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
- 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

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:
- 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, includina:

- vomiting
- nausea bloating
- dizziness
- stomach (abdominal) cramping headache
- urinate less than usual
- trouble drinking clear liquid • ulcers of the bowel or bowel problems

HIGHLIGHTS OF PRESCRIBING INFORMATION

RECENT MAJOR CHANGES
Warnings and Precautions, Aspiration: (5.7)

Preparation and Administration (2.1):
• Correct fluid and electrolyte abnorm

事

(ischemic colitis). Tell your healthcare provider right away if you have severe stomach-area (abdomen) pain or rectal bleeding.

These highlights do not include all the information needed to use GAYILYTE-G safely and effectively. See full prescribing information for

GAVILYTETM-G (PEG-3350 (236 g) and Electrolytes for Oral Solution, USP) Initial U.S. Approval: 1984

----- INDICATIONS AND USAGE -

Gavilyte-G is a combination of PEG 3350, an osmatic laxative, and electrolytes indicated for cleansing of the colon in preparation for colonoscopy and barium enema X-ray examination in adults (1)

Correct nation and electroryte conformations server recurrent war.
Reconstitute Govilyte-6 with water prior to ingestion.
Do not take oral medications within 1 hour before the start or during administration of Govilyte-6. (2.1)
Do not take other loxatives while taking Govilyte-6.

--- DOSAGE AND ADMINISTRATION

malities before treatment with Gavilyte-G.

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
- · Store mixed (reconstituted) solution of Gavilyte-G at 36° to 46°F (2°C to 8°C). Do not
- 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

Active ingredients: polyethylene glycol 3350, sodium sulfate, sodium bicarbonate, sodium

chloride, and potassium chloride. **Inactive ingredients:** Lemon Flavored GaviLyte-G only (natural lemon flavor,

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

Manufactured by: **Novel Laboratories, Inc.**

Somerset, NJ 08873

maltodextrin, sodium saccharin)

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
- 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.

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

Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, MD 21202

SAP code: 275343 Rev: 01/2024

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.

- Do not consume solid food within 2 hours before starting Gavilyte-G.
 Adult Design 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 ounce 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 FORMAN AND STREMETUS.
- ----- 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 p chloride and 2 g favoring agent supplied in one 4 liter disposable jug. (3)

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
- 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.

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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

you get a new medicine.

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

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- 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
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 - 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.

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- nausea
- stomach (abdominal) fullness
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- 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.

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- Use mixed (reconstituted) solution of Gavilyte-G
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Inactive ingredients: Lemon Flavored GaviLyte-G only (natural lemon flavor, maltodextrin, sodium saccharin)

Novel Laboratories, Inc. Somerset, NJ 08873 Manufactured for: Lupin Pharmaceuticals, Inc

Rev: 01/2024

Instructions for Use Gavilyte-G (PEG-3350 and Electrolytes) for oral solution

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1. This preparation can be used with or without the lemon flavor pack. The pharmacist will add packet instructions)

- 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
- 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

5. Throw away (discard) unused Gavilyte-G solution within 48 hours (2 days). Keep Gavilyte-G and all medicines out of the

20 to 30 ml per minute (1.2 or 1.8 liters per hour).

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

Somerset, NJ 08873 Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, MD 21202 SAP code: 275343

colonoscopy.

Do not consume solid food within 2 hours before starting Gavilyte-G.

Do not consume solid food within 2 hours before starting Gavilyte-G.
Adult Design 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 ownces every 10 minutes, until 4 liters are consumed, or retal effluent is clear.
For complete information on dosing, preparation and administration, see the full prescribing information. (2.1, 2.2)

DOSAGE FORMA AND STREMETUS.

Consume only clear liquids; avoid red and purple liquids.
 Consume water or other clear liquids up until 2 hours before the time of the

----- DOSAGE FORMS AND STRENGTHS For Oral Solution: 236 g polyethylene glycol 3330, 22.74 g sodium sulfate (anhydrous), 6.74 g sodium bicarbonate, 5.86 g sodium chloride, 2.97 g pr chloride and 2 g favoring agent supplied in one 4 liter disposable jug. (3)

RECENT MAJOR CHANGES
Warnings and Precautions, Aspiration: (5.7)

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

----- INDICATIONS AND USAGE -

These highlights do not include all the information needed to use GAVILYTE-G safely and effectively. See full prescribing information for

- Preparation and Administration (2.1):
 Correct fluid and electrolyte abnorm malities 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
- Do not take oral medications within 1 hour before t administration of Gavilyte-G. (2.1)
 Do not take other laxatives while taking Gavilyte-G.

