POLYETHYLENE GLYCOL-3350 AND ELECTROLYTES WITH FLAVOR PACK - polyethylene glycol-3350 and electrolytes with flavor pack powder, for solution Novel Laboratories, Inc.

PEG-3350 (240 g) and Electrolytes for Oral Solution, USP with flavor pack

Rx Only

4 Liters

For Gastrointestinal Lavage

DESCRIPTION

PEG-3350 (240 g) and Electrolytes for Oral Solution, USP with flavor pack is a white, colon lavage preparation provided as water-soluble components for solution. In solution this preparation with lemon flavor pack added 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

Flavor ingredients 0.500

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 an isosmotic solution, for oral administration, having mild salty taste. This preparation can be used without the lemon flavor pack and is administered orally or via nasogastric tube.

Each lemon flavor pack (2 g) contains natural lemon flavor powder, saccharin sodium, maltodextrin.

CLINICAL PHARMACOLOGY

PEG-3350 (240 g) and electrolytes for oral solution with flavor pack 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 (240 g) and Electrolytes for Oral Solution, USP with flavor pack is indicated for bowel cleansing prior to colonoscopy or barium enema X-ray examination.

CONTRAINDICATIONS

PEG-3350 (240 g) and electrolytes for oral solution with flavor pack is contraindicated in patients known to be hypersensitive to any of the components. PEG-3350 (240 g) and electrolytes for oral solution with flavor pack is contraindicated in patients with ileus, gastrointestinal obstruction, gastric retention, bowel perforation, toxic colitis or toxic megacolon.

WARNINGS

Flavor pack is for use only in combination with the contents of the accompanying 4 liter container. No other additional ingredients (e.g., flavorings) should be added to the solution. PEG-3350 (240 g) and electrolytes for oral solution with flavor pack 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 (240 g) and electrolytes for oral solution with flavor pack, 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 (240 g) and electrolytes for oral solution with flavor pack.

Information for Patients

PEG-3350 (240 g) and electrolytes for oral solution with flavor pack produces a watery stool which cleanses the bowel prior to examination.

For best results, no solid food should be ingested during the 3 to 4 hour period prior to the initiation of PEG-3350 (240 g) and electrolytes for oral solution with flavor pack administration. In no case should solid foods be eaten within 2 hours of drinking PEG-3350 (240 g) and electrolytes for oral solution with flavor pack.

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 (240 g) and electrolytes for oral solution with flavor pack administration.

Administration of PEG-3350 (240 g) and electrolytes for oral solution with flavor pack should be continued until the watery stool is clear and free of solid matter. This normally requires the consumption of approximately 3 to 4 liters (3 to 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 (240 g) and electrolytes for oral solution with flavor pack 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 (240 g) and electrolytes for oral solution with flavor pack, and it is not known whether PEG-3350 (240 g) and electrolytes for oral solution with flavor pack can affect reproductive capacity or harm the fetus when administered to a pregnant patient. PEG-3350 (240 g) and electrolytes for oral solution with flavor pack 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 (240 g) and electrolytes for oral solution with flavor pack 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 (240 g) and electrolytes for oral solution with flavor pack 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 to 4 liters.

NASOGASTRIC TUBE:

PEG-3350 (240 g) and electrolytes for oral solution with flavor pack is administered at a rate of 20 to 30 mL per minute (1.2 to 1.8 L/hour).

PREPARATION OF PEG-3350 (240 g)and Electrolytes for Oral Solution, USP with flavor pack SOLUTION:

This preparation can be used with or without the lemon flavor pack.

- 1. To add flavor, tear open lemon flavor pack at the indicated marking and pour contents into the bottle BEFORE reconstitution.
- 2. SHAKE WELL to incorporate flavoring into the powder.
- 3. Add tap water to FILL line. Replace cap tightly and mix or shake well until all ingredients have dissolved. (No other additional ingredients, e.g. flavorings, should be added to the solution.)

Note: If not using flavor pack, omit steps one and two, above.

HOW SUPPLIED

PEG-3350 (240 g) and Electrolytes for Oral Solution, USP with flavor pack is supplied in 4 liter bottles with an attached lemon flavor pack. 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. This preparation is supplied in powdered form, for oral administration as a solution.

PEG-3350 (240 g)and Electrolytes for Oral Solution, USP with flavor pack 4liter:

NDC 40032-060-19

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.

Manufactured by:

Novel Laboratories, Inc.

400 Campus Drive

Somerset, NJ 08873, USA

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 40032-060-19

PEG-3350 (240 g) and Electrolytes for Oral Solution, USP with flavor pack

Rx Only

Instructions to the pharmacist:

Dispense bottle and attached flavor pack to the patient.

