GOLYTELY - peg-3350 and electrolytes powder, for solution
Physicians Total Care, Inc.

BRAINTREE LABORATORIES
GoLYTELY

DESCRIPTION

A white powder in a 4 liter jug for reconstitution, 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. When dissolved in water to a volume of 4 liters, GoLYTELY for Oral Solution is an isosmotic solution having a mildly salty taste. GoLYTELY for Oral Solution is administered orally or via nasogastric tube as a gastrointestinal lavage.

CLINICAL PHARMACOLOGY

GoLYTELY for Oral Solution induces a diarrhea which rapidly cleanses the bowel, usually within four hours. The osmotic activity of polyethylene glycol 3350 and the electrolyte concentration result in virtually no net absorption or excretion of ions or water. Accordingly, large volumes may be administered without significant changes in fluid or electrolyte balance.

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

GoLYTELY for Oral Solution is contraindicated in patients known to be hypersensitive to any of the components. GoLYTELY for Oral Solution is contraindicated in patients with gastrointestinal obstruction, gastric retention, bowel perforation, toxic colitis, toxic megacolon or ileus.

WARNINGS

No additional ingredients, e.g. flavorings, should be added to the solution. GoLYTELY for Oral Solution should be used with caution in patients with severe ulcerative colitis.

PRECAUTIONS:

General: Patients with impaired gag reflex, unconscious, or semiconscious patients, and patients prone to regurgitation or aspiration should be observed during the administration of GoLYTELY for Oral Solution, especially if it is administered via nasogastric tube. 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 for Oral Solution.

Information for patients: GoLYTELY for Oral Solution produces a watery stool which cleanses the bowel before examination. Prepare the solution according to the instructions on the bottle. It is more palatable if chilled. For best results, no solid food should be consumed during the 3 to 4 hour period before drinking the solution, but in no case should solid foods be eaten within 2 hours of taking GoLYTELY for Oral Solution.

Drink 240 mL (8 oz.) every 10 minutes. Rapid drinking of each portion is better than drinking small amounts continuously. The first bowel movement should occur approximately one hour after the start of GoLYTELY for Oral Solution administration. 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 these symptoms disappear. Continue drinking until the watery stool is clear and free of solid matter. This usually requires at least 3 liters and it is best to drink all of the solution. Any unused portion should be discarded.

Drug Interactions: Oral medication administered within one hour of the start of administration of GoLYTELY for Oral Solution may be flushed from the gastrointestinal tract and not absorbed.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenic and reproductive studies with animals have not been performed.

Pregnancy: Category C. Animal reproduction studies have not been conducted with GoLYTELY for Oral Solution. It is also not known whether GoLYTELY for Oral Solution can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. GoLYTELY for Oral Solution should be given to a pregnant woman only if clearly needed. **Pediatric Use:** Safety and effectiveness in children have not been established.

ADVERSE REACTIONS:

Nausea, abdominal fullness and bloating are the most common adverse reactions (occurring in up to 50% of patients) to administration of GoLYTELY for Oral Solution. Abdominal cramps, vomiting and anal irritation occur less frequently. These adverse reactions are transient and 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-ELS 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.

DOSAGE AND ADMINISTRATION:

The recommended dose for adults is 4 liters of GoLYTELY for Oral Solution solution prior to gastrointestinal examination, as ingestion of this dose produces a satisfactory preparation in over 95% of patients. Ideally, the patient should fast for approximately three or four hours prior to GoLYTELY for Oral Solution administration, but in no case should solid food be given for at least two hours before the solution is given.

GoLYTELY for Oral Solution is usually administered orally, but may be given via nasogastric tube to patients who are unwilling or unable to drink the solution. **Oral administration** is 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. **Nasogastric tube administration** is at the rate of 20-30 mL per minute (1.2-1.8 liters per hour). The first bowel movement should occur approximately one hour after the start of GoLYTELY for Oral Solution administration.

Various regimens have been used. One method is to schedule patients for examination in midmorning or later, allowing the patients three hours for drinking and an additional one hour period for complete bowel evacuation. Another method is to administer GoLYTELY for Oral Solution on the evening before the examination, particularly if the patient is to have a barium enema.

Preparation of the solution: GoLYTELY for Oral Solution solution is prepared by filling the container to the 4 liter mark with water and shaking vigorously several times to ensure that the ingredients are dissolved. Dissolution is facilitated by using lukewarm water. The solution is more palatable if chilled before administration. The reconstituted solution should be refrigerated and used

within 48 hours. Discard any unused portion.

HOW SUPPLIED

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

GoLYTELY for Oral Solution is available in a disposable jug 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 (NDC 54868-0054-0).

STORAGE

Store in sealed container at 59°-86°F. When reconstituted, keep solution refrigerated. Use within 48 hours. Discard unused portion.

GoLYTELY for Oral Solution NDC 54868-0054-0

Distributed by Braintree Laboratories, Inc., Braintree, MA 02185

A 11/00

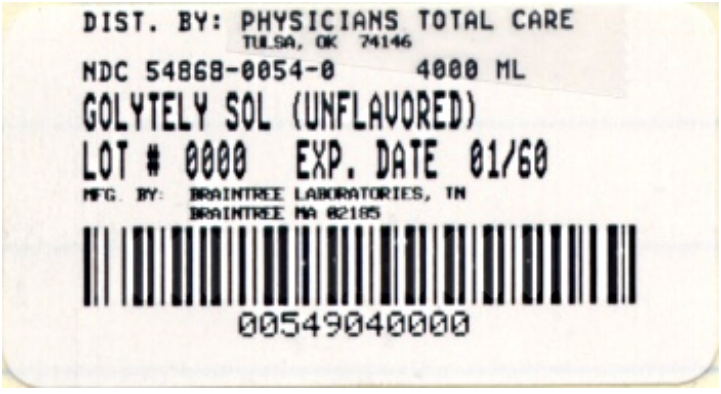
Relabeling of "Additional Barcode Label" by: Physicians Total Care, Inc., Tulsa, OK 74146

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL

GoLYTELY for Oral Solution

Rx Only

NDC 54868-0054-0



GOLYTELY

peg-3350 and electrolytes powder, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:54868-0054(NDC:52268-100)
Route of Administration	ORAL, NASOGASTRIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL 3350 - UNII:G2M7P15E5P)	POLYETHYLENE GLYCOL 3350	236 g in 2 L
SODIUM SULFATE ANHYDROUS (UNII: 36KCS0R750) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM SULFATE ANHYDROUS	22.74 g in 2 L
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM BICARBONATE	6.74 g in 2 L
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	5.86 g in 2 L
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	2.97 g in 2 L

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54868-0054-0	4 L in 1 JUG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019011	09/04/2007	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel, repack

Revised: 8/2011 Physicians Total Care, Inc.