**INDICATIONS AND USAGE**

GoLYTELY® is a polyethylene glycol electrolyte solution, for oral administration, for bowel preparation for colonoscopy and for barium enema X-ray examination in adults.

** Dosage and Administration **

- GoLYTELY® supplied as a powder must be reconstituted with water before administration.
- For oral solution: One 4 liter jug with powder for reconstitution with water.
- For nasogastric tube (NGT): rate is 1.2% of body weight per hour, until 4 liters are consumed or the rectal effluent is clear. For nasogastric tube (NGT), rate is 1:2 to 1:4 times per hour.

**Dosage Forms and Strengths**

For oral solution: A single 4 liter jug with powder for reconstitution with water. Each 4 liter jug contains: polyethylene glycol 3350 236 g, sodium sulfate (anhydrous) 22.74 g, sodium chloride 5.86 g, potassium chloride 2.97 g. The solution is clear and colorless.

**Contraindications**

- Known allergy or hypersensitivity to any component of GoLYTELY [see How Supplied/Storage and Stability].
- For oral solution: Chloride 35 mmol/L, bicarbonate 20 mmol/L and potassium 10 mmol/L.

**Warnings and Precautions**

- Use with caution in patients with severe active ulcerative 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 bowel preparation products in patients with no prior history of ischemic colitis has resulted in increased risk of seizure, such as patients taking medications that lower the seizure threshold (e.g., valproic acid, lamotrigine, ethosuximide, carbamazepine, phenytoin), patients with a history of convulsions, and in patients at risk for such spontaneous convulsions (e.g., those with Down’s syndrome).

**Drug Interactions**

Use with caution in patients with a history of seizures and in patients at risk for such spontaneous convulsions.

**Adverse Reactions**

Nausea, abdominal fullness and bloating are the most common adverse reactions (occurred in up to 75% of patients). Other adverse reactions include: cramping, vomiting, diarrhea, headache, dizziness, flushing, urticaria, pruritus, rash, angioedema, anaphylactic reaction, constipation, proctitis, myalgia, back pain, arthralgia, fever, chills, malaise, back pain, arthralgia, fever, chills, malaise.

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**General Considerations**

- The solution is more palatable if consumed or rectal effluent is clear. For nasogastric tube (NGT), rate is 1:2 to 1:4 times per hour.

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- The solution is more palatable if consumed or rectal effluent is clear. For nasogastric tube (NGT), rate is 1:2 to 1:4 times per hour.
These changes can cause:

- abdominal pain that may cause death
- seizures. This can happen even if you have never had a seizure.

Your chance of having fluid loss and changes in body salts with GoLYTELY is higher if you:

- have heart problems
- have water pills or non-steroidal anti-inflammatory drugs (NSAIDS)
- have kidney problems
- have a low blood salt (sodium) level
- are withdrawing from drinking alcohol
- have problems with swallowing or gastric reflux
- have ulcerative colitis
- have stomach or bowel problems
- have heart problems

What is the most important information I should know about GoLYTELY?

- Stop taking GoLYTELY 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
  - diuresis
  - unfeeling less 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 clears 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 intestine (obstruction)
- an operable blockage of food or intestinal tract (bowel perforation)
- a very dilated intestine (general retention)
- ate too much food or gas (diabetes)
- have an acute abdomen (abdominal pain)
- have any medical conditions
- have a very dilated intestine (general retention)
- any other medical conditions
- have a low blood salt (sodium) level
- have kidney problems
- have problems with swallowing or gastric reflux
- have a very dilated intestine (general retention)
- have any other medical conditions
- have a very dilated intestine (general retention)

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
- diuresis
- unfeeling less than normal
- headache

What is the active ingredient in GoLYTELY?

The active ingredient in GoLYTELY is polyethylene glycol 3350.

Storage

Store in a sealed container at 4°F to 30°C (40°F to 86°F). When reconstituted, store refrigerated.

Keep out of reach of children.

GoLYTELY NDC 52268-100-01

Polyethylene glycol 3350 236 g, sodium sulfate (anhydrous) 22.74 g, sodium bicarbonate (anhydrous) 17.64 g, potassium chloride 2.97 g, citric acid monohydrate 3.62 g, sodium saccharin, BHA, boric acid, natural and artificial pineapple flavor, maltodextrin, gum arabic, silicon dioxide.

These are not all the possible side effects of GoLYTELY. For more information, ask your healthcare provider or pharmacist.

GoLYTELY NDC 52268-700-01

For more information, go to www.braintreelabs.com or call 1-800-874-6756.

If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist.

This Medication Guide summarizes important information about GoLYTELY. If you would like more information, talk with your healthcare provider or pharmacist for information that is written for health care professionals.

For more information, go to www.branomedsafe.com or call 1-800-474-6756.