



**16 HOW SUPPLIED/STORAGE AND HANDLING**

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

NuLYTELY is available in a disposable jug in powdered form containing:

**NuLYTELY with Flavor Packs:** polyethylene glycol 3350 420 g, sodium bicarbonate 5.72 g, sodium chloride 11.2 g, potassium chloride 1.48 g and flavoring ingredients 2.0 g (optional). When made up to 4 liters volume with water, the solution contains PEG-3350 31.3 mmol/L, sodium 65 mmol/L, chloride 53 mmol/L, bicarbonate 17 mmol/L and potassium 5 mmol/L. Each jug has an attached package containing 4 flavor packs (optional); one each 2.0 g: Cherry, Lemon-Lime, Orange and Pineapple flavoring, in powdered form, for the addition of ONE pack by the pharmacist prior to dispensing.

**Lemon-Lime Flavor NuLYTELY:** polyethylene glycol 3350 420 g, sodium bicarbonate 5.72 g, sodium chloride 11.2 g, potassium chloride 1.48 g and flavoring ingredients 2.0 g. When made up to 4 liters volume with water, the solution contains PEG-3350 31.3 mmol/L, sodium 65 mmol/L, chloride 53 mmol/L, bicarbonate 17 mmol/L and potassium 5 mmol/L.

**Storage:**

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature]. When reconstituted, keep solution refrigerated. Use within 48 hours. Discard unused portion.

Keep out of reach of children.

NuLYTELY with Flavor Packs	NDC 52268-400-01
Lemon-Lime Flavor NuLYTELY	NDC 52268-302-01

**Medication Guide****NuLYTELY® (Noo-lite-ly)**

(PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride oral solution)

Read this Medication Guide before you start taking NuLYTELY. 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 NuLYTELY?**

**NuLYTELY 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 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 NuLYTELY 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 NuLYTELY:**

- 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 NuLYTELY” for more information about side effects.**

**What is NuLYTELY?**

NuLYTELY is a prescription medicine used by adults to clean the colon before a colonoscopy. NuLYTELY cleans 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.

NuLYTELY is safe and effective for use in pediatric patients aged 6 months and older.

**Who should not take NuLYTELY?**

Do not take NuLYTELY 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)
- problems with food and fluid emptying from your stomach (gastric retention)
- a very dilated intestine (bowel)
- an allergy to any of the ingredients in NuLYTELY. See the end of this leaflet for a complete list of ingredients in NuLYTELY.

**What should I tell my healthcare provider before taking NuLYTELY?**

**Before you take NuLYTELY, 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
- any other medical conditions
- are pregnant. It is not known if NuLYTELY 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 NuLYTELY passes into your breast milk. You and your healthcare provider should decide if you will take NuLYTELY while breastfeeding.

**Tell your healthcare provider about all the medicines you take,** including prescription and non-prescription medicines, vitamins, and herbal supplements.

NuLYTELY may affect how other medicines work. Medicines taken by mouth may not be absorbed properly when taken within 1 hour before the start of NuLYTELY.

**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 NuLYTELY?**

**You must read, understand, and follow these instructions to take NuLYTELY the right way.**

- Take NuLYTELY exactly as your healthcare provider tells you to take it.
- Drink 240 mL (8 oz.) every 10 minutes. Rapid drinking of each portion is better than drinking small amounts.
- The first bowel movement should occur approximately one hour after you start drinking the solution.
- 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 the discomfort goes away.
- Continue drinking until the watery stool is clear and free of solid matter. This usually requires 3 liters and it is best to drink all of the solution.
- **Do not take undissolved NuLYTELY powder that has not been mixed with water (diluted), it may increase your risk of nausea, vomiting and fluid loss (dehydration).**
- Each jug of NuLYTELY must be reconstituted with water (diluted) to 4 liters total volume before drinking.
- Do not take other laxatives while taking NuLYTELY.
- **Do not eat solid foods on the day before your colonoscopy and until after your colonoscopy.** Drink only clear liquids:
  - the day before your colonoscopy
  - while taking NuLYTELY
  - after taking NuLYTELY until 2 hours before your colonoscopy

**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 NuLYTELY.
- 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 NuLYTELY solution may be flushed from the GI tract and the medication may not be absorbed completely.

Distributed by Braintree Laboratories, Inc. Braintree, MA 02185

**What are the possible side effects of NuLYTELY?**

NuLYTELY can cause serious side effects, including:

- **See Section “What is the most important information I should know about NuLYTELY?”**
- **changes in certain blood tests.** Your healthcare provider may do blood tests after you take NuLYTELY to check your blood for changes. Tell your healthcare provider if you have any symptoms of too much fluid loss, including:
  - vomiting
  - nausea
  - bloating
  - dizziness
  - stomach (abdominal) cramping
  - headache
  - urinate less than usual
  - trouble drinking clear liquid
- **heart problems. NuLYTELY may cause irregular heartbeats.**
- **seizures**
- **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 NuLYTELY include:

- nausea
- stomach (abdominal) fullness
- bloating
- stomach (abdominal) cramps
- vomiting
- anal irritation

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 NuLYTELY. 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 NuLYTELY?**

- Store NuLYTELY at room temperature, between 59°F to 86°F (15°C to 30°C).

**Keep NuLYTELY and all medicines out of the reach of children.**

**General information about the safe and effective use of NuLYTELY.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use NuLYTELY for a condition for which it was not prescribed. Do not give NuLYTELY 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 NuLYTELY. 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.

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

**What are the ingredients in NuLYTELY?**

**Active ingredients:** polyethylene glycol 3350, sodium bicarbonate, sodium chloride, and potassium chloride.

**Inactive ingredients:** cherry flavoring, lemon-lime flavoring, orange flavoring, pineapple flavoring (flavor only)

Braintree Laboratories, Inc.  
Braintree, MA 02185, USA

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Revised 9/2013