



MYLAN
Quality
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Products



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MYLAN

PEG-3350, SODIUM CHLORIDE, SODIUM BICARBONATE &
POTASSIUM CHLORIDE FOR ORAL SOLUTION WITH
FLAVOR PACKS

New Product Announcement
Mylan Pharmaceuticals Introduces
PEG-3350, SODIUM CHLORIDE, SODIUM BICARBONATE &
POTASSIUM CHLORIDE FOR ORAL SOLUTION WITH FLAVOR PACKS

Compare To: NuLytely® with Flavor Packs
Therapeutic Rating: AA
Expiration Dating: 24 months
ANDA Number: 090409
Product Category: Laxatives

† Please See Attached Full Prescribing Information

| | |
|-----------------------|--|
| Strength: | Polyethylene Glycol 3350 (420 g), Sodium Chloride (11.2 g), Sodium Bicarbonate (5.72 g) and Potassium Chloride (1.48 g) |
| Form: | Oral Solution (upon reconstitution) |
| Description: | A white powder in a disposable jug. Each jug has an attached package containing four flavor packs each containing an off-white to yellow powder. |
| Package Size: | 4 Liter Jug with Four Flavor Packs (cherry, orange, lemon-lime, & pineapple) |
| NDC #: (0378-) | 6664-40 |
| AWP ‡: | \$26.41 |
| Case Pack: | 4 |
| Inner Pack: | 1 x 4 |
| Length: | 15 1/2 |
| Width: | 10 3/4 |
| Height: | 10 1/4 |
| Cube: | 0.96 |
| Weight: | 5.5 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.

PEG-3350, SODIUM CHLORIDE, SODIUM BICARBONATE AND POTASSIUM CHLORIDE FOR ORAL SOLUTION WITH FLAVOR PACKS

Rx only

DESCRIPTION: PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is 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, PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is an isosmotic solution having a pleasant mineral water taste. PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is administered orally or via nasogastric tube as a gastrointestinal lavage. PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution flavor packs are available in cherry, lemon-lime, orange and pineapple. This preparation can be used without the addition of a PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution flavor pack.

CLINICAL PHARMACOLOGY: PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride 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: PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is indicated for bowel cleansing prior to colonoscopy.

CONTRAINDICATIONS: PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is contraindicated in patients known to be hypersensitive to any of the components. PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is contraindicated in patients with ileus, gastrointestinal obstruction, gastric retention, bowel perforation, toxic colitis or toxic megacolon.

WARNINGS: PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution 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. PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution should be used with caution in patients with severe ulcerative colitis. Use of PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution 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 one child and hypokalemia has been reported in three children.

PRECAUTIONS: General: Patients with impaired gag reflex, unconscious, or semiconscious patients, and patients prone to regurgitation or aspiration should be ob-

served during the administration of PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride 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 PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution.

Information for Patients: PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride 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 PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution.

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 PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride 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.

Use of PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution 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 one child and hypokalemia has been reported in three children.

Drug Interactions: Oral medication administered within one hour of the start of administration of PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride 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 PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution. It is also not known whether PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution should be given to a pregnant woman only if clearly needed.

Pediatric Use: Safety and effectiveness of PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution in pediatric patients aged 6 months and older is supported by evidence from adequate and well

controlled clinical trials of PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution 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 PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride 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: PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride 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. Ideally, the patient should fast for approximately 3 or 4 hours prior to PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution administration, but in no case should solid food be given for at least 2 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 mL to 30 mL per minute (1.2 to 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 PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution administration. Ingestion of 4 liters of PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution prior to gastrointestinal examination, produces a 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 3 hours for drinking and an additional one hour period for complete bowel evacuation. Another method is to administer PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution on the evening before the examination.

Preparation of the solution: PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride 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. 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: PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution with flavor packs is supplied in a disposable jug, in powdered form (white powder), for oral administration as a solution following reconstitution. Each jug has an attached package containing four 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 (NDC 0378-6664-40) contains: 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.

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.

Distributed by:



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Morgantown, WV 26505

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