

16 HOW SUPPLIED/STORAGE AND HANDLING

In powdered form, for oral administration as a solution following reconstitution.

GoLYTELY is available in a disposable jug and a packet in powdered form containing:

Disposable Jug: 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 made up to 4 liters volume with water, the solution contains PEG-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.

Packet: polyethylene glycol 3350 227.1 g, sodium sulfate (anhydrous) 21.5 g, sodium bicarbonate 6.36 g, sodium chloride 5.53 g, potassium chloride 2.82 g. When made up to 4 liters volume with water, the solution contains PEG-3350 60 g/L, sodium sulfate 5.86 g/L, sodium bicarbonate 1.68 g/L, sodium chloride 1.46 g/L and potassium chloride 0.745 g/L.

Pineapple Flavor GoLYTELY: 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, flavoring ingredients 3 g. When made up to 4 liters volume with water, the solution contains PEG-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.

Storage:

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.

GoLYTELY	NDC 52268-100-01
GoLYTELY Packet	NDC 52268-700-01
Pineapple Flavor GoLYTELY	NDC 52268-101-01

Medication Guide**GoLYTELY® (Go-lite-ly)**

(PEG-3350 and Electrolytes for Oral Solution)

Read this Medication Guide before you start taking GoLYTELY. 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 GoLYTELY?

GoLYTELY and other osmotic bowel preparations can cause serious side effects, including:

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

These changes can cause:

- **abnormal heartbeats that can cause death**
- **seizures.** This can happen even if you have never had a seizure.
- **kidney problems**

Your chance of having fluid loss and changes in body salts with GoLYTELY 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 GoLYTELY:

- 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 GoLYTELY” for more information about side effects.

What is GoLYTELY?

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

Who should not take GoLYTELY?

Do not take GoLYTELY if your healthcare provider has told you that you have:

- a blockage in your bowel (obstruction)
- an opening in the wall of your stomach or intestine (bowel perforation)
- problems with food and fluid emptying from your stomach (gastric retention)
- a very dilated intestine (toxic megacolon)
- an allergy to any of the ingredients in GoLYTELY. See the end of this leaflet for a complete list of ingredients in GoLYTELY.

What should I tell my healthcare provider before taking GoLYTELY?

Before you take GoLYTELY, tell your healthcare provider if you:

- have heart problems
- have stomach or bowel problems
- have ulcerative colitis
- have problems with swallowing or gastric reflux
- have a history of seizures
- are withdrawing from drinking alcohol
- have a low blood salt (sodium) level
- have kidney problems
- any other medical conditions
- are pregnant. It is not known if GoLYTELY 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 GoLYTELY passes into your breast milk. You and your healthcare provider should decide if you will take GoLYTELY while breastfeeding.

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

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

Especially tell your healthcare provider if you take:

- medicines for blood pressure or heart problems
- medicines for kidney problems
- medicines for seizures
- water pills (diuretics)
- non-steroidal anti-inflammatory medicines (NSAID) pain medicines
- laxatives

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure if you are taking any of the medicines listed above.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take GoLYTELY?

You must read, understand, and follow these instructions to take GoLYTELY the right way.

- Take GoLYTELY exactly as your healthcare provider tells you to take it.
- Drink 240 mL (8 oz.) every 10 minutes. Rapid drinking of each portion is better than drinking small amounts.
- The first bowel movement should occur approximately one hour after you start drinking the solution.
- You may experience some abdominal bloating and distention before the bowels start to move. If severe discomfort or distention occur, stop drinking temporarily or drink each portion at longer intervals until the discomfort goes away.
- Continue drinking until the watery stool is clear and free of solid matter. This usually requires 3 liters and it is best to drink all of the solution.
- **Do not take undissolved GoLYTELY powder that has not been mixed with water (diluted), it may increase your risk of nausea, vomiting and fluid loss (dehydration).**
- Each jug of GoLYTELY must be reconstituted with water (diluted) to 4 liters total volume before drinking.
- Do not take other laxatives while taking GoLYTELY.
- **Do not eat solid foods on the day before your colonoscopy and until after your colonoscopy.** Drink only clear liquids:
 - the day before your colonoscopy
 - while taking GoLYTELY
 - after taking GoLYTELY until 2 hours before your colonoscopy

Do not eat or drink anything 2 hours before your colonoscopy.

- Drink clear liquids before, during, and after you take GoLYTELY to avoid fluid loss (dehydrated). Examples of clear liquids are:
 - water
 - clear fruit juices without pulp including apple, white grape, or white cranberry
 - strained limeade or lemonade
 - coffee or tea (Do not use any dairy or non-dairy creamer)
 - clear broth
 - clear soda
 - gelatin (without added fruit or topping)
 - popsicles without pieces of fruit or fruit pulp

Do not eat or drink anything colored red or purple.

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 aspiration.
- Not to take other laxatives while they are taking GoLYTELY.
- 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 colonoscopy.
- 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 oral medication administered within one hour of the start of administration of GoLYTELY solution may be flushed from the GI tract and the medication may not be absorbed completely.

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What are the possible side effects of GoLYTELY?

GoLYTELY can cause serious side effects, including:

- **See Section “What is the most important information I should know about GoLYTELY?”**
- **changes in certain blood tests.** Your healthcare provider may do blood tests after you take GoLYTELY to check your blood for changes. Tell your healthcare provider if you have any symptoms of too much fluid loss, including:
 - vomiting
 - nausea
 - bloating
 - dizziness
 - stomach (abdominal) cramping
 - headache
 - urinate less than usual
 - trouble drinking clear liquid
- **heart problems. GoLYTELY may cause irregular heartbeats.**
- **seizures**
- **ulcers of the bowel or bowel problems (ischemic colitis).** Tell your healthcare provider right away if you have severe stomach-area (abdomen) pain or rectal bleeding.

The most common side effects of GoLYTELY include:

- nausea
- stomach (abdominal) fullness
- bloating
- stomach (abdominal) cramps
- vomiting
- anal irritation

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of GoLYTELY. 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 GoLYTELY?

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

Keep GoLYTELY and all medicines out of the reach of children.

General information about the safe and effective use of GoLYTELY.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use GoLYTELY for a condition for which it was not prescribed. Do not give GoLYTELY 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 GoLYTELY. 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, go to www.braintreelabs.com or call 1-800-874-6756.

What are the ingredients in GoLYTELY?

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

Inactive ingredients: Pineapple Flavored GoLYTELY **only** (natural and artificial pineapple flavor powder, maltodextrin, gum arabic, sodium saccharin, silicon dioxide)

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

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