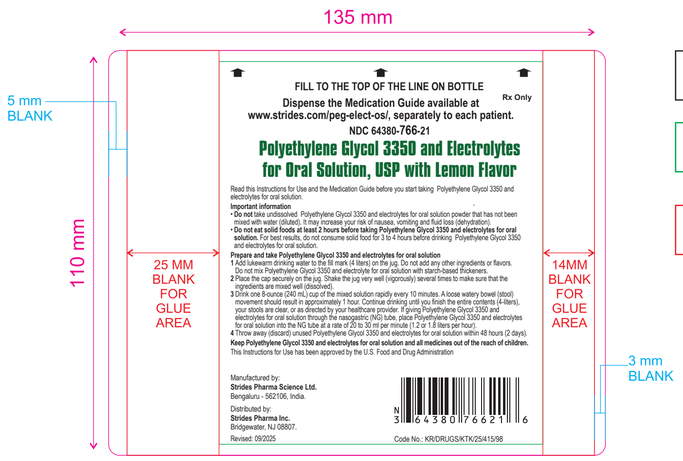

BASE LABEL

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PAPER AREA

PRINTING AREA (FILL ALL TEXT AND GRAPHIC INSIDE GREEN AREA)

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NON PRINTING COLOR

MFG. LOCATION: KRSG

ARTWORK DETAIL LABEL

Product	**PEG-3350 and Electrolyte for Oral Solution, USP with Lemon Flavor**				
Buyer/Country	STRIDES PHARMA INC - US	Component	FIX-A-FORM - LABEL		
Dimension	**135 x 110mm (open size: 574 x 110mm)**			Pack	5 LTR
New Item Code	**1052538**	Old Item Code	1050987		
Colour Shades	CMYK			No. of Colours	4

Change Control No.	PC-ODF/2025/408 - Record Number: 460262 & PC-TSG/2025/052 - Record Number: 463027	Artwork Version	9.0
Design/Style	Self adhesive labels in Roll-form with Rounded Corners		
Substrate	LABEL: 78-80 GSM Chromo Paper with 32 GSM PET (Polyster) (release liner) with Aqueous full varnish & Adhesive - 20 GSM +1 GSM Hot Melt. LEAFLET: 90 GSM Art paper with OPM (Over printing medium) Varnish		
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.		
Autocartonator Requirements	NA		

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. **DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.**

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angioedema, anaphylaxis and anaphylactic shock *(see Contraindications (4), Warnings and Precautions (5.8))*
• Gastrointestinal (GI) obstruction, bowel perforation, toxic colon, and toxic megacolon have been reported (occurred in up to 50% of patients). Other less common adverse reactions include abdominal cramps, vomiting, "butterfly-like" infiltrates on chest X-ray after vomiting and aspirating PEG, anal irritation, and urticaria. Serious events occur rarely with Mallory-Weiss tear, esophageal perforation (usually with gastroesophageal reflux disease (GERD).

7 DRUG INTERACTIONS

7.1 Drugs that May Increase Risks Due to Fluid and Electrolyte Abnormalities
Use Polyethylene Glycol 3350 and electrolytes for oral solution for patients with conditions and/or who are using medications that increase the risk for fluid and electrolyte disturbances or may increase the risk of renal impairment, seizure, arrhythmias, and prolonged QT in the setting of fluid and electrolyte abnormalities *(see Warnings and Precautions (5.1, 5.2, 5.3, 5.4, 5.5))*. Consider additional patient evaluations as appropriate.

7.2 Potential for Reduced Drug Absorption
Polyethylene Glycol 3350 and electrolytes for oral solution can reduce the absorption of other administered drugs. Administer oral medications within one hour before the start of administration of Polyethylene Glycol 3350 and electrolytes for oral solution *(see Dosage and Administration (2.1))*.

