PEG-3350 AND ELECTROLYTES- polyethylene glycol 3350, sodium chloride, potassium chloride, sodium bicarbonate, and sodium sulfate powder, for solution
Lannett Company, Inc.

PEG-3350 & ELECTROLYTES FOR ORAL SOLUTION
Rx Only

DESCRIPTION:

PEG-3350 & ELECTROLYTES is a colon lavage preparation provided as water-soluble components for solution. In solution each PEG-3350 & ELECTROLYTES preparation delivers the following, in grams per liter.

Polyethylene glycol 3350	60.00
Sodium chloride	1.46
Potassium chloride	0.745
Sodium bicarbonate	1.68
Sodium sulfate	5.68

When dissolved in sufficient water to make 4 liters, the final solution contains 125 mEq/L sodium, 10 mEq/L potassium, 20 mEq/L bicarbonate, 80 mEq/L sulfate, 35 mEq/L chloride and 18 mEq/L polyethylene glycol 3350. The reconstituted solution is isosmotic and has a mildly salty taste. PEG-3350 & ELECTROLYTES is administered orally or via nasogastric tube.

CLINICAL PHARMACOLOGY:

PEG-3350 & ELECTROLYTES cleanses the bowel by induction of diarrhea. The osmotic activity of polyethylene glycol 3350, in combination with the electrolyte concentration, results in virtually no net absorption or excretion of ions or water. Accordingly, large volumes may be administered without significant changes in fluid and electrolyte balance.

INDICATIONS AND USAGE:

PEG-3350 & ELECTROLYTES is indicated for bowel cleansing prior to colonoscopy or barium enema X-ray examination.

CONTRAINDICATIONS:

PEG-3350 & ELECTROLYTES is contraindicated in patients known to be hypersensitive to any of the components. PEG-3350 & ELECTROLYTES is contraindicated in patients with ileus, gastrointestinal obstruction, gastric retention, bowel perforation, toxic colitis or toxic megacolon.

WARNINGS:

No additional ingredients (e.g., flavorings) should be added to the solution. PEG-3350 & ELECTROLYTES 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 PEG-3350 & ELECTROLYTES, especially if it is administered via nasogastric tube.

If gastrointestinal obstruction or perforation is suspected appropriate studies should be performed to rule out these conditions before administration of PEG-3350 & ELECTROLYTES.

INFORMATION FOR PATIENTS:

PEG-3350 & ELECTROLYTES produces a watery stool which cleanses the bowel prior to examination.

For best results, no solid food should be ingested during the 3 – 4 hour period prior to the initiation of PEG-3350 & ELECTROLYTES administration. In no case should solid foods be eaten within 2 hours of drinking PEG-3350 & ELECTROLYTES.

The rate of administration is 240 mL (8 fl. oz.) every 10 minutes. Rapid drinking of each portion is preferred rather than drinking small amounts continuously.

The first bowel movement should occur approximately one hour after the start of PEG-3350 & ELECTROLYTES administration.

Administration of PEG-3350 & ELECTROLYTES should be continued until the watery stool is clear and free of solid matter. This normally requires the consumption of approximately 3–4 liters (3–4 quarts), although more or less may be required in some patients. The unused portion should be discarded.

DRUG INTERACTIONS:

Oral medication administered within one hour of the start of administration of PEG-3350 & ELECTROLYTES may be flushed from the gastrointestinal tract and not absorbed.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY:

Studies to evaluate carcinogenic or mutagenic potential or potential to adversely affect male or female fertility have not been performed.

PREGNANCY:

Category C

Animal reproduction studies have not been conducted with PEG-3350 & ELECTROLYTES, and it is not known whether PEG-3350 & ELECTROLYTES can affect reproductive capacity or harm the fetus when administered to a pregnant patient. PEG-3350 & ELECTROLYTES should be given to a pregnant patient only if clearly needed.

PEDIATRIC USE:

Safety and effectiveness in pediatric patients have not been established.

GERIATRIC USE:

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.

ADVERSE REACTIONS:

Nausea, abdominal fullness and bloating are the most frequent adverse reactions, occurring in up to 50% of patients. Abdominal cramps, vomiting and anal irritation occur less frequently. These adverse reactions are transient. Isolated cases of urticaria, rhinorrhea, dermatitis, and rarely anaphylaxis, angioedema, tongue edema, and face edema have been reported which may represent allergic reactions.