- within 48 hours.
- Keep GaviLyte-G and all medicines out of the

people, even if they are going to have the same procedure you are. It may harm them.

for healthcare professionals.

chloride, and potassium chloride.

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

Baltimore, MD 21202 SAP code: 275343

FILL TO THE LINE ON TOP OF THE BOTTLE

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

do not consume solid food for 3 to 4 hours before drinking Gavilyte-G.

Prepare and take Gavilyte-G

the lemon flavor pack prior to dispensing (see 2. Add lukewarm drinking water to the fill mark (4 liters) on the jug. Do not add any other

- sure that the ingredients are mixed well 4. Drink one 8-ounce (240 mL) cup of the mixed
- Manufactured by: **Novel Laboratories, Inc.**

Rev: 01/2024

GAVILYTETM-G (PEG-3350 (236 g) and Electrolytes for Oral Solution, USP) Initial U.S. Approval: 1984

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Colonic mucosal ulcerations and ischemic colitis [500 Warnings and Precautions (5.7.)]

ADVERSE REACTIONS

Fortunes are reports of generalized hands closed some control of control of

WARNINGS AND PRECAUTIONS

recoutions on Precoutions of Gavilyte-G [see Warnings and Precoutions

For Oral Solution. 236 g polysallyease (glycal 3350, 23.0, 43 scalums sulfarte (and Solution. 236 g polysallyease). 28.6 g sodium disorde and 2.97 g potassium chloride are white to off-white powder. When reconstituted with water to a volume of 4 liters, the solution contains 59 g/L PEG-330, 5.6 9 g/L sodium sternbornone, 24.6 p.L. sodium disorde and 6.6 p.L. sodiu

nstruct patients to take Gavilyte-G in conjunction with clear liquids as follows: ded dosage regiment for Gavilyte-G early in the evening on the day

os ton od • of the colonoscopy.

2 | DOSAGE KND KAININISTRATION |
2.1 | Important Preparation and Administration Instructions |
3.1 | Important Preparation and Administration Instructions |
4.2 | Important Preparation and Administration Instructions |
4.3 | Warnings and Precautions (5.1)|.
5 | Reconstitute Gualybe & with water prior to ingestion, or not reconstitute with other prior to the mixing conditions (5.2)|.
6 | Do not lake only lead to the condend shickeness to the anxing container (5.4)|.
7 | Do not lake only lead to the condend shickeness to the about of or during and Precautions (5.2)|.
8 | Do not lake only lead the condend shickeness of the properties of the properties of the condend ship of the condended ship of the

DOSAGE AND ADMINISTRATION

pavityre-o is indicated for bowel cleansing prior to colonoscopy and barium enema INDICATIONS AND USAGE

FULL PRESCRIBING INFORMATION Sections or subsections omitted from the full prescribing information are not listed.

16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION

CLINICAL PROPERMACOLOGY

12.1 Mechanism of Action

12.2 Pharmacodynamics

12.3 Pharmacokinetics 11 11

Pediatric Use

USE IN SPECIFIC POPULATIONS

DRUG INTERACTIONS ADVERSE REACTIONS

noitariqsA eznesin Patients with Significant Gastrointestinal Disease

esovsie2 Renal Impariment Colonic Mucosal Ulcerations and Issamic Colitis السناح المستقدية المس cardiac Arrhythmias

INDICATIONS AND DASGE
DOACE AND ADMINISTRATION
I.S. Important Preparation and Admin
I.S. Dosage Regimen
C.S.

FULL PRESCRIBING INFORMATION: CONTENTS*

Aost common adverse reactions are: nausea, abdomin bdominal cramps, vomiting and anal irritation (6)

• $\frac{\text{cardiac arrhythmias:}}{\text{increased risk of serious cardiac arrhythmias.}}$

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

preparations can cause serious side effects, Gavilyte-G and other osmotic bowel should know about GaviLyte-G?

