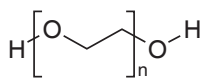


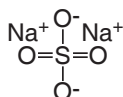


Polyethylene Glycol 3350, NF



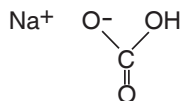
Sodium Sulfate, USP

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:



Potassium Chloride, USP

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



## 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

GoLYTELY induces as diarrhea which rapidly cleanses the bowel, usually within four hours.

### 12.3 Pharmacokinetics

The pharmacokinetics of PEG3350 following administration of GoLYTELY were not assessed. Available pharmacokinetic information for oral PEG3350 suggests that it is poorly absorbed.

## 16 HOW SUPPLIED/STORAGE AND HANDLING

GoLYTELY (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 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.

GoLYTELY 4 Liter Disposable Jug

NDC 52268-100-01

### Storage

Store in sealed container at 15° to 30°C (59° to 86°F).

Store reconstituted solution of GoLYTELY 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 GoLYTELY with water prior to ingestion.
- Not to take other laxatives while they are taking GoLYTELY.
- Not to take oral medications within 1 hour before the start or during the administration of GoLYTELY.
- 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)].

Manufactured by Braintree Laboratories, Inc. 270 Centre Street Holbrook, MA 02343  
Marketed by Braintree, a part of Sebelo Pharmaceuticals®. 60 Columbian Street West Braintree, MA 02185

### 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 (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 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 (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 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).
- 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 GoLYTELY. See the end of this Medication Guide 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.
- have 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. Do not take medicines by mouth within 1 hour of starting GoLYTELY or after you start taking 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
- See the “Instructions for Use” on the bottle label for instructions on how to mix, take or give GoLYTELY.

**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).**

- Do not take other laxatives while taking GoLYTELY.
- 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 GoLYTELY.** You may eat a light breakfast 2 hours before taking GoLYTELY. For best results, do not consume solid food for 3 to 4 hours before drinking GoLYTELY.
- Drink only water and clear liquids:
  - the day before your colonoscopy
  - while taking GoLYTELY
  - after taking GoLYTELY until 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 broth
  - clear fruit juices without pulp including apple, white grape, or white cranberry
  - clear soda
  - gelatin (without added fruit or topping)
  - strained limeade or lemonade
  - popsicles without pieces of fruit or fruit pulp
  - coffee or tea (Do not use any dairy or non-dairy creamer)
- 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 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 before and 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
  - stomach (abdominal) cramping
  - nausea
  - headache
  - bloating
  - urinate less than usual
  - dizziness
  - 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 GoLYTELY include:

- nausea
- chest x-ray that shows water in the lungs (infiltrate) after vomiting or inhaling food or liquid (aspirate).
- stomach (abdominal) fullness
- inhalation food or liquid (aspirate).
- bloating
- anal irritation
- stomach (abdominal) cramps
- esophageal bleeding
- vomiting

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 in a sealed container at room temperature, between 59°F to 86°F (15°C to 30°C).
- Store mixed (reconstituted) solution of GoLYTELY at 36° to 46°F (2°C to 8°C). Do not freeze.
- Use mixed (reconstituted) solution of GoLYTELY within 48 hours.
- After 48 hours, throw away (discard) any mixed (reconstituted) solution of GoLYTELY that is not used.

**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.

#### What are the ingredients in GoLYTELY?

GoLYTELY comes in a 4-liter jug with GoLYTELY powder.

##### Active ingredients:

**Powder for solution:** polyethylene glycol 3350, sodium sulfate (anhydrous), sodium bicarbonate, sodium chloride, and potassium chloride.

Manufactured by Braintree Laboratories, Inc.

270 Centre Street

Holbrook, MA 02343

Marketed by Braintree, a part of Sebelo Pharmaceuticals®

60 Columbian Street West

Braintree, MA 02185

For more information go to [www.braintreelabs.com](http://www.braintreelabs.com) or call 1-800-874-6756.