Instructions for the patient:

- PEG-3350 (240 g) and Electrolytes for Oral Solution, USP with flavor pack can be used with or without the addition of lemon flavor pack.
 - a. If you prefer an unflavored solution, discard the flavor pack and proceed to step 5.
 - b. If you prefer the flavored solution proceed to step 2.
- Tear open lemon flavor pack at the indicated marking and pour the contents into the bottle BEFORE adding any water.
- 3. SHAKE WELL to incorporate flavoring into the powder.
- 4. Add tap water to the top of the FILL line marked 4 liters. Recap tightly and mix or shake well until the powder has completely dissolved. No additional ingredients should be added to the solution.
- 5. Refrigerate the solution until ready to drink. Chilling improves taste. Store no longer than 48 hours.
- For best results, solid food should not be eaten during the 3 to 4 hour period before you start drinking the solution. Never eat solid food within 2 hours of drinking the solution.
- 7. Drink a glassful (8 oz.) of solution every 10 minutes. It is best to drink the solution rapidly, rather than sipping slowly. Continue drinking glassful every 10 minutes until your watery stool is clear and free of solid matter. This normally requires drinking 3 to 4 liters (3 to 4 quarts). The bottle should be empty (4liters consumed) or the remaining solution should be at or below the 1 liter mark (at least 3 liters consumed).

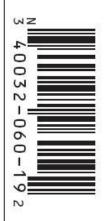
KEEP RECONSTITUTED SOLUTION REFRIGERATED.
USE WITHIN 48 HOURS. DISCARD UNUSED PORTION.



Novel Laboratories, Inc., 400 Campus Drive Somerset, NJ 08873

4 liters





NDC 40032-060-19 Note to Pharmacial: Dispense boths and attached lencon theory pack to the patients. Package insert

PEG-3350 (240 g) and Electrolytes for Oral Solution, USP with Flavor Pack

Rx Only

This bottle contains the following ingredients:
Polyethylane Glycol 3550 280,00 grams
Sodium Chloride 5,84 grams
Potassium Chloride 2,88 grams
Sodium Silarbonate 2,72 grams
Sodium Silarbonate 7,72 grams
Sodium Silarbonate 2,72 grams
127 graps 1,72 grams
128 mGgL, sodium, 10 mGgL, potassium, 20 mGgL, bicarbonate, 80 mGgL, sustins, 55 mGgL, choired and 18 mGgL, polyethylane glycol 3550.
Store at 201* to 25°C (88° to 77°F); excursions permitted between 15° to 30°C (86° to 86°F). en 15° to 30°C

SORDE IS ON THE SECONDARY OF THE RECONSTITUTED SOLUTION REFRIGERATED, USE WITHIN 48 HOURS, DISCARD UNUSED PORTION, APPROXIMATE NET WEIGHT IS 278 GRAMS





frequent adverse reactions, occurring in up to 50% of patients. Abdominat drant, vorniting and and inflation occurring in up to 50% of patients. Abdominat drant, vorniting and and inflation occurries frequently. These adverse reactions are iteratives: Lodded cases of utilizaria, ritinomhea, demaitis, and readwinant-management in the patient. 'butterfly-like' infiltrate on chest x-ray after vomiting ADVERSE REACTIONS: Nausea, abdomina fulln se for Oral Solution with flavor pack rater-soluble components for vor pack added delivers the

PEG-3350 (240 g) and Electrolytes for Oral Solution, USP with flavor pack

For Gastrointestinal Langa DESCRIPTON: PECS 3500 (540 g) and Bedrotyles bro is a while, coon inage pregration provided as water-soal and and and an analysis of the cool of th

solution with flavor pack can be administered orally or by nasoguatine tube. Paten should use at all east 3 hours prior to administration. Anne hour wating period after appearance of dear figuid stood be allowed prior to examination to compete appearance or dear figuid school should be generalled prior to bowe executation. No forode except dear fluruls should be generalled prior to examinaton after PEG-3350 (240 g) and electrolytes for or all solution with favor p epresent allergic reactions. DOSAGE AND ADMINISTRATION: PEG-3350 (240 g) and electrolytes for o

Software in surrorem water to make 4 liters, the final solution contains 125 fpt, softium, 10 mEQL, pobassium, 20 mEQL, bicanchorad, 80 mEQL, sulfabil, 35 spt, chloride and 18 mEQL, poyethylene gived 3390. The reconstituted solution is becamble solution, for oral administration, having mild safety used. The propragnon is be used without the flavor pack and is administrated orally or via masogustic buto, at learn flavor pack (2.9) contains natural lemon flavor powder, asochamic sodium.

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CLINICAL PHARRACOLOGY: PEG-3350 (240,g) and electrolytes for oral soution
with fanor pack cleanses the bowel by induction of diarrhea. The centrolic activity of
polythyties or poor oral pack of the electrolic concentration, results in
virtual y no not absorption or exception of one or water. Accordingly, large volumes
may be administered without eight fand changes in fluid and electroly the busy virtual may be administered without eight fand changes in fluid and electroly to busy virtual and the performance of the performan

administration (ORAL: The seconmended shall orist dose is 240 mt (8 ft. oz.) every 10 minuse (e) RPG-RMATION FOR PATTENTS). Lavage is compliate when focal discharge is consistent MASOAS TRUCH UBER: PEGG-380 ft. (Pagg-19 and ed-20 by files for call solution with MASOAS TRUCH UBER: PEGG-380 ft. (Pagg-19 and ed-20 by files for call solution with filescope axis a saminished set a state of 20 to 30 mt, per minute (1.2 to 1.8 Lhouz). PEREPARATION OF EG-330 (24 g) and Electrolytes for Oral Solution, USP with filavor peak SOLUTION.

