



MYLAN
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Products



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MYLAN

POLYETHYLENE GLYCOL 3350 AND ELECTROLYTES FOR
ORAL SOLUTION, USP

New Product Announcement
Mylan Pharmaceuticals Introduces
POLYETHYLENE GLYCOL 3350 AND ELECTROLYTES
FOR ORAL SOLUTION, USP†

Compare To: GoLyteLy®
Therapeutic Rating: AA
Expiration Dating: 24 months
ANDA Number: 090928
Product Category: Laxatives

† Please See Attached Full Prescribing Information

Strength:	Polyethylene Glycol 3350 (236 g), Sodium Sulfate Anhydrous (22.74 g), Sodium Bicarbonate (6.74 g), Sodium Chloride (5.86 g) & Potassium Chloride (2.97 g)
Form:	Oral Solution (upon Reconstitution)
Description:	A white powder in a disposable jug.
Package Size:	4 Liter Jug
NDC #: (0378-)	6669-40
AWP‡:	\$18.94
Case Pack:	4
Inner Pack:	1 x 4
Length:	15 1/2
Width:	10 3/4
Height:	10 1/4
Cube:	0.96
Weight:	2.75 lbs.

‡AWP for a Mylan product is reported by Mylan with reference to AWP for a brand company's therapeutically-equivalent product, as reported by American Druggist, First Data Bank or another nationally recognized publication. AWP reported by Mylan, however, is not necessarily the same as the AWP that might be independently established and reported by the publisher. AWP does not take into account any discounts, chargebacks, rebates, or other reductions in price that may be provided. AWP should not be relied upon as the actual cost to the pharmacy or to the customer or consumer. AWP is subject to change at any time.

POLYETHYLENE GLYCOL 3350 AND ELECTROLYTES FOR ORAL SOLUTION, USP

R only

DESCRIPTION: Polyethylene glycol 3350 and electrolytes for oral solution is a white powder in a 4 liter jug for reconstitution, containing 236 g polyethylene glycol 3350, 22.74 g sodium sulfate (anhydrous), 6.74 g sodium bicarbonate, 5.86 g sodium chloride and 2.97 g potassium chloride. When dissolved in water to a volume of 4 liters, polyethylene glycol 3350 and electrolytes for oral solution is an isotonic solution having a mildly salty taste. Polyethylene glycol 3350 and electrolytes for oral solution is administered orally or via nasogastric tube as a gastrointestinal lavage.

CLINICAL PHARMACOLOGY: Polyethylene glycol 3350 and electrolytes for oral solution induces a diarrhea which rapidly cleanses the bowel, usually within 4 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: Polyethylene glycol 3350 and

electrolytes for oral solution is indicated for bowel cleansing prior to colonoscopy and barium enema X-ray examination.

CONTRAINDICATIONS: Polyethylene glycol 3350 and electrolytes for oral solution is contraindicated in patients known to be hypersensitive to any of the components. Polyethylene glycol 3350 and electrolytes for oral solution is contraindicated in patients with gastrointestinal obstruction, gastric retention, bowel perforation, toxic colitis, toxic megacolon or ileus.

WARNINGS: No additional ingredients, e.g. flavorings, should be added to the solution. Polyethylene glycol 3350 and electrolytes for oral solution 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 polyethylene glycol 3350 and electrolytes for oral solution 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 polyethylene glycol 3350 and electrolytes for oral solution.

Information for Patients: Polyethylene glycol 3350 and electrolytes for oral solution 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 polyethylene glycol 3350 and electrolytes for oral solution.

Drink 240 mL (8 oz.) every 10 minutes. 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 polyethylene glycol 3350 and electrolytes for oral solution 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. Continue drinking until the watery stool is clear and free of solid matter. This usually requires at least 3 liters and it is best to drink all of the solution. Any unused portion should be discarded.

Drug Interactions: Oral medication administered within one hour of the start of administration of polyethylene glycol 3350 and electrolytes for oral solution 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: Teratogenic Effects. Category C: Animal reproduction studies have not been conducted with polyethylene glycol 3350 and electrolytes for oral solution. It is also not known whether polyethylene glycol 3350 and electrolytes for oral solution can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Polyethylene glycol 3350 and electrolytes for oral solution should be given to a pregnant woman only if clearly needed.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Nausea, abdominal fullness and bloating are the most common adverse reactions (occurring in up to 50% of patients) to administration of polyethylene glycol 3350 and electrolytes for oral solution. 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 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.

DOSAGE AND ADMINISTRATION: The recommended dose for adults is 4 liters of polyethylene glycol 3350 and electrolytes for oral solution prior to gastrointestinal examination, as ingestion of this dose produces a satisfactory preparation in over 95% of patients. Ideally, the patient should fast for approximately 3 or 4 hours prior to polyethylene glycol 3350 and electrolytes for oral solution administration, but in no case should solid food be given for at least 2 hours before the solution is given.

Polyethylene glycol 3350 and electrolytes for oral solution is usually administered orally, but may be given via nasogastric tube to patients who are unwilling or unable to drink the solution. **Oral administration** is at a rate of 240 mL (8 oz.) every 10 minutes, until 4 liters are

consumed or the rectal effluent is clear. Rapid drinking of each portion is preferred to drinking small amounts continuously. **Nasogastric tube administration** is at a rate of 20 to 30 mL per minute (1.2 to 1.8 liters per hour). The first bowel movement should occur approximately one hour after the start of polyethylene glycol 3350 and electrolytes for oral solution administration.

Various regimens have been used. One method is to schedule patients for examination in midmorning or later, allowing the patients 3 hours for drinking and an additional one hour period for complete bowel evacuation. Another method is to administer polyethylene glycol 3350 and electrolytes for oral solution on the evening before the examination, particularly if the patient is to have a barium enema.

Preparation of the solution: Polyethylene glycol 3350 and electrolytes for oral 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. The reconstituted solution should be refrigerated and used within 48 hours. Discard any unused portion.

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

Polyethylene glycol 3350 and electrolytes for oral solution, USP is available in a disposable jug (NDC 0378-6669-40) in powdered form (white powder) containing: polyethylene glycol 3350 236 g, sodium sulfate (anhydrous) 22.74 g, sodium bicarbonate 6.74 g, sodium chloride 5.86 g, potassium chloride 2.97 g. When made up to 4 liters volume with water, the solution contains PEG-3350 17.6 mmol/L, sodium 125 mmol/L, sulfate 40 mmol/L, chloride 35 mmol/L, bicarbonate 20 mmol/L and potassium 10 mmol/L.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.] **When reconstituted, keep solution refrigerated. Use within 48 hours. Discard unused portion.**

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Morgantown, WV 26505

RM6669N
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FILL TO THE TOP OF THE LINE ON BOTTLE

TO PHARMACIST AND PATIENT: Mixing information is on base label. Package insert may be removed before dispensing.

 NDC 0378-6669-40

POLYETHYLENE GLYCOL 3350 and ELECTROLYTES FOR ORAL SOLUTION, USP

When reconstituted with water to a volume of 4 liters, this solution contains 125 mmol/L sodium, 10 mmol/L potassium, 40 mmol/L sulfate, 20 mmol/L bicarbonate, 35 mmol/L chloride and 17.6 mmol/L polyethylene glycol 3350.

Each disposable jug contains, in powdered form: polyethylene glycol 236 g, sodium sulfate (anhydrous) 22.74 g, sodium bicarbonate 6.74 g, sodium chloride 5.86 g, potassium chloride 2.97 g.

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PULL DOWN TO OPEN