I noitomrofini traproqui teom oht zi tadW about your medical condition or your treatment. place of talking with your healthcare provider GaviLyte-G. This information does not take the

Read this Medication Guide before you start taking

(PEG-3350 (236 g) and Electrolytes for Oral (O-3TIJ-99-VAO) O-MT91VJivDO

(92U ,noitulo2

Medication Guide

Manufactured by:
Novel Laboratories, Inc.
Somerset, NJ 08873
SAP code: 275343
Rev: 07/2024

or they experience severe bloating, distention or abdominal pain, to slow or temporarily discontinue drinking the solution and to contact their healthcare

colonoscopy.

• To follow the directions in the Instructions for Use on how to prepare and administer the product.

To take only clear liquids but avoid red and purple liquids.
To consume water or other clear liquids during the bowel preparation and after expedition in the burning the bower preparation or the

notizegin of virtin be dividied of with water prior to ingestion.

• To reconstitute Govilyte-C with water prior to find a find to the other law in the water of the water ordinaries out in a find the water of the

.(esU tor long). dayse the patient to read the FDA-Approved Patient Labeling (Medication Guide and 7 PATIENT COUNSELING INFORMATION

of Gavilyte & at 2° to 8°C (36° to 46°F). Do not freeze [see Dosage and ealed container at 15° to 30°C (59° to 86°F). Store rec

Povinge & (noivolative) and object of the control o

16 HOW SUPPLIED/STORAGE AND HANDLING The pharmacokinetics of PEG 3350 following administration of 6 and yet 6 associated with the second of the first strenges associated of the second vision vi

2.3 Pharmacokine

2 Pharmacodynamics Lyte-G induces as diarrhea which rapidly cleanses the bowel, usually within four

I.S.1 Mechanism of Action. Thought to be through the osmotic effect of The primary mode of earline is thought to be neutrined of the colon and polydrhydrog given gives (35SC) which couses water to be retained in the colon and properties of waters stool.

12 CLINICAL PHARMACOLOGY

ical name is KCl. The average Molecular Weight: 74.52. The structural

"Na" Cl

The chemical name is MaCl. The average Molecular Weight: 58.44. The structural odium Chloride, USP

HÓ OтьИ

al name is MaHCO₃. The average Molecular Weight is 84.01. The

-O Na+ I Na+

<u>-</u>مٰ 92U ,etailuz muiboZ The Chemical name is Na2SQ4. The average Molecular Weight is 142.04. The structural formula is:

winzol zitonzon na. Q2EE lozyte ganty/riacholonion old zervinzo. David 9-41/luo david polityle 9-5 in consideration on side 3-41/luo david polityle 9-5 in david polityle 2-5 in david 2-5 in david

Ројуећујеле Бјусој 3350, ИF

Revised: 01/2024

8.6 Renal Impoirment

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2.8. Gerichric Use
Clinical studies of Govilyte-6 did not include sufficient numbers of subjects age
Clinical studies of Govilyte-6 did not include sufficient numbers of subjects
ond over to determine rehearing the support differenties in servores
Divine reported clinical experience has missified differences in represent the editor.

Divine reported clinical experience has not supported to the support of the

Safety and effectiveness of GaviLyte-G in pediatric patients have no been 924 Pediatric Use nomow gnisrun a ot ber

E.8 Morterum Morthers are more than the decrease and the morn of the constraint of the constraint of the constraint of the control of the con regnant woman only if clearly needed.

8.1 Pregnancy
Animal reproduction studies have not been conducted with Gavityne-6. It is also not home to a prognant known whether Gavityne-6 can couse fetal harm when administered to a prognant women or can offer teproductive copacity, Gavityne-6 should be given to a USE IN SPECIFIC POPULATIONS

E.S. Stimulant Lexaritives.

2.3 Stimulant Lexaritives and Gontyle-6 may increase the risk of e.g., and contained see at instruction for schemic clothis. As and estimulant leaves to definite a contained beaution or standard such a price contained (5.c.) and (5.c.)

V.2 Potential for Reduced Drug Absorption Conference and drugs. Administer and lowlyke Conference and drugs. Administer and lowelian reduce the about before the start of administration of Gavilyte-G [see Occasion of Administration (2.1.)].