This progradion can be used with or without the lemon flavor pack.

1. To add share, role are the wind relay pack at the indicated marking at contents in the boths BEFORE reconstitution.

2. SHAKE WELL to incorporate flavoring into the powder.

3. Add by waiter bit PLIL lies. Reques cap lightly and mix or thale well ingradients have dissolved. (No ther additional ingradients, as addition to the solution.)

Nohs: If not using flavor pack, omit steps one and two, above.

HOW SUPPLIED: PEG-3330 (240 g) and Electrolytes for Oral Solution, USP with flavor pack is supplied in 4 lifer bottles with an attached lemon favor pack. Each 4 preparation is supplied in powdered brm. (or oral administration as a solution PEG-3350 (240 g) and Electrolytes for Oral Solution, USP with flavor pack 4liter: NDC 40032-060-19 RECONSTITUTED SOLUTION REFRIGERATED. USE WITHIN 48 HOURS

MARNINGS. Flavor pack is bruse only in combination with the contents of the accompanying if the container. No other and found inpredients (e.g., flavorings) hould be added to the soution. PEG-350 (24.0g) and electrolytes brused soution this flavor pack should be used with seation in patients with severe ubsersalite collisis PRECAUTIONS: General: Patients with impaired gag refex, unconspicus or enema A: reg semination.

CONTRANDICATIONS: PEG-3359 (240 g) and elect object for oral solution with form pack is contraindised in patients known to be intropersentative to any of the components. PEG-350 (240 g) and electrolytes for oral solution with flavor pack is contraindicated in patients with leaus, pasterioriestinal dost ordinoring spatric referation, lower pedication, two collisies or took meganotion. ointestinal obstruction or perforation is suspected appropriate studies should need to rule out these conditions before administration of PEG-3350 (240 g) a rived during the administration of PEG-3350 (240 g) and electrolytes for oral ion with flavor pack, especially if it is administered via nasogastric tube. scious patients and patients prone to regur

tolytes for oral solution with flavor pack.

RMATION FOR PATIENTS: PEG-3350 (240 g) and electrolytes for oral solution

best results, no solid food should be ingested during the 3 to 4 hour period prior initiation of PEG-3390 (240 g) and electrolytes for oral solution with flavor pack inistration. In no case should solid foods be eaten within 2 hours of drinking

r be flushed from the gastrointestinal tract and not absorbed. RCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Studies JRUG INTERACTIONS: Oral medication.

POLYETHYLENE GLYCOL-3350 AND ELECTROLYTES WITH FLAVOR PACK

polyethylene glycol-3350 and electrolytes with flavor pack powder, for solution

Product Information NDC:40032-060 Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) ORAL Route of Administration

Active Ingredient/Active Moiety Basis of Strength Ingredient Name Strength POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL POLYETHYLENE GLYCOL 240 g in 278.26 g 3350 - UNII:G2M7P15E5P) 3350 5.84 g SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698) SODIUM CHLORIDE in 278.26 g SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION -6.72 g SODIUM BICARBONATE UNII:LYR4M0NH37) in 278.26 g POTASSIUM CHLORIDE (UNII: 660 YQ98 I10) (POTASSIUM CATION -2.98 g POTASSIUM CHLORIDE in 278.26 g UNII:295O53K152) SODIUM SULFATE ANHYDROUS (UNII: 36KCS0R750) (SULFATE ION -SODIUM SULFATE 22.72 g ANHYDROUS in 278.26 g UNII:7IS9N8KPMG)

Inactive Ingredients Ingredient Name Strength ACACIA (UNII: 5C5403N26O)

SACCHARIN SODIUM (UNII: SB8ZUX40TY)

MALTODEXTRIN (UNII: 7CVR7L4A2D)

ALPHA-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	LEMON	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:40032-060-19	278.26 g in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA090186	06/01/2009		

Labeler - Novel Laboratories, Inc. (793518643)

Registrant - Novel Laboratories, Inc. (793518643)

Establishment					
Name	Address	ID/FEI	Business Operations		
Novel Laboratories, Inc.		793518643	MANUFACTURE, REPACK		

Establishment			
Name	Address	ID/FEI	Business Operations
Dow Chemical Company		801038019	API MANUFACTURE

Establishment			
Name	Address	ID/FEI	Business Operations
Mallinckrodt Baker Inc.		0 0 12 13 48 1	API MANUFACTURE

Establishment			
Name	Address	ID/FEI	Business Operations
Church and Dwight Co, Inc.		001211952	API MANUFACTURE

Revised: 6/2009 Novel Laboratories, Inc.