7.3 Stimulant Laxatives
Concurrent use of stimulant laxatives and Polyethylene Glycol 3350 and electrolytes for oral solution may increase the risk of mucosal ulceration or ischemic colitis. Avoid use of stimulant laxatives (e.g., bisacodyl, sodium picosulfate) while taking Polyethylene Glycol 3350 and electrolytes for oral solution *(see Warnings and Precautions (5.6))*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
Animal reproduction studies have not been conducted with Polyethylene Glycol 3350 and electrolytes for oral solution. It is unknown 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.

8.3 Nursing Mothers
It is unknown whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Polyethylene Glycol 3350 and electrolytes for oral solution is administered to a nursing woman.

8.4 Pediatric Use
Safety and effectiveness of Polyethylene Glycol 3350 and electrolytes for oral solution in pediatric patients less than 6 years of age have not been established.

8.5 Geriatric Use
Clinical studies of Polyethylene Glycol 3350 and electrolytes for oral solution did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

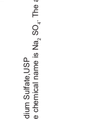
8.6 Renal Impairment
Use Polyethylene Glycol 3350 and electrolytes for oral solution with caution in patients with renal impairment or who are at risk for fluid and electrolyte disturbances *(see Warnings and Precautions (5.1))*. These patients may be at risk for renal injury. Advise these patients of the importance of adequate hydration and consider performing baseline and post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN) and consider performing baseline and post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN) in these patients *(see Warnings and Precautions (5.5))*.

11 DESCRIPTION
Polyethylene Glycol 3350 and electrolytes for oral solution is a combination of polyethylene glycol 3350, an osmotic laxative, and electrolytes (sodium sulfate, sodium chloride, sodium bicarbonate and potassium chloride) for oral solution supplied in a 5 liter disposable jug 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 as a white powder.

Polyethylene Glycol 3350 and electrolytes for oral solution is a combination of polyethylene glycol 3350, an osmotic laxative, and electrolytes (sodium sulfate, sodium chloride, sodium bicarbonate and potassium chloride) for oral solution supplied in a 5 liter disposable jug containing 236 g polyethylene glycol 3350, 22.74 g sodium sulfate (anhydrous), 6.74 g sodium bicarbonate, 5.86 g sodium chloride, 2.97 g potassium chloride, acesulfame potassium 0.2 grams and lemon flavor 0.1 gram as a white powder.

Polyethylene Glycol 3350 and electrolytes for oral solution is a combination of polyethylene glycol 3350, an osmotic laxative, and electrolytes (sodium sulfate, sodium chloride, sodium bicarbonate and potassium chloride) for oral solution supplied in a 5 liter disposable jug containing 236 g polyethylene glycol 3350, 22.74 g sodium sulfate (anhydrous), 6.74 g sodium bicarbonate, 5.86 g sodium chloride, 2.97 g potassium chloride, acesulfame potassium 0.2 grams and orange flavor 0.4 grams as a white powder.

Polyethylene Glycol 3350, NF



Sodium Sulfate,USP
The chemical name is Na_2SO_4. The average Molecular Weight is 142.04. The structural formula is:

Sodium Bicarbonate,USP
The chemical name is $NaHCO_3$. The average Molecular Weight is 84.01. The structural formula is:

Sodium Chloride,USP
The chemical name is NaCl. The average Molecular Weight: 58.44. The structural formula is:

Na+ Cl-

Potassium Chloride,USP
The chemical name is KCl. The average Molecular Weight: 74.55. The structural formula is:

K-Cl

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
The therapeutic effect of polyethylene glycol 3350 is thought to be through the osmotic effect of polyethylene glycol 3350 which causes water to be retained in the colon and produces a watery stool.

12.2 Pharmacodynamics
Polyethylene Glycol 3350 and electrolytes for oral solution induces as diarrhea which rapidly cleanses the bowel within a few hours.

12.3 Pharmacokinetics
The pharmacokinetics of PEG3350 following administration of Polyethylene Glycol 3350 and electrolytes for oral solution were not assessed. Available pharmacokinetic information for oral PEG3350 suggests that absorption is minimal.