7.7 Drugs that May Increase Risks Due to Fluid and Electrolyte

The colours and against an extending several several may be returnings that returnings and streamings that several many against and against a several many against a several s

anoitivant gastrointestinal disease [see Warmings and Precautions

oesings:

• Renal impairment [see Warnings and Precautions (5.4)]

• Colonic mucosal ulcerations and ischemic colitis [see Warnings and Precautions of Colors (2.2)]

ant ini arahwasla badrozeab ara znortoaan asvavba masitingiz yllazinilo gaiwollof ah Consider Contains Reactions
Consider Contains PEC and amor cause serious hypersensitivity reactions including
immediate medical can as a contain such as a c ADVERSE REACTIONS

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patients toking concomitorn medications that may affect renal function (such as patients toking concomitorn medications that may affect renal function (such as or new statement of the such as the su Tell your healthcare provider right away if

tnemined lenes 4-2 to notitural lenes service with the service of the service of

under when prescribing bourlyate-5 for parlams with a history of seizunes and einst ail increased rake of seizune, such as patients taking medicitations from the estizure that historial and increased rake a prividure annual parlams with the parlams with a parlams of the pa "Diete hove been reports of generalized lonit-clonic seizures ona/or loss of lone of l

unnyminment (1947)

2. Cardiac Arrhymnias

Breath of Participation

Breath of Parti

recoutions any component of Gavilyte Gee Warnings and Precautions - Govilyae-O is controindeicated in the following conditions:
- Gertuchines (5.6)
- Government (5.6)
- Bowe performion (5ee Warmings and Precautions (5.6))
- Floxic Colif or back magacolon
- Cloxic Colif or a colif megacolon
- Government (5.6)

for Onal Souriers, 236 g volyamhytens gybol 3350, 7350, as onlinns surface to Torol Torol

ingreferant are discovers, and expensively 10 minutes until the entire contents are some ingredents are discovers. In order of 8 ounces every 10 minutes until the entire consumed or the rectal effluent is clear. A loose watery bowel movement should be not at the rectal time of the constitution, keep sultion retirigented 2° to 8°C (36° to 46°F). Do not freeze, Les within 48 hours, faccard unused portion.

Administration are de absorgatic Liber for potients with a nesogestric tube, and minute of 10°F or 10°

4 Litter Lyg

- Fill has supplied container container to the definer fill ine

- This has the definer fill ine

- Do not add any other ingredients, flavors, etc.

- After caping the container, solies vigorously several times to ensure that the ingredients are dissolved.

- This definer is the fill increase severy 10 minutes until the entire contents are.

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

** Decade Regimen

They may be after order the depte deliver the colonoscopy procedure, they may branter adult plaints that on the day before the storting Gonlyte-B. Begin the normen or light beneficial orders of the depter storting to the depter depter or order orders or order orders or order orders or order orders. • The solution is more polariable if chilled prior to administration.

• The solution is more epotentiable if chilled prior to administration of the person in ordinary and prior to a construction of the continuous build boat on a four solution and instantion or the continuous and the continuous an

and offset completion of the bowel preparation up until 2 hours before the time of the completion of the bowel preparation up until 2 hours before the time of the completion.

2 DOSAGE KIND ADMINISTRATION
21.1 Important Preparation and Administration in Instructions
21.1 Important Preparation and Administration in Instructions
21.1 Important Preparation and Administration in Instructions
22.1 Important Preparation (2.0)...

Wornings and Precaulories (5.1)...

Wornings and Precaulories (5.1)...

Becompleted, Issue Bossage and Administration (2.2.1). To not reconstitute with other inputs of including and Precaulories (5.1)...

Do not late only medications within 1 hour before the start of or during administration of borlyhebe (1 see brug intervolories (2.1)...

Do not late only medications within 1 hour before the start of or during the administration of borlyhebe (1 see brug intervolories (2.1)...

Do not late only intervolories and in clarify and intervolories (2.3)...

Do not late only dear (quids, production by unit) (2.3)...

Do not late only only dear (quids, production up unit) (2.3)...

Potients were consume water or other clear (inputs during the bowel proportation and drift consume water or other clear (inputs during the bowel proportation and drift consume water or other clear (inputs during the bowel proportation and drift consume water or other clear (inputs during the bowel proportation and drift consume water or other clear (inputs during the bowel proportation and drift complex consume water or other clear (inputs during the bowel proportation and drift consume water or other clear (inputs during the bowel proportation of the bow

DOSAGE AND ADMINISTRATION iovityte-G is indicated for bowel cleansing prior to colonoscopy and barium enema-ray examination in adults.

