HIGHLIGHTS OF PRESCRIBING INFORMATION

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

GoLYTELY (polyethylene glycol 3350 and electrolytes oral solution)
Initial U.S. Approval: 1984

----------RECENT MAJOR CHANGES----------

Warnings and Precautions (5) 9/2013

----------INDICATIONS AND USAGE----------

GoLYTELY 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----------

- GoLYTELY, supplied as a powder, must be reconstituted with water before its use (2.1, 5.8)
- On day prior to colonoscopy, instruct patients to:
  - Eat a light breakfast or have clear liquids (avoid red and purple liquids) (2.2).
  - Early in the evening prior to colonoscopy, obtain a food grade container with a volume of at least one gallon. After cutting open the packet, pour the entire contents into the container. Add lukewarm water to bring the volume of solution to 1 gallon (2.2).
  - 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 **r**ate of 240 mL (8 oz.) every 10 minutes, until 1 gallon is consumed or rectal effluent is clear. For nasogastric tube (NGT), rate is 1.2 to 1.8 liters per hour (2.3)

----------DOSAGE FORMS AND STRENGTHS----------

For oral solution: polyethylene glycol 3350 227.1 grams, sodium sulfate (anhydrous) 21.5 grams, sodium bicarbonate 6.36 grams, sodium chloride 5.53 grams, potassium chloride 2.82 grams; supplied in one gallon packet (3)

----------CONTRAINDICATIONS----------

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

----------WARNINGS AND PRECAUTIONS----------

- 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 or perforation – rule out the diagnosis before 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)

----------ADVERSE REACTIONS----------

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

To report SUSPECTED ADVERSE REACTIONS, contact Braintree Laboratories, Inc. at 1-800-874-6756 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 properly (7.2)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 9/2013

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

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

2 DOSAGE AND ADMINISTRATION

2.1 Dosage Overview

GoLYTELY, 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 1 gallon reconstituted GoLYTELY solution contains: 227.1 grams of polyethylene glycol (PEG) 3350, 21.5 grams sodium sulfate (anhydrous), 6.36 grams of sodium bicarbonate, 5.53 grams of sodium chloride, and 2.82 grams of potassium chloride.

2.2 Administration Instructions Prior to Dosage

On the day prior to the colonoscopy, instruct patients to:

a) Take only clear liquids, but avoid red and purple liquids. Patients may consume a light breakfast.
   Early in the evening prior to colonoscopy, obtain a food grade container with a volume of at least one gallon. After cutting open the packet, pour the entire contents into the container. Add lukewarm water (to facilitate dissolution) to bring the volume of solution to 1 gallon.
b) The solution is clear and colorless when reconstituted to a final volume of 1 gallon.
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 GoLYTELY solution for adults. 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 up to 1gallon at a rate of 240 mL (8 oz.) every 10 minutes, until 1 gallon is 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 GoLYTELY administration. Continue drinking until the watery stool is clear and free of solid matter.

3 DOSAGE FORMS AND STRENGTHS

For oral solution: A packet with powder for reconstitution with water to 1 gallon.

Each packet contains: polyethylene glycol 3350 227.1 g, sodium sulfate (anhydrous) 21.5 grams, sodium bicarbonate 6.36 g, sodium chloride 5.53 g, potassium chloride 2.82. When made up to 1 gallon volume with water, the solution contains PEG-3350 60 g/L, sodium sulfate 5.58 g/L sodium bicarbonate 1.68 g/L, sodium chloride 1.46 g/L, and potassium 0.745 g/L.

4 CONTRAINDICATIONS

GoLYTELY is contraindicated in the following conditions:

- Gastrointestinal (GI) obstruction, ileus, or gastric retention
- Bowel perforation
- Toxic colitis or toxic megacolon
- Known allergy or hypersensitivity to any component of GoLYTELY [*see How Supplied/Storage and Handling (16)*]

5 WARNINGS AND PRECAUTIONS

5.1 Serious Fluid and Serum Chemistry Abnormalities

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

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

5.2 Cardiac Arrhythmias

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

5.3 Seizures

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

Use caution when prescribing GoLYTELY for patients with a history of seizures and in patients at increased risk of seizure, such as patients taking medications that lower the seizure threshold (e.g., tricyclic antidepressants), patients withdrawing from alcohol or benzodiazepines, or patients with known or suspected hyponatremia.

5.4 Renal Impairment

Use caution when prescribing GoLYTELY 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.