DOSAGE AND ADMINISTRATION:

PEG-3350 & ELECTROLYTES can be administered orally or by nasogastric tube. Patients should fast at least 3 hours prior to administration. A one hour waiting period after the appearance of clear liquid stool should be allowed prior to examination to complete bowel evacuation. No foods except clear liquids should be permitted prior to examination after PEG-3350 & ELECTROLYTES administration.

ORAL:

The recommended adult oral dose is 240 mL (8 fl. oz.) every 10 minutes (see INFORMATION FOR PATIENTS). Lavage is complete when fecal discharge is clear. Lavage is usually complete after the ingestion of 3–4 liters.

NASOGASTRIC TUBE:

PEG-3350 & ELECTROLYTES is administered at a rate of

20-30 mL per minute (1.2-1.8 L/hour).

PREPARATION OF PEG-3350 & ELECTROLYTES SOLUTION:

4 Liter: Add tap water to FILL line. Replace cap tightly and mix or shake well until all ingredients have dissolved. (No additional ingredients, e.g. flavorings, should be added to the solution.)

HOW SUPPLIED:

PEG-3350 & ELECTROLYTES is supplied in 4 liter bottles. Each 4 liter bottle contains polyethylene glycol 3350 240 g, sodium chloride 5.84 g, potassium chloride
2.98 g, sodium bicarbonate 6.72 g, sodium sulfate (anhydrous) 22.72 g. The preparation is supplied in powdered form for oral administration as a solution.

PEG-3350 & ELECTROLYTES 4 liter NDC 62175-446-01

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F).

KEEP RECONSTITUTED SOLUTION REFRIGERATED. USE WITHIN 48 HOURS. DISCARD UNUSED PORTION.

Distributed by:

Kremers Urban Pharmaceuticals Inc.

Princeton, NJ 08540, USA

L2152J Rev. 3E 01/2011

INSTRUCTIONS

1.To make PEG-3350 & ELECTROLYTES solution, add tap water to the top of the FILL line marked 4 liters. Replace cap tightly and mix or shake well until ingredients have dissolved. (No additional ingredients should be added to the solution.)

2.Refrigerate the solution until ready to drink. Chilling improves the taste. Store no longer than 48 hours.

3.For best results, solid food should not be eaten during the 3 – 4 hour period before you start drinking

the solution. Never eat solid food within 2 hours of drinking the solution.

4.Drink a large glassful (8 fl. oz.) of PEG-3350 & ELECTROLYTES every 10 minutes. It is best to drink the PEG-3350 & ELECTROLYTES rapidly, rather than sipping slowly. Continue drinking a glassful every 10 minutes until your watery stool is clear and free of solid matter. This normally requires drinking approximately 3 – 4 liters (3 – 4 quarts). Using the bottle marks as a guide this means either the entire bottle should be empty (4 liters consumed), or the solution should be at or below the 1 liter mark (at least 3 liters consumed).

KEEP RECONSTITUTED SOLUTION REFRIGERATED.

USE WITHIN 48 HOURS. DISCARD UNUSED PORTION.

DATE RECONSTITUTED: _____TIME RECONSTITUTED: _____

PRINCIPAL DISPLAY PANEL - 4 Liter Bottle Label

PEEL HERE

NDC 62175-446-01

Note to pharmacist: See base label for mixing information. Package insert enclosed. Remove before dispensing.

PEG-3350 & ELECTROLYTES
for Oral Solution

Rx Only

L2152J Rev. 3E 01/2011

4 Liters

This bottle contains the following ingredients:

Polyethylene glycol 3350	240.00 grams
Sodium Chloride	5.84 grams
Potassium Chloride	2.98 grams
Sodium bicarbonate	6.72 grams
Sodium sulfate (anhydrous)	22.72 grams

When dissolved in sufficient water to make 4 liters, the final solution contains 125 mEq/L sodium, 10 mEq/L potassium, 20 mEq/L bicarbonate, 80 mEq/L sulfate, 35 mEq/L chloride and 18 mEq/L polyethylene glycol 3350.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F)