39A2U GNA 2NOITADIGNI FULL PRESCRIBING INFORMATION Sections or subsections omitted from the full prescribing information are not listed. 6 HOW SUPPLIED/STORGEE AND HANDLING
7 PATIENT COUNSELING INFORMATION
(Softiens of subpostings and page 1)

> CLINICAL PHARMACOLOGY ш DESCRIPTION 2.8

> > 8.3

USE IN SPECIFIC POPULATIONS 7.5 Potential for Reduced Drug Absorption solution Action Paragraph 2.7. S.T. Stimulant Laxatives Drugs that May Increase Risks Due to Fluid and Electrolyte Abnormalities ĽZ **SNOITSARTIONS** ADVERSE REACTIONS

use in Patients with Significant Gastrointestinal Disease Colonic Mucosal Ulcerations and Ischemic Colitis cardiac Arrhythmias 2.7. Dosage regiment of the control of the control

noitariqs.

INDICATIONS AND USAGE
DOSAGE AND ADMINISTRATION
I SHOW THE STATE OF TH FULL PRESCRIBING INFORMATION: CONTENTS*

(7.1) segming a flow on the final ond electrolyte changes (7.1) see 17 for PATIENT COUNSELING INFORMATION and Medical 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/medwatdr. kost common adverse reactions are: nausea, abdomin bdominal cramps, vomiting and anal irritation (6)

(-5, 4, 1, 2, 6) (-5, 4, 2, 6) (-5, 4, nts with renal impoliment or taking concomitant medications that affect f<u>unction</u>: Use caution, ensure adequate hydration and consider testing. 18.67

 Seizures: Use coution in patients with a history of seizures and patients of the should.
 Increased risk of seizure, including medications that lower the seizure threshold. • <u>Cardiac arrhythmias</u>: Consider pre-dose and post-colonoscopy ECGs in patients at increased risk of serious cardiac arrhythmias. (5.2) fer use. (5.1, 5.2, 7.1) Sisk of fluid and electrolyte abnormalities: Encourage adequate hydration, assessments prior to and assess concurrent medications, and consider laboratory assessments prior to and other use. (5.1, 5.2, 7.1) components of Gavilyte-G (4, 5.8)

• WARNINGS AND PRECAUTIONS —

> (6.2, 4) notizourized (10) lanitestriointeae
> (6.2, 4) notizourized
> (9.2, 4) notizourized
> (4) notizourized provision (4)
> (7) notizourized provision (4) CONTRAINDICATIONS

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GaviLyte-G. See the end of this Medication ni stnəibərgni ədt to ynp ot ygrəlla na •

 an opening in the wall of your stomach or • a blockage in your bowel (obstruction).

has told you that you have:

Who should not take GaviLyte-G?

inside of your colon more clearly during your

colon helps your healthcare provider see the

have diarrhea (loose stools). Cleaning your

GaviLyte-G cleans your colon by causing you to or barium enema X-ray examination.

adults to clean the colon before a colonoscopy

GaviLyte-G is a prescription medicine used by

lam normal less often than normal \circ

effects of Gavilyte-G?" for more information

o vomiting that prevents you from keeping

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in body salts with GaviLyte-G is higher if you:

Your chance of having fluid loss and changes

o seizures. This can happen even if you have

o abnormal heartbeats (arrhythmias)

Tell your healthcare provider right away if

anti-inflammatory drugs (NSAIDS).

o take water pills or non-steroidal

o have kidney problems. o have heart problems.

○ kidney problems

never had a seizure.

that can cause death

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about side effects.

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View couldon when prescribing Govizyte-G for patients with conditions and/or who are busing and and a prescribing government of the condition of the country of the countr

GaviLyte-G.

your intestines (ileus).

has told you that you have:

your stomach (gastric retention).

Guide for a complete list of ingredients in

GaviLyte-G. See the end of this Medication

ni stnəibərgni ədt to ynn ot ygrəlla na 🛚

• a problem with food moving too slowly through

problems with food and fluid emptying from

• a blockage in your bowel (obstruction).

