGT, rate is 20-30 mL per minute (1.2 – 1.8 liters per hour). The first bowel movements should occur approximately one hour after the start of Gaviltyte-G administration. Continue drinking until the watery stool is clear and free of solid matter.

# 3 DOSAGE FORMS AND STRENGTHS For oral solution: One 4 liter jug with powder for reconstitution with water.

rea ora sourous. Use 4 me 1g Warm power to reconstruct with waters. Each 4 liter jug contains; polyethylene glycol 3350 236 g, sodium sulfate (anhydrous) 22.74 g, sodium bicarbonate 6.74 g, sodium chloride 5.86 g, potassium chloride 2.97 g. When mode up to 4 liters volume with water, the solution contains FEG.3350 17.6 mmol/l, sodium 125 mmol/l, sulfate 40 mmol/L, chloride 35 mmol/l, bicarbonate 20 mmol/L and potassium 10 mmol/L.

# 4 CONTRAINDICATIONS

- Govilyte-6 is contraindicated in the following conditions:
  Gastrointestinal (61) obstruction, ileus, or gastric retention
  Bowel perforation
  Toxic collist or toxic inegacolon
  Known allergy or hypersensitivity to any component of Gavilyte-6 [see How Supplied/Storage and Handling [16]]

WARNINGS AND PRECAUTIONS

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 induding
signs of orthostactic hypotension after taking Gavilyte-G. consider performing
post-colonoscopy lab tests (electrolytes, creatinine, and BUN) and treat accordingly.
Fluid and electrolyte distribunances can lead to serious adverse events including
cardiac arrhythmias, seizures and read impairment. Fluid and electrolyte abnormalities should be corrected 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

3.2. Curroute Arrhymmus

There have been rare reports of serious arrhythmias associated with the use of ionic 
somotic locative products for bowel preparation. Use caution when prescribing 
Garvitytes for potients at increased sick of arrhythmiss (e.g., patients with a history 
of prolonged QT, uncontrolled arrhythmias, recent myocardial infarction, unstable augina, congestive\_heart failure\_or cardiomyopathy)\_Pre-dose and\_post-colonoscopy\_ ECGs should be considered in patients at increased risk of serious cardiac arrhythmias. ELGs smolla are considered in parents as increases.

S.a. 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 ahonormalities (e.g., hyponatrenia, hypokalemia, hypokalemia, hypokalemia, on hypotalemia, 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., tricytic antidepresons), patients withdrawing from alcohol or benzodiazepines, or patients with known or suspected

Information and 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). 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.

Section: Managed Winestations and Ischemic Colitis

# 5.5 Colonic Mucosal Ulcerations and Ischemic Colitis

5.5 Colonic Mucosal Ulcerations and Ischemic Colitis Administration of osmotic hazative products may produce rolonic mucosal uplathous-ulcerations, and there have been reports of more serious cases of ischemic colitis requiring hospitalization. Concurrent use of stimulant loxatives and Govilyte-6 may increase this risk. The potential for mucosal ulcerations resulting from the bowel preparation should be considered 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. If a diagnostic studies to rule out these conditions before administering bourlytes. It pertient experiences severe blooting, distention or abdominal pain, administration should be slowed or temporarily discontinued until the symptoms abote. If gastrointestinal obstruction or perforation is suspected, appropriate studies should be performed to rule out these conditions before administration of Govilyte-G. Use with coulin in patients with severe active ulcerative colitis.

5.7 Aspiration
Use with caution in patients with impaired gag reflex, unconscious, or semiconsciou patients, and patients prone to regurgitation or aspiration. Such patients should be observed during administration of GaviLyte-G, especially if it administrated via nasogastric tube.

5.8 Not for Direct Ingestion
The contents of each jug must be diluted with water to a final valume of 4 liters (4L) and ingestion of additional water is important to patient tolerance. Direct ingestion of the undissolved powder may increase the risk of nauseo, vonthing, dehydration,

# ADVERSE REACTIONS

The following adverse reactions have been identified during post-approval use of Gavilyte-6. Because these reactions are reported voluntarily from a population of unartenia size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Nousea, abdominal fullness and bloating are the most common adverse reactions (occurred in up to 50% of patients) to administration of Gavilyte-G. Abdominal cramps, vomiting and and irritation occur less frequently. These adverse reactions are transient and usually subside regidly. Isolated cases of urticaria, rhinorrhea, dermatitis and (rarely) anaphylactic reaction have been reported which may represent allergic reactions.

Published literature contains isolated reports of serious adverse reactions following the administration of PEG-electrolyte solution products in patients over 60 years of age. These adverse events include upper GI bleeding from Mallon-Ywliss Tear, esophageal perforation, exystole, sudden dyspane with pulmonary adema, and "butterfly-like" infiltrates on chest X-ray after vomiting and aspirating PEG.

# DRUG INTERACTIONS 7.1 Drugs that May Lead to Fluid and Electrolyte Abnorm

Use cution when prescribing Govilyte-6 for patients 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 prolonged QT in the setting of fluid and electrolyte abornalities. Consider additional patient evaluations or appropriate [see Warnings and Precurious (5.1, 5.2, 5.3, and 5.4)] in patients taking these exceedings are distributions.

7.2 Potential for Altered Drug Absorption
Oral medication administered within one hour of the start of administration of
Govilyte-G may be flushed from the gastraintestinal tract and the medication in
not be absorbed properly. 7.3 Stimulant Laxatives
Concurrent use of stimulant laxatives and Gaviltyte-G may increase the risk of
muccsal uleration or ischemic colitis. Avoid use of stimulant laxatives (e.g.,
bisacodyl, sodium picosulfate) while taking Gaviltyte-G.