16 HOW SUPPLIED/STORAGE AND HANDLING
Polyethylene Glycol 3350 and electrolytes for oral solution, USP is supplied in a 5-liter disposable jug containing 236 g polyethylene glycol 3350, 22.74 g sodium sulfate (anhydrous), 6.74 g sodium bicarbonate, 5.86 g sodium chloride, 2.97 g potassium chloride as a white powder. NDC 64380-765-21
Polyethylene Glycol 3350 and electrolytes for oral solution, USP with Lemon Flavor is supplied in a 5-liter disposable jug containing 236 g polyethylene glycol 3350, 22.74 g sodium sulfate (anhydrous), 6.74 g sodium bicarbonate, 5.86 g sodium chloride, 2.97 g potassium chloride, acesulfame potassium 0.2 g and lemon flavor 0.1 g as a white powder. NDC 64380-766-21
Polyethylene Glycol 3350 and electrolytes for oral solution, USP with Orange Flavor is supplied in a 5-liter disposable jug containing 236 g polyethylene glycol 3350, 22.74 g sodium sulfate (anhydrous), 6.74 g sodium bicarbonate, 5.86 g sodium chloride, 2.97 g potassium chloride, acesulfame potassium 0.2 g and orange flavor 0.4 g as a white powder. NDC 64380-767-21
• When reconstituted with water to a volume of 4 liters, the solution contains 59 g/L PEG3350, 5.69 g/L sodium sulfate, 1.69 g/L sodium bicarbonate, 1.47 g/L sodium chloride and 0.743 g/L potassium chloride.
Polyethylene Glycol 3350 and electrolytes for oral solution, USP is available in following flavors:

Drug product	NDC	Package
Polyethylene Glycol 3350 and electrolytes for oral solution, USP	64380-765-21	5 L disposable jug with a 4 L fill line
Polyethylene Glycol 3350 and electrolytes for oral solution, USP with Lemon Flavor	64380-766-21	
Polyethylene Glycol 3350 and electrolytes for oral solution, USP with Orange Flavor	64380-767-21	

Storage
Store at 25°C (77°F); excursions permitted to 15-30°C [59-86°F] [see Controlled Room Temperature].

Store reconstituted solution of Polyethylene Glycol 3350 and electrolytes for oral solution at 2° to 8°C (36° to 46°F). Do not freeze *[see Dosage and Administration (2.1)]*.

17 PATIENT COUNSELING INFORMATION
Advise the patient to read the FDA-Approved Patient Labeling (Medication Guide and Instructions for Use).

Instruct patients
• Not to take Polyethylene Glycol 3350 and electrolytes for oral solution with water prior to ingestion.
• Not to take other laxatives while they are taking Polyethylene Glycol 3350 and electrolytes for oral solution.
• Not to take oral medications within 1 hour before the start or during the administration of Polyethylene Glycol 3350 and electrolytes for oral solution.
• To consume only clear liquids until 2 hours before the time of the colonoscopy.
• To consume water or other clear liquids during the bowel preparation and after completion of the bowel preparation up until 2 hours before the time of the colonoscopy.
• If they experience severe bloating, distention or abdominal pain, to slow or temporarily discontinue the administration of Polyethylene Glycol 3350 and electrolytes for oral solution.
• To contact their healthcare provider if they develop signs and symptoms of dehydration or if they experience altered consciousness or seizures. *(see Warnings and Precautions (5.1, 5.2, 5.3, 5.4))*
• To inform their healthcare provider if they develop signs and symptoms of a hypersensitivity reaction *(see Warnings and Precautions (5.8))*.

Manufactured by:
Strides Pharma Science Ltd.
Bengaluru - 562106, India.

Distributed by:
Strides Pharma Inc.
Bridgewater, NJ 08807.