5.5 Colonic Mucosal Ulcerations and Ischemic Colitis

Administration of osmotic laxative products may produce colonic mucosal aphthous ulcerations, and there have been reports of more serious cases of ischemic colitis requiring hospitalization. Concurrent use of stimulant laxatives and GoLYTELY 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 GoLYTELY. If a patient experiences severe bloating, distention or abdominal pain, administration should be slowed or temporarily discontinued until the symptoms abate. If gastrointestinal obstruction or perforation is suspected, appropriate studies should be performed to rule out these conditions before administration of GoLYTELY.

Use with caution in patients with severe active ulcerative colitis.

5.7 Aspiration

Use with caution in patients with impaired gag reflex, unconscious, or semiconscious patients, and patients prone to regurgitation or aspiration. Such patients should be observed during administration of GoLYTELY, especially if it administered via nasogastric tube.

5.8 Not for Direct Ingestion

The contents of each packet must be diluted with water to a final volume of 1 gallon and ingestion of additional water is important to patient tolerance. Direct ingestion of the undissolved powder may increase the risk of nausea, vomiting, dehydration, and electrolyte disturbances.

6 ADVERSE REACTIONS

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

Nausea, abdominal fullness and bloating are the most common adverse reactions (occurred in up to 50% of patients) to administration of GoLYTELY. Abdominal cramps, vomiting and anal irritation occur less frequently. These adverse reactions are transient and usually subside rapidly. 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 Mallory-Weiss Tear, esophageal perforation, asystole, sudden dyspnea with pulmonary edema, and "butterfly-like" infiltrates on chest X-ray after vomiting and aspirating PEG.

7 DRUG INTERACTIONS

7.1 Drugs that May Lead to Fluid and Electrolyte Abnormalities

Use caution when prescribing GoLYTELY 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 abnormalities. Consider additional patient evaluations as appropriate [*see Warnings and Precautions (5.1, 5.2, 5.3, and 5.4)*] in patients taking these concomitant medications.

7.2 Potential for Altered Drug Absorption

Oral medication administered within one hour of the start of administration of GoLYTELY may be flushed from the gastrointestinal tract and the medication may not be absorbed properly.

7.3 Stimulant Laxatives

Concurrent use of stimulant laxatives and GoLYTELY may increase the risk of mucosal ulceration or ischemic colitis. Avoid use of stimulant laxatives (e.g., bisacodyl, sodium picosulfate) while taking GoLYTELY.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C.

Animal reproduction studies have not been conducted with GoLYTELY. It is also not known whether GoLYTELY can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. GoLYTELY 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 GoLYTELY is administered to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness of GoLYTELY in pediatric patients have not been established.

8.5 Geriatric Use

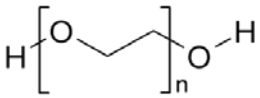
Clinical studies of GoLYTELY did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

11 DESCRIPTION

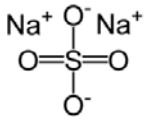
For oral solution: Each 1 gallon GoLYTELY packet contains a white powder for reconstitution. GoLYTELY is a combination of polyethylene glycol 3350, an osmotic laxative, and electrolytes (sodium sulfate, sodium chloride, sodium bicarbonate and potassium chloride) for oral solution.

Each 1 gallon packet contains: polyethylene glycol 3350 227.1g, sodium sulfate (anhydrous) 21.5 g, sodium bicarbonate 6.36 g, sodium chloride 5.53 g, potassium chloride 2.82 g. The solution is clear and colorless when reconstituted to a final volume of 1 gallon with water.

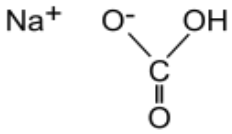
Polyethylene Glycol 3350, NF



Sodium Sulfate, USP
The chemical name is Na_2SO_4. The average Molecular Weight is 142.04. The structural formula is:



Sodium Bicarbonate, USP
The chemical name is $NaHCO_3$. The average Molecular Weight is 84.01. The structural formula is:



Sodium Chloride, USP
The chemical name is NaCl. The average Molecular Weight: 58.44. The structural formula is:

$Na^+ Cl^-$

Potassium Chloride, USP
The chemical name is KCl. The average Molecular Weight: 74.55. The structural formula is:

K-Cl

12 CLINICAL PHARMACOLOGY

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

12.2 Pharmacodynamics
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.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Long term studies in animals have not been performed to evaluate carcinogenic potential of GoLYTELY. Studies to evaluate the possible impairment of fertility or mutagenic potential of GoLYTELY have not been performed.

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 1 gallon volume with water, the solution contains PEG-3350 60 g/L, sodium sulfate 5.86/L, sodium bicarbonate 1.68 g/L, sodium chloride 1.46 g/L and potassium chloride 0.745g/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 3g. 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 59º to 86°F (15ºC 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

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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