8 USE IN SPECIFIC POPULATIONS

# 8.1 Pregnancy

Fregnancy Category C.
Animal reproduction studies have not been conducted with Govityte-G. It is also not
known whether Govityte-G can cause fetal harm when administered to a pregnant
woman or can affect reproductive capacity. Govilyte-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.

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. For oral solution: Each 4 liter (41) Govilyte-G jug contains a white powder for reconstitution. Govilyte-G is a combination of polyethylene glycol 3350, an asmotic lazative, and electrolytes (sodium sulface, sodium chloride, sodium bicarbonate and potassium chloride) for oral solution.

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Each 4 liter jug contains: polyethylene glycol 3350 236 g, sodium sulfate (anhydrous) 22.74 g, sodium bicarbonate 6.74 g, sodium chloride 5.86 g potassium chloride 2.97 g. The solution is clear and colorless when recons a final volume of 4 liters with water. Polyethylene Glycol 3350, NF

$$H = \begin{pmatrix} 0 & -1 & 0 \\ 0 & -1 & 0 \end{pmatrix}$$

Sodium Sulfate, USP
The chemical name is Na<sub>2</sub>SO<sub>4</sub>. The average Molecular Weight is 142.04. The structural formula is:

Sodium Bicarbonate, USP The chemical name is NaHCO<sub>3</sub>. 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:

No<sup>+</sup> 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 polyathylene glycul 3350 which causes water to be retained in the colon a produces a watery stool.

12.2 Pharmacodynamics
Gavilyte-G induces as diarrhea which rapidly cleanses the bowel, usually within four

12.3 Pharmacokinetics
The pharmacokinetics of PEG3350 following administration of Govilyte-G were not assessed. Available pharmacokinetic information for oral PEG3350 suggests that in

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Long term studies in animals have not been performed to evaluate carcinogenic
potential of Gavity-te-S. Studies to evaluate the possible impairment of fertility or
mutagenic potential of Gavityte-G have not been performed. 16 HOW SUPPLIED/STORAGE AND HANDLING In powdered form, for oral administration as a solution following reconstitution. GaviLyte-G is available in a disposable jug in powdered form containing:

Disposable Jug: polyathylene glycol 3350 236 g., sodium sulfate (anhydrous) 22.74 g., sodium bicarbonate 6.74 g., sodium chloride 5.86 g., potassium chloride 2.97 g. When made up 14 filters volume with water, the solution contains PEG-3330 17.6 mol/L, sodium 15.7 mmol/L, sodium 15.0 mmol/L, sodium 15.0 mmol/L and potassium 10 mmol/L.

Store in sealed container at 59° to 86°F (15°C to 30°C). When reconstituted, keep solution refrigerated. Use within 48 hours, Discard unused portion.

Keep out of reach of children. GaviLyte-G NDC 43386-090-19

# 17 PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling (Medication Guide). Instruct patients:

• To let you know if they have trouble swallowing or are prone to regurgitation or

sopiration.

Not to take other laxatives while they are taking Gavityte-G.

To consume water or clear liquids during the bowel preparation and after completion of the bowel preparation up until 2 hours before the time of the

coloniscopy.

That if they experience severe bloating, distention or abdominal pain, the administration of the solution should be slowed or temporarily discontinued until the symptoms abate. Advise patients to report these events to their health care

provider.

That if they have hives, rashes, or any allergic reaction, they should discontinue the medication and contact their health care provider. Medication should be discontinued until they speak to their physician.

To contact their healthcare provider if they develop signs and symptoms of dehydration. [see Warnings and Precautions (5.1)].

That are a medication administered within one hour of the start of administration of Gavityte-5 solution may be flushed from the GI tract and the medication may not be absorbed completely.

Manufactured for Manufactured by: GAVIS Pharmaceuticals, LLC. Somerset, NJ 08873 Novel Laboratories, Inc. Somerset, NJ 08873

# **Medication Guide** GaviLyte™-G (GAV-ee-LITE-G)

# (PEG-3350 (236 g) and Electrolytes for Oral

GLB-090-4L-02

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 im should know about GaviLyte-G?

GaviLyte-G and other osmotic bowel preparations can cause serious side effects,

Serious loss of body fluid (dehydration) and changes in blood salts (electrolytes) in your blood.

# These changes can cause:

- o abnormal heartbeats that can cause
- death o seizures. This can happen even if you have
- never had a seizure. o kidney problems
- Your chance of having fluid loss and changes in body salts with GaviLyte-G is higher if

# have heart problems

- $\circ \ \mathsf{have} \ \mathsf{kidney} \ \mathsf{problems}$
- o 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: o vomiting that prevents you from keeping

- down the solution
- dizziness  $\circ$  urinating less often than normal
- o 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.

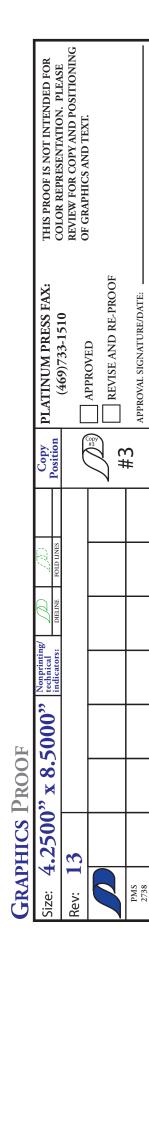
# Who should not take GaviLyte-G? Do not take GaviLyte-G if your healthcare provider

has told you that you have:  $\circ$  a blockage in your bowel (obstruction)

- o an opening in the wall of your stomach or
- intestine (bowel perforation) o problems with food and fluid emptying from

your stomach (gastric retention)

o a very dilated intestine (toxic megacolon) o 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.



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