Revised: 09/2025

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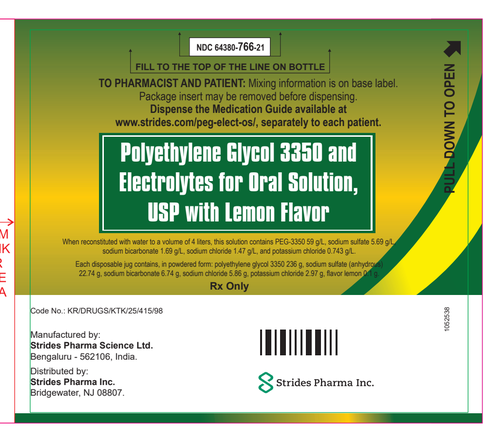

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HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use **POLYETHYLENE GLYCOL 3350 and ELECTROLYTES FOR ORAL SOLUTION, USP with LEMON FLAVOR** safely and effectively. See the full prescribing information for **POLYETHYLENE GLYCOL 3350 and ELECTROLYTES FOR ORAL SOLUTION.**
POLYETHYLENE GLYCOL 3350 and ELECTROLYTES for ORAL SOLUTION, USP with LEMON FLAVOR
Initial U.S. Approval: 1984

—INDICATIONS AND USAGE—
Polyethylene Glycol 3350 and electrolytes for oral solution is a combination of PEG 3350, an osmotic laxative, and electrolytes for oral solution indicated for use in the colon in preparation for colonoscopy and barium enema X-ray examination in adults. (1)

—DOSAGE AND ADMINISTRATION—
Preparation and Administration (2.1)
• Do not take undissolved powder before taking treatment with Polyethylene Glycol 3350 and electrolytes for oral solution.
• Do not take Polyethylene Glycol 3350 and electrolytes for oral solution with water prior to ingestion.
• Do not take other laxatives while taking Polyethylene Glycol 3350 and electrolytes for oral solution.
• Do not take oral medications within one hour before the start or during administration of Polyethylene Glycol 3350 and electrolytes for oral solution. (2.1)
• Consume only clear liquids, avoid red and purple liquids.
• Consume water or other clear liquids up until 2 hours before the time of the colonoscopy.
• Consume water or other clear liquids 2 hours before taking Polyethylene Glycol 3350 and electrolytes for oral solution.
Adult Dosage Regimen (2.2):
• On day prior to colonoscopy, instruct patients to consume only clear liquids for the entire day and 2 hours after starting Polyethylene Glycol 3350 and electrolytes for oral solution.
• Begin the recommended dosage regimen for Polyethylene Glycol 3350 and electrolytes for oral solution in the morning of the day before the colonoscopy.
• Prepare the reconstituted solution at a rate of 8 ounces every 10 minutes, until 4 liters are consumed, or as directed by your doctor.
• For complete information on dosing, preparation and administration, see the full prescribing information. (2.1, 2.2).

—DOSAGE FORMS AND STRENGTHS—
For Oral Solution: 236 g polyethylene glycol 3350, 22.74 g sodium sulfate (anhydrous) 22.74 grams, sodium bicarbonate 6.74 grams, sodium chloride 5.86 grams, potassium chloride 2.97 grams, and flavor lemon 0.1 gram powder in a 5 liter disposable jug containing 236 g polyethylene glycol 3350, 22.74 g sodium sulfate (anhydrous), 6.74 g sodium bicarbonate, 5.86 g sodium chloride, 2.97 g potassium chloride, acesulfame potassium 0.2 grams and lemon flavor 0.1 gram as a white powder. (3)

—CONTRAINDICATIONS—
• Gastrointestinal (GI) obstruction *(see Warnings and Precautions (5.6))*
• Bowel perforation *(see Warnings and Precautions (5.6))*
• Toxic colitis or toxic megacolon
• Gastric retention
• Ileus
• Hypersensitivity to any component of Polyethylene Glycol 3350 and electrolytes for oral solution *(see Warnings and Precautions (5.8))*