KEEP RECONSTITUTED SOLUTION REFRIGERATED.
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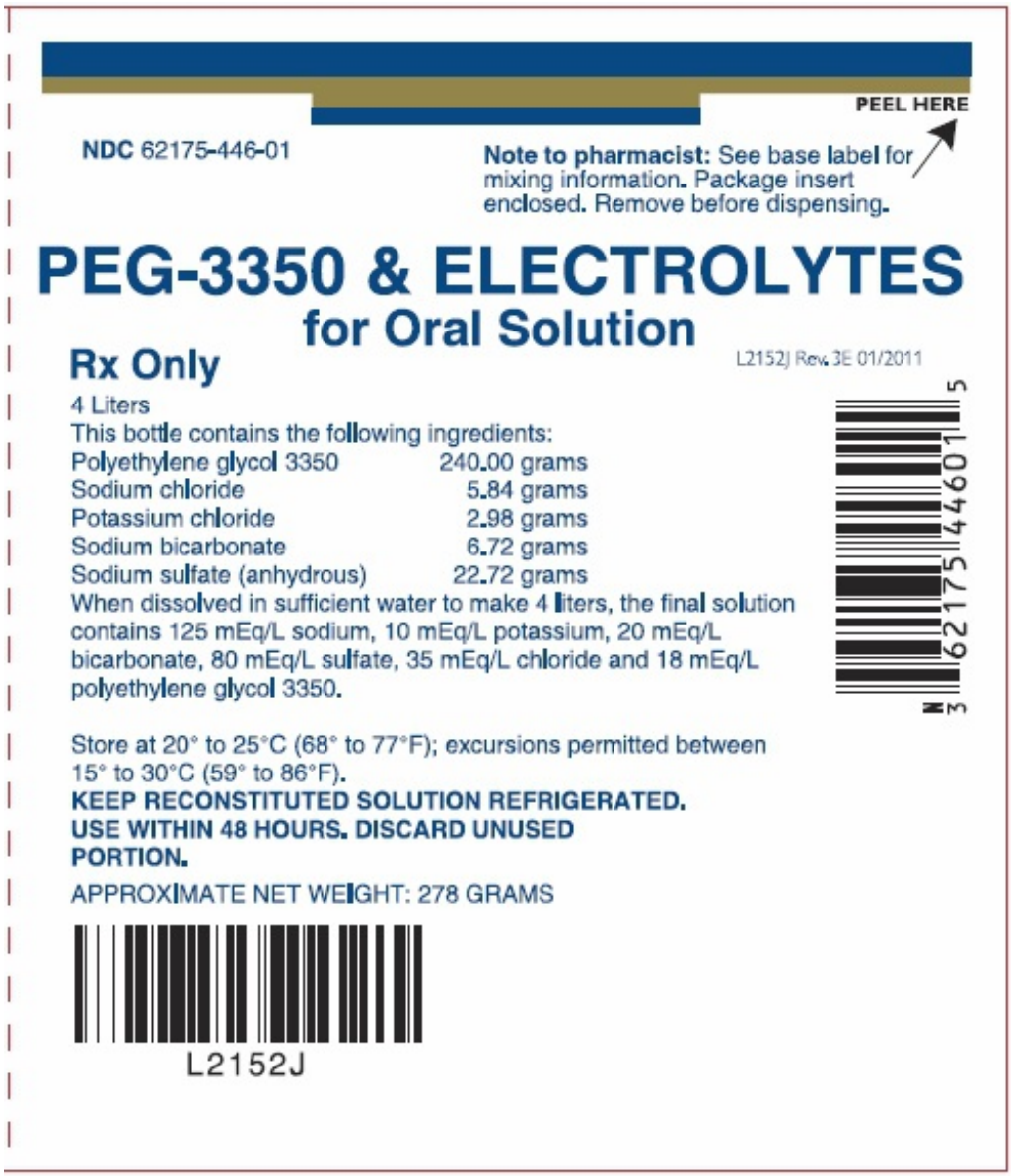
APPROXIMATE NET WEIGHT: 278 GRAMS

L2152J



PEG-3350 AND ELECTROLYTES

polyethylene glycol 3350, sodium chloride, potassium chloride, sodium bicarbonate, and sodium sulfate powder, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62175-446
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	240 g in 4 L
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	5.84 g in 4 L
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	2.98 g in 4 L

SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM BICARBONATE	6.72 g in 4 L
SODIUM SULFATE (UNII: 0YPR65R21J) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM SULFATE	22.72 g in 4 L

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62175-446-01	4 L in 1 BOTTLE; Type 0: Not a Combination Product	10/26/1984	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA AUTHORIZED GENERIC	NDA018983	10/26/1984	

Labeler - Lannett Company, Inc. (006422406)

Revised: 1/2011 Lannett Company, Inc.