

NULYTELY - peg-3350, sodium chloride, sodium bicarbonate and potassium chloride powder, for solution

Physicians Total Care, Inc.

NuLYTELY® with Flavor Packs

PEG-3350, Sodium Chloride, Sodium Bicarbonate and Potassium Chloride for Oral Solution

Rx only

DESCRIPTION:

A white powder for reconstitution containing 420 g polyethylene glycol 3350, 5.72 g sodium bicarbonate, 11.2 g sodium chloride, 1.48 g potassium chloride and one 2.0 g flavor pack (optional). When dissolved in water to a volume of 4 liters, NuLYTELY (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution) is an isosmotic solution having a pleasant mineral water taste. NuLYTELY is administered orally or via nasogastric tube as a gastrointestinal lavage. NuLYTELY Flavor Packs are available in Cherry, Lemon -Lime, Orange and Pineapple. This preparation can be used without the addition of a NuLYTELY Flavor Pack.

CLINICAL PHARMACOLOGY:

NuLYTELY 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:

NuLYTELY is indicated for bowel cleansing prior to colonoscopy.

CONTRAINDICATIONS:

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

WARNINGS:

NuLYTELY Flavor Packs are for use only in combination with the contents of the accompanying 4 liter container. No additional ingredients, e.g. flavorings, should be added to the solution. NuLYTELY should be used with caution in patients with severe ulcerative colitis. Use of NuLYTELY in children younger than 2 years of age should be carefully monitored for occurrence of possible hypoglycemia, as this solution has no caloric substrate. Dehydration has been reported in 1 child and hypokalemia has been reported in 3 children.

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 NuLYTELY, 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 NuLYTELY.

Information for patients: NuLYTELY 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 NuLYTELY.

Adults drink 240 mL (8 oz.) every 10 minutes. Continue drinking until the watery stool is clear and free of solid matter. This usually requires at least 3 liters. Any unused portion should be discarded. Pediatric patients (aged 6 months or greater) drink 25 mL/kg/hour. Continue drinking until the watery stool is clear and free of solid matter. Any unused portion should be discarded. 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 NuLYTELY 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.

Use of NuLYTELY in children younger than 2 years of age should be carefully monitored for occurrence of possible hypoglycemia, as this solution has no caloric substrate. Dehydration has been reported in 1 child and hypokalemia has been reported in 3 children.

Drug Interactions: Oral medication administered within one hour of the start of administration of NuLYTELY 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 NuLYTELY. It is also not known whether NuLYTELY can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. NuLYTELY should be given to a pregnant woman only if clearly needed.

Pediatric Use: Safety and effectiveness of NuLYTELY in pediatric patients aged 6 months and older is supported by evidence from adequate and well-controlled clinical trials of NuLYTELY in adults with additional safety and efficacy data from published studies of similar formulations.

ADVERSE REACTIONS:

Nausea, abdominal fullness and bloating are the most common adverse reactions (occurring in up to 50% of patients) to administration of NuLYTELY. 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 reaction 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:

NuLYTELY is usually administered orally, but may be given via nasogastric tube to patients who are unwilling or unable to drink the solution. Ideally, the patient should fast for approximately three or four hours prior to NuLYTELY administration, but in no case should solid food be given for at least two hours before the solution is given.

Oral administration: Adults: At a rate of 240 mL(8 oz.) every 10 minutes, until the rectal effluent is clear or 4 liters are consumed. **Pediatric Patients (aged 6 months or greater):** At a rate of 25 mL/kg/hour, until the rectal effluent is clear. Rapid drinking of each portion is preferred to drinking

small amounts continuously. **Nasogastric tube administration: Adults:** At a rate of 20-30 mL per minute (1.2-1.8 liters per hour). **Pediatric Patients (aged 6 months or greater):** At a rate of 25 mL/kg/hour, until the rectal effluent is clear.

The first bowel movement should occur approximately one hour after the start of NuLYTELY administration. Ingestion of 4 liters of NuLYTELY solution prior to gastrointestinal examination produces satisfactory preparation in over 95% of patients.

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 NuLYTELY on the evening before the examination.

Preparation of the solution: NuLYTELY 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. However, chilled solution is not recommended for infants. The reconstituted solution should be refrigerated and used within 48 hours. Discard any unused portion.

HOW SUPPLIED:

NuLYTELY, Cherry Flavor NuLYTELY, Lemon-Lime Flavor NuLYTELY, Orange Flavor NuLYTELY are available in a disposable jug, in powdered form, for oral administration as a solution following reconstitution.

4 liter Plastic Bottle NDC 54868-4233-0

NuLYTELY with Flavor Packs is supplied in a disposable jug, in powdered form, for oral administration as a solution following reconstitution. Each jug has an attached package containing 4 flavor packs; 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.

Each jug contains:

NuLYTELY: polyethylene glycol 3350 420 g, sodium bicarbonate 5.72 g, sodium chloride 11.2 g, potassium chloride 1.48 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.

Cherry 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.

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.

Orange 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.

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.

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.

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

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Relabeling of "Additional" label by:

Physicians Total Care, Inc.

Tulsa, OK 74146

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL

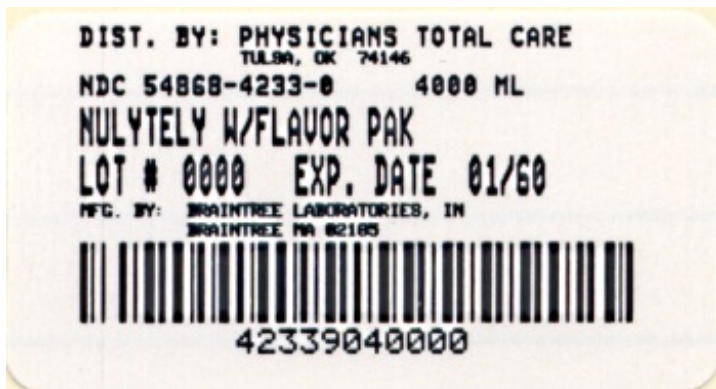
NDC 54868-4233-0

NuLYTELY®

(PEG-3350, Sodium Chloride, Sodium Bicarbonate and Potassium Chloride for Oral Solution)

With Flavor Packs

Rx Only



NULYTELY

peg-3350, sodium chloride, sodium bicarbonate and potassium chloride powder, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:54868-4233(NDC:52268-400)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL 3350 - UNII:G2M7P15E5P)	POLYETHYLENE GLYCOL 3350	210 g in 2 L
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM BICARBONATE	2.86 g in 2 L
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	5.6 g in 2 L

POTASSIUM CHLORIDE (UNII: 660YQ98110) (POTASSIUM CATION - UNII:295O53K152)

POTASSIUM CHLORIDE

0.74 g
in 2 L

Inactive Ingredients

Ingredient Name	Strength
CHERRY (UNII: BUC5I9595W)	
ORANGE (UNII: 5EVU04N5QU)	
PINEAPPLE (UNII: 2A88ZO081O)	
LEMON (UNII: 24RS0A988O)	
LIME (UNII: C7X2M0VVNH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-4233-0	4 L in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019797	07/19/2001	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

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

Revised: 10/2009

Physicians Total Care, Inc.