—WARNINGS AND PRECAUTIONS—
• Risk of fluid and electrolyte abnormalities; medications, and consider laboratory assessments and cardiac monitoring. (5.1, 5.2, 7.1)
• Cardiac arrhythmias. Consider pre-dose and post-colonoscopy ECGs in patients with increased risk of cardiac arrhythmias. (5.2, 7.1)
• Seizures. Use caution in patients with a history of seizures or in patients with conditions or taking medications that lower the seizure threshold. Consider laboratory assessments to ensure adequate hydration and consider testing. (5.3, 7.1)
• Renal impairment or taking concomitant medications that may affect renal function or cause ulcerations when interpreting colonoscopy findings in patients with renal impairment. Consider laboratory assessments and post-colonoscopy laboratory tests in these patients. (5.5, 7.3)
• Gastric retention. Use caution in patients with gastric retention. Observe during administration. (5.7)
• Aspiration. Use caution in patients at risk for aspiration. Inform patients to seek immediate medical care if symptoms occur. (5.8)

—ADVERSE REACTIONS—
Most common adverse reactions are: nausea, vomiting and anal irritation. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Strides Pharma Inc. at 1-855-724-3375 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

—DRUG INTERACTIONS—
Some drugs increase risks due to fluid and electrolyte disturbances. (7.1)
See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 09/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

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2 DOSAGE AND ADMINISTRATION
2.1 Important Preparation and Administration Instructions
2.2 Dosage Regimen
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
5.1 Serious Fluid and Serum Chemistry Abnormalities
5.2 Cardiac Arrhythmias
5.3 Seizures
5.4 Renal Impairment
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12.1 Mechanism of Action
12.2 Pharmacodynamics
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16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION
*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 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 in adults.

2 DOSAGE AND ADMINISTRATION

2.1 Important Preparation and Administration Instructions
• Correct fluid and electrolyte abnormalities before treatment with Polyethylene Glycol 3350 and electrolytes for oral solution *(see Warnings and Precautions (5.1))*.
• Reconstitute Polyethylene Glycol 3350 and electrolytes for oral solution with water prior to ingestion. Do not reconstitute with other liquids and/or add starch-based thickeners to the mixing container *(see Warnings and Precautions (5.7))*.
• Administer oral medications within one hour before the start of or during administration of Polyethylene Glycol 3350 and electrolytes for oral solution *(see Drug Interactions (7.2))*.
• Do not take other laxatives while taking Polyethylene Glycol 3350 and electrolytes for oral solution.
• Consume only clear liquids, avoid red and purple liquids.
• Polyethylene Glycol 3350 and electrolytes for oral solution is a combination of polyethylene glycol 3350, an osmotic laxative, and electrolytes (sodium sulfate, sodium chloride, sodium bicarbonate and potassium chloride) for oral solution supplied in a 5 liter disposable jug 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 as a white powder.
• Polyethylene Glycol 3350 and electrolytes for oral solution is a combination of polyethylene glycol 3350, an osmotic laxative, and electrolytes (sodium sulfate, sodium chloride, sodium bicarbonate and potassium chloride) for oral solution supplied in a 5 liter disposable jug containing 236 g polyethylene glycol 3350, 22.74 g sodium sulfate (anhydrous), 6.74 g sodium bicarbonate, 5.86 g sodium chloride, 2.97 g potassium chloride, acesulfame potassium 0.2 grams and lemon flavor 0.1 gram as a white powder.
• Polyethylene Glycol 3350 and electrolytes for oral solution is a combination of polyethylene glycol 3350, an osmotic laxative, and electrolytes (sodium sulfate, sodium chloride, sodium bicarbonate and potassium chloride) for oral solution supplied in a 5 liter disposable jug containing 236 g polyethylene glycol 3350, 22.74 g sodium sulfate (anhydrous), 6.74 g sodium bicarbonate, 5.86 g sodium chloride, 2.97 g potassium chloride, acesulfame potassium 0.2 grams and orange flavor 0.4 grams as a white powder.

