NULYTELY (polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride) is a combination of polyethylene glycol 3350, an osmotic laxative, and electrolytes (sodium chloride, sodium bicarbonate, and potassium chloride) for oral use.

**INDICATIONS AND USAGE**

NULYTELY is a cleansing enema indicated for cleansing of the colon in preparation for colonoscopy in adults and pediatric patients aged 6 months or greater (1).

**CONTRAINDICATIONS**

NULYTELY is contraindicated in patients with known or suspected inflammatory bowel disease (IBD), patients prone to regurgitation or aspiration, and patients with known or suspected hyponatremia.

**WARNINGS AND PRECAUTIONS**

5.7 Aspiration

In patients with impaired gag reflex, oesophageal, or nasopharyngeal reflexes, and patients prone to regurgitation or aspiration, fluid should be administered at a rate slow enough to avoid the possibility of aspiration.

**ADVERSE REACTIONS**

6 ADVERSE REACTIONS

6.1 General Disorders and Administration Site Reactions

6.2 Special Senses

6.3 Systemic Disorders

6.4 Metabolism and Nutrition

6.6 Adverse Reactions Associated with Use of Bowel Preparation Products

6.8 Reports of Adverse Events Submitted to the FDA

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.2 Nursing Mothers

8.3 Children

8.4 Pediatric Use

8.5 Geriatric Use

8.6 Hypersensitivity Reactions

8.7 Idiopathic Sialorrhea

8.8 Enhanced Effect of Sympathomimetic Amines

8.9 Geriatric Use

8.10 Pediatric Use

8.11 Hypersensitivity Reactions

8.12 Idiopathic Sialorrhea

8.13 Enhanced Effect of Sympathomimetic Amines

11 DESCRIPTION

11.1 Clinical Pharmacology

11.2 Pharmacokinetics

11.3 Pharmacodynamics

11.4 Mechanism of Action

11.5 Safety and Efficacy

11.6 Use in Specific Populations

11.7 Clinical Pharmacology

11.8 Pharmacokinetics

11.9 Pharmacodynamics

11.10 Mechanism of Action

11.11 Safety and Efficacy

11.12 Use in Specific Populations

11.13 Clinical Pharmacology

11.14 Pharmacokinetics

11.15 Pharmacodynamics

11.16 Mechanism of Action

11.17 Safety and Efficacy

11.18 Use in Specific Populations

11.19 Clinical Pharmacology

11.20 Pharmacokinetics

11.21 Pharmacodynamics

11.22 Mechanism of Action

11.23 Safety and Efficacy

11.24 Use in Specific Populations
Do not take NuLYTELY if your healthcare provider has told you that you have:

- active bowel problems or bowel obstructions

Who should not take NuLYTELY?

- patients who have certain health conditions
- women who are pregnant or plan to become pregnant
- people who likely have problems with food and fluid emptying from your stomach (gastric retention)
- patients with an opening in the wall of your stomach or intestine (bowel perforation)
- patients with ulcerative colitis
- patients with stomach or bowel problems

Tell your healthcare provider right away if you have any of these symptoms

- vomiting
- stomach (abdominal) cramps
- mouth sores or ulcers
- diarrhea
- bloating
- diarrhea or more than 4 bowel movements
- dizziness
- stomach problems
- numbness or weakness in your hand(s) or foot(s)
- urinating less often than normal
- abnormal heartbeats that can cause death

Your chance of having fluid loss and changes in body salts (electrolytes) in your blood:

- abnormal heartbeats that can cause death
- stomach (abdominal) cramps
- diarrhea
- more than 4 bowel movements

Tell your healthcare provider if you have any of these side effects that bother you or that do not go away.

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

What are the possible side effects of NuLYTELY?

- nausea
- mouth sores or ulcers
- diarrhea
- more than 4 bowel movements

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.

Medication Guide

NuLYTELY (Reo-he-l)

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

INACTIVE INGREDIENTS:

- polyethylene glycol 3350, sodium bicarbonate, sodium chloride, potassium chloride.

Active ingredients:

- polyethylene glycol 3350 420 g, sodium bicarbonate 5.72 g, sodium chloride 53 mmol/L, potassium chloride 17 mmol/L.

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

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

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

- NuLYTELY with Flavor Packs:

- 16 HOW SUPPLIED/STORAGE AND HANDLING

Storage:

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

- When reconstituted, keep solution refrigerated. Use within 48 hours. Discard unused portion.

- Keep out of reach of children.

NuLYTELY with Flavor Packs NDC 52268-000-901
- NuLYTELY with Flavor Packs NDC 52268-900-01

17 PATIENT COUNSELING INFORMATION

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For the complete Patient Medication Guide, see http://www.nulyte.com

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