Do not take GaviLyte-G if your healthcare provider

It is not known if GaviLyte-G is safe and effective

roy guirub ylael saom nolo ruoy do ebizni

colon helps your healthcare provider see the

GaviLyte-G cleans your colon by causing you to

adults to clean the colon before a colonoscopy GaviLyte-G is a prescription medicine used by

effects of GaviLyte-G?" for more information

o vomiting that prevents you from keeping

you have any of these symptoms of a loss of

in body salts with GaviLyte-G is higher if you:

Your chance of having fluid loss and changes

o seizures. This can happen even if you have

o abnormal heartbeats (arrhythmias)

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

preparations can cause serious side effects,

I noitomrofni tnotroqmi teom əht zi todW about your medical condition or your treatment.

place of talking with your healthcare provider

GaviLyte-G. This information does not take the

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

(O-3TIJ-99-VAD) O-MT9TYJIVDO

Read this Medication Guide before you start taking

Medication Guide

provides:

To contoct their healthcare provides if They develop signs and symptoms of the contoct their healthcare provides if They develop scales or setzures. (see dehydrotion or if They according to the contoct their healthcare provides if They are develop symptoms of a hypersensitivity reaction [see Wormings provides if they develop symptoms of a hypersensitivity reaction [see Wormings and they are according to the symptoms of the symptoms of the symptoms.)

or some properties of the solution of the solution or abdominal paint, to slow or the solution or abdominal paint solution or the solution and to contact their healthcare and the solution and to contact their healthcare.

Collow the directions in the Instructions for Use on how to prepare and

rstruct patients:

In reconstitute Contype-6 with water prior to ingestion.

In for other locatives while they are taking Gentyla-6.

Mot to take other locatives while they are taking Gentyla-6.

Mot to take only clear (with the control of the co

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

Store in scaled container at 15° to 30°C (59° to 40°E). Store reconstituted solution at General Lees Desage and diministration (2.1).

When reconstituted with water to a volume of 4 liters, the solution contains 99 g/L 2002. As dolum bicarbonate, 99 g/L 2003. As 90 L, 90 g/L solum bicarbonate, 10 g/L 2003. As 10 g/L solum and bicarbonate, 10 g/L 10 g/L solum and 10 ground 10 ground

Genityte G (polyeitylene glycol 3350 and electrolytes for oral solution) is supplie solution that deposelbe glycol 350, 227.4 g solution suffield (elmyflout), 6.74 g solution biochooning, 5.86 g solution chloride and 2.97 g potessium chloride as a while to aff while powder.

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2 Pharmacodynamics ilyse-G induces as diarrhea which rapidly cleanses the bowel, usually within four

cal name is KCI. The average Molecular Weight: 74.55. The structural

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+6N | +6N O=2=0

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out and it can are a considerable and a considerabl

8.6 Renal Impoirment

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8.2. Gericatric Use
Clinical studies of Govilyte-G did not include sufficient numbers of subjects aged 6.5
Clinical studies of Govilyte-G did not include sufficient numbers of subjects.
Ond over to determine whealher they respond differently from younger subjects.
Detween the elderly and younger patients.
Detween the elderly and younger patients.

naed for overlyteness of GaviLyte-G in pediatric patients have not been

K.3 Morariam Monthers and the drug is excreted in human milk. Because many drugs is excreted in the many forms is dead in the second in the se

Programmy

Aminol reproduction studies have not been conducted with Govilyte-G. It is also not hongly the Aminol reproduction studies have not been standing the administrated to a program to a program when the Covilyte-G con cause feld harmy Forlyte-G and pure to a program on the program of the control of

Experiment Lexerines in the Adjuración and increasa the risk el concurrent to est inmunion or inferention or inferential or inferential

e is NaHCO3. The average Molecular Weight is 84.01. The

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nical name is NaCl. The average Molecular Weight: 58.44. The structural

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12.1 Meclanism of Action
12.1 Meclanism
12.1 Meclanism
12.1 Meclanism
13.1 Meclan

TY PATIENT COUNSELING INFORMATION

16 HOW SUPPLIED/STORAGE AND HANDLING

Bul əldəzoqziQ rətiJ 4 Ə-ətylivə

2.3 Pharmacokinetics

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Polyethylene Glycol 3350, NF

92.4 Pediatric Use

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USE IN SPECIFIC POPULATIONS

Revised: 01/2024

Gavilyte-G and other osmotic bowel

should know about GaviLyte-G?