2.2 Dosage Regimen
Instruct adult patients that on the day before the colonoscopy procedure, they may consume a light breakfast and a clear liquid lunch. Administer the recommended dosage regimen for Polyethylene Glycol 3350 and electrolytes for oral solution *early* in the evening on the day before colonoscopy.
Instruct patients to take Polyethylene Glycol 3350 and electrolytes for oral solution in conjunction with clear liquids as follows:
• Fill the provided container containing the Polyethylene Glycol 3350 and electrolytes for oral solution powder with lukewarm drinking water to the 4-liter fill line.
• Do not add any other ingredients, flavors, etc.
• Place the cap securely on the jug. Shake the jug very well several times to ensure that the ingredients are dissolved.
• Drink at a rate of 8 ounces every 10 minutes until the entire contents are consumed or the rectal effluent is clear. A loose watery bowel movement should result in approximately one hour.
• Prepare the reconstituted solution in refrigerated 2° to 8°C (36° to 46°F) but not freeze. Use within 48 hours, discard unused portion.

Administration via a Nasogastric Tube:
For administration via a nasogastric tube, administer the reconstituted Polyethylene Glycol 3350 and electrolytes for oral solution at a rate of 20 to 30 mL per minute (1.2 to 1.8 liters per hour).

3 DOSAGE FORMS AND STRENGTHS
For Oral Solution: 236 g polyethylene glycol 3350, 22.74 g sodium sulfate (anhydrous), 6.74 g sodium bicarbonate, 5.86 g sodium chloride, 2.97 g potassium chloride, and flavor powder in a 5 liter disposable jug with water to a volume of 4 liters, the solution contains 59 g/L PEG-3350, 5.69 g/L sodium sulfate, 1.69 g/L sodium bicarbonate, 1.47 g/L sodium chloride and 0.743 g/L potassium chloride (acesulfame potassium 0.2 g and lemon flavor 0.1 g for lemon flavor , acesulfame potassium 0.2 g and flavor orange 0.4 g for orange flavor).

4 CONTRAINDICATIONS
Polyethylene Glycol 3350 and electrolytes for oral solution is contraindicated in the following conditions:
• Gastrointestinal (GI) obstruction *(see Warnings and Precautions (5.6))*
• Bowel perforation *(see Warnings and Precautions (5.6))*
• Toxic colitis or toxic megacolon
• Gastric retention
• Ileus
• Hypersensitivity to any component of Polyethylene Glycol 3350 and electrolytes for oral solution *(see Warnings and Precautions (5.8))*

5 WARNINGS AND PRECAUTIONS

5.1 Serious Fluid and Serum Chemistry Abnormalities
Advise patients to hydrate adequately before, during, and after the use of Polyethylene Glycol 3350 and electrolytes for oral solution. Use caution in patients with congestive heart failure when replacing fluids. If a patient develops signs or symptoms of dehydration including signs of orthostatic hypotension after taking Polyethylene Glycol 3350 and electrolytes for oral solution, consider additional fluid administration and laboratory tests (electrolytes, creatinine, and BUN) and treat accordingly. Fluid and electrolyte disturbances can lead to cardiac arrhythmias and changes in mental status, particularly in the elderly. Correct fluid and electrolyte abnormalities before treatment with Polyethylene Glycol 3350 and electrolytes for oral solution.

In addition, use caution when prescribing Polyethylene Glycol 3350 and electrolytes for oral solution for patients who have conditions or are taking medications that increase the risk for fluid and electrolyte disturbances or may increase the risk of renal injury. Advise these patients of the importance of adequate hydration and consider performing baseline and post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN) and treat accordingly. Fluid and electrolyte disturbances can lead to cardiac arrhythmias and changes in mental status, particularly in the elderly. Correct fluid and electrolyte abnormalities before treatment with Polyethylene Glycol 3350 and electrolytes for oral solution.

