INDICATIONS AND USAGE
GoLYTELY is indicated for bowel cleansing prior to colonoscopy and barium enema X-ray examination.

CONTRAINdications
GoLYTELY 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 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, 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.

Information for patients: GoLYTELY produces a watery stool which quickly 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.

ADVERSE REACTIONS
Nausea, abdominal fullness and bloating are the most common adverse reactions occurring 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 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” infiltrate on chest X-ray after vomiting and aspirating PEG.

DOSAGE AND ADMINISTRATION
The recommended dose for adults is 4 liters of GoLYTELY 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 administration, but in no case should solid food be given for at least two hours before the solution is given.

GoLYTELY 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 a 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 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 on the evening before the examination, particularly if the patient is to have a barium enema.

Preparation of the solution: GoLYTELY solution is prepared by filling the container to the 4 liter mark with water and shaking vigorously several times to insure 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® is available in a disposable jug and a packet in powdered form containing:

DisposabLe JUG: polyethylene glycol 3350 236g, sodium sulfate (anhydrous) 22.74g, sodium bicarbonate 6.74g, sodium chloride 5.865g, potassium chloride 2.97g. When made up to 4 liters volume with water, the solution contains PEG-3350 17.6 mmol/L, sodium 125 mmol/L, chloride 35 mmol/L, bicarbonate 20 mmol/L and potassium 10 mmol/L.

Packet: polyethylene glycol 3350 227.1g, anhydrous sodium sulfate 21.5 g, sodium bicarbonate 6.36g, sodium chloride 5.53g, potassium chloride 2.82g. When made up to 1 gallon volume with water, the solution contains PEG-3350 60 g/L, sodium sulfate 5.68 g/L, sodium bicarbonate 1.68 g/L, sodium chloride 1.46 g/L and potassium chloride 0.745 g/L.

Pineapple Flavor GoLYTELY is available in a disposable jug in powdered form containing:

DisposabLe JUG: polyethylene glycol 3350 236g, sodium sulfate (anhydrous) 22.74g, sodium bicarbonate 6.74g, sodium chloride 5.865g, potassium chloride 2.97g, flavoring ingredients 3.0g. When made up to 4 liters volume with water, the solution contains PEG-3350 17.6 mmol/L, sodium 125 mmol/L, chloride 35 mmol/L, bicarbonate 20 mmol/L and potassium 10 mmol/L.

Rx only

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

NDC 52268-100-01
Distributed by Braintree Laboratories, Inc., Braintree, MA 02185

© 2001 Braintree Laboratories, Inc. TRE-0571 November, 2001