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anti-inflammatory drugs (NSAIDS).

○ take water pills or non-steroidal

o have kidney problems.

o have heart problems.

○ kidney problems

These changes can cause:

:gnibuləni

(92U ,noitulo2

Manufactured by: Novel Laboratories, Inc. Somerset, NJ 08873 SAP code: 275343 Rev: 01/2024

never had a seizure.

that can cause death

See Section "What are the possible side

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have diarrhea (loose stools). Cleaning your

or barium enema X-ray examination.

FD-9tyliva Si tarlW

about side effects.

 \circ headache

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taking GaviLyte-G:

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your stomach (gastric retention).

intestine (bowel perforation). an opening in the wall of your stomach or

Who should not take GaviLyte-G?

• a very dilated intestine (toxic megacolon).

· problems with food and fluid emptying from

GaviLyte-G. Guide for a complete list of ingredients in

> your intestines (ileus). a problem with food moving too slowly through your stomach (gastric retention). problems with food and fluid emptying from • a very dilated intestine (toxic megacolon). your stomach (gastric retention). intestine (bowel perforation).
>
> • problems with food and fluid emptying from

To Ruce INTERACTIONS

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Do not take GaviLyte-G if your healthcare provider It is not known if GaviLyte-G is safe and effective

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Vis. Martine in pulses with imperied gag reflex, unconscious, or semiconscious by A.Z. Pepriention. Uses with control on pulses are supported by the property of the property

[see Drug Interactions (7.1)].

24. Recold Importment
Use coulton when prescribing Govilyte-G for patients with impoired renal function or
Use coulton when prescribing Govilyte-G for patients with impoired the order of the order of the order of the order order of the order or See Section "What are the possible side taking GaviLyte-G:

Use coution when prescribing bowlynes the properties of palatory of selzures and in palatory and increased state of the palatory of selzures and no palators that controlled (2.5 under the palatory of the pa

These changes can cause:

2. NARNINGS AND PRECAUTIONS
5.1. Serious Value and Serious Commissions the use of Active potential by the commentary of the use of Active potential of the use of Deviate potential of the use of Convilyne C. Use coulino in potential with congestive heart folluce us the performance of the use of the confidence of the performance of the use of the confidence of the use of the confidence of the use of the confidence of the use o

4 CONTRAINDICATIONS

Do not odd any other ingredients, flovors, etc.
 Miles capping the container, shoke vigorously several times to ensure that the ingredients are edstoyled.

Ingredient are edstoyled.

2.7 Docage regimes

CONTRAINDICATIONS

S.3 Serious Fluid and Serum Chemistry Abnormalities

S.3 Serious Fluid and Serum Chemistry Abnormalities

S.3 Serious Fluid and Serum Chemistry Abnormalities

To report SUSPECTED ADVERSE REACTIONS, contact Lupin Pharmacenticals, Inc. at 1-866-403-7592 or FDA at 1-800-FDA-1088 or

Patients with renal impairment or taking concomitant medications that affect renal function: Use caution, ensure adequate hydration and consider testing. (5.4, 7.7, 8.6)

• Risk of Huid and electrolyte abnormalities: Encourage adequate hydration, a cases concurrent medications, and consider laboratory use, $\{S_1, S_2, X_1\}$

 (6.2, 4) notizutida (61) abativosino (4, 2.6)
 Bowel perforation (4, 2, 6)
 inoinosion (4)
 inoinosion (4)
 inoinosion (4)
 inoinosion (4) CONTRAINDICATIONS

DRUG INTERACTIONS

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

See 17 for PATIENT COUNSELING INFORMATION and Medic

Seizures: Use coution in patients with a history of seizures and patients at increased risk of seizure, including medications that lower the seizure threshold.

Hypersensitivity to components of Gavilyte-G (4, 5.8)

WARNINGS AND PRECAUTIONS —
WARNINGS AND PRECAUTIONS —

2.2. Cardiac Arrayments (1971). An experiment of the configuration (1971). In configuration (1971). As Cardiac Arrayments of the configuration of the con

Eowitze (5.2)

- Govitze (5.2)

- Govitze (6.2)

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The solution is more palatable if chilled prior to administration.

The solution is more palatable if chilled prior to administration.

The solution solution and in the prior prior

8.6 Renal Impairment **DESCRIPTION**