Use caution when prescribing Polyethylene Glycol 3350 and electrolytes for oral solution for patients who are taking medications that increase the risk for fluid and electrolyte disturbances or may increase the risk for renal injury. *(See Drug Interactions (7.1))*

5.2 Cardiac Arrhythmias
There have been reports of serious arrhythmias associated with the use of ionic osmotic laxatives. Consider pre-dose and post-colonoscopy ECGs in patients at increased risk of serious cardiac arrhythmias.

5.3 Seizures
There have been reports of generalized tonic-clonic seizures and/or loss of consciousness associated with use of bowel preparation products in patients with no prior history of seizures. The seizure cases were associated with electrolyte abnormalities (e.g., hypovolemia, hypokalemia, hypocalcemia, and hypomagnesemia) and/or hyponatremia and/or osmolality. The neurologic abnormalities resolved with correction of fluid and electrolyte abnormalities.

Use caution when prescribing Polyethylene Glycol 3350 and electrolytes for oral solution for patients with a history of seizures or in patients with conditions or taking medications that lower the seizure threshold (e.g., tricyclic antidepressants), patients withdrawing from alcohol or benzodiazepines, or patients with known or suspected hyponatremia *(see Drug Interactions (7.1))*.

5.4 Renal Impairment
Use caution when prescribing Polyethylene Glycol 3350 and electrolytes for oral solution for patients with impaired renal function or patients taking concomitant medications that may affect renal function (such as diuretics, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, or non-steroidal anti-inflammatory drugs) or cause ulcerations when interpreting colonoscopy findings. Advise adequate hydration and consider performing baseline and post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN) in these patients *(see Use in Specific Populations (8.6))*.

5.5 Ischemic Colitis and Ulcerations and Ischemic Colitis
Administration of osmotic laxative products may produce colonic mucosal aphthous ulcerations, and there have been reports of more serious cases of ischemic colitis requiring hospitalization. Concurrent use of stimulant laxatives and Polyethylene Glycol 3350 and electrolytes for oral solution may increase the risk *(see Drug Interactions (7.3))*. Use with caution in patients with severe ulcerative colitis.

5.6 Use in Patients with Significant Gastrointestinal Disease
If gastrointestinal obstruction or perforation is suspected, perform appropriate diagnostic studies to rule out these conditions before administering Polyethylene Glycol 3350 and electrolytes for oral solution *(see Contraindications (4))*. Use with caution in patients with severe ulcerative colitis.

5.7 Aspiration
Use with caution in patients with impaired gag reflex, unconscious, or semiconscious patients, and patients at risk for aspiration. Consider the use of an appropriately placed nasogastric tube. Polyethylene Glycol 3350 and electrolytes for oral solution, especially if it is administered via nasogastric tube.

Do not combine Polyethylene Glycol 3350 and electrolytes for oral solutions with starch-based thickeners and administer only with water. Do not add any other ingredients, flavors, etc. to the mixing container and electrolytes for oral solutions, when mixed with starch-thickened liquids reduces the viscosity of the starch-thickened liquid. When a PEG-based product used for another indication was mixed in starch-based thickened liquids, aspiration of the mixture has been associated with severe pulmonary injury and potential aspiration events.

5.8 Hypersensitivity Reactions
Polyethylene Glycol 3350 and electrolytes for oral solution contains PEG and may cause serious hypersensitivity reactions including anaphylaxis, angioedema, and anaphylactic shock. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care if they develop these signs and symptoms.

6 ADVERSE REACTIONS
The following clinically significant adverse reactions are described elsewhere in the labeling:
• Renal impairment *(see Warnings and Precautions (5.4))*
• Colonic mucosal ulcerations and ischemic colitis *(see Warnings and Precautions (5.5))*
• Gastrointestinal obstruction *(see Warnings and Precautions (5.6))*
• Aspiration *(see Warnings and Precautions (5.7))*
• Hypersensitivity *(see Warnings and Precautions (5.8))*
• Nervous system: tremor, seizure *(see Warnings and Precautions (5.3))*

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PAGE 01

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PAGE 02

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