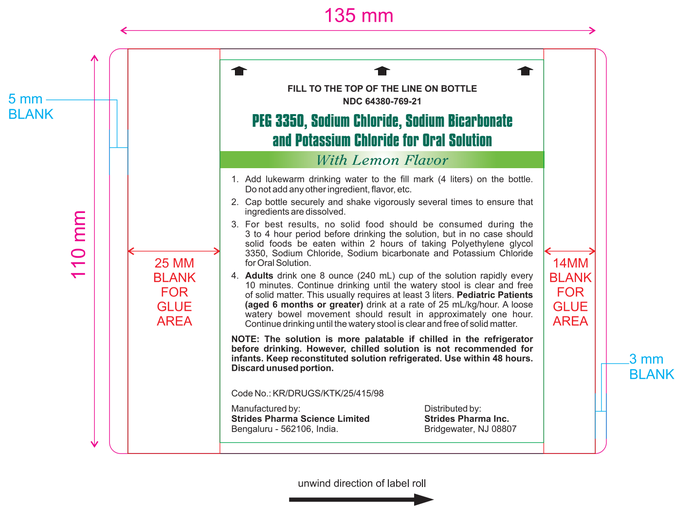

PAPER AREA

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

GLUE AREA MUST BE BLANK

IP PART - 1 FRONT

6 ADVERSE REACTIONS
The following serious or otherwise important adverse reactions are described elsewhere in the labeling:
- Severe Acute Hypersensitivity Reactions (Including Anaphylaxis) *[see Warnings and Precautions (5.1)]*
- Cardiac Arrhythmias *[see Warnings and Precautions (5.2)]*
- Seizures *[see Warnings and Precautions (5.3)]*
- Fluid and Electrolyte Disturbances *[see Warnings and Precautions (5.4)]*
- Colonic Mucosal Ulcerations, Ischemic Colitis and Ulcerative Colitis *[see Warnings and Precautions (5.5)]*
- Severe Cutaneous Adverse Reactions (SCAR) *[see Warnings and Precautions (5.6)]*
- Aspiration *[see Warnings and Precautions (5.7)]*

The most common adverse reactions (incidence greater than 5%) are abdominal distension, nausea, abdominal fullness and bloating are the most common adverse reactions (occurred in up to 50% of patients) to administration of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.
Nausea, abdominal fullness and bloating are the most common adverse reactions (occurred in up to 50% of patients) to administration of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.
These adverse reactions are transient and usually subside rapidly. Isolated cases of urticaria, rhinorrhea, dermatitis and (rarely) anaphylactic reaction have been reported which may represent allergic reactions.
Cardiac arrhythmias have been observed in patients with underlying cardiac disease after administration of PEG-electrolyte solution 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 myocardial infarction within two weeks after vomiting and aspiration gastric.

7 DRUG INTERACTIONS
7.1 Drugs that May Lead to Fluid and Electrolyte Abnormalities
Use caution when prescribing polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution for patients who are using medications that increase the risk for fluid and electrolyte disturbances or may increase the risk of adverse events of seizure, arrhythmias, and renal impairment. Fluid and electrolyte abnormalities should be corrected before initiation of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and monitored as appropriate *[see Warnings and Precautions (5.1, 5.2, 5.3, and 5.4)]* in patients taking these concomitant medications.

7.2 Potential for Altered Drug Absorption
Oral medications taken within approximately 1 hour of the start of administration of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution may be flushed from the gastrointestinal tract before adequate absorption has occurred.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Concurrent use of stimulant laxatives and polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution may increase the risk of mucosal ulceration or ischemic colitis.
Avoid use in patients with bowel obstruction, severe inflammatory bowel disease, or toxic colitis or toxic megacolon and consider alternative treatments for bowel cleansing prior to colonoscopy in patients taking polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution.

8.4 Pediatric Use
Safety and effectiveness of polyethylene glycol 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 studies of polyethylene glycol 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. Use of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution in pediatric patients aged 6 months and older 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 3 children.

8.5 Geriatric Use
Clinical studies of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride 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.

11 DESCRIPTION
For oral solution: Each 5 liter (5L) polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution contains: 420 grams of polyethylene glycol 3350, 11.2 grams sodium chloride, 5.72 grams sodium bicarbonate and 1.48 grams potassium chloride for oral solution. Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is a combination of polyethylene glycol 3350, an osmotic laxative, and electrolytes (sodium chloride, sodium bicarbonate and potassium chloride) for oral solution. Polyethylene glycol 3350 is a polydisperse polyether diol. Sodium chloride and potassium chloride for oral solution is available in unflavored, lemon and orange flavors.
Each 5 liter jug contains: polyethylene glycol 3350 USPNF 420 g, sodium bicarbonate USP 5.72 g, sodium chloride USP 11.2 g, potassium chloride USP 1.48 g and flavoring ingredients acesulfame potassium 0.1 gram and flavor lemon 0.4 grams while orange flavor powder contains acesulfame potassium 0.1 gram and flavor orange 0.6 grams respectively. The following inactive ingredients are added during reconstitution: sodium chloride USP, potassium chloride USP, Polyethylene Glycol 3350, NF.

Sodium Bicarbonate, USP
The chemical name is NaHCO3. 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 laxative action of this product 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, sodium chloride, sodium bicarbonate and potassium chloride for oral solution induces a diarrhea which rapidly cleanses the bowel, usually within four hours.

12.3 Pharmacokinetics
The pharmacokinetics of PEG 3350 following administration of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution have not been elucidated. Available pharmacokinetic information for oral PEG 3350 suggests that it is poorly absorbed.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Long term studies in animals have not been performed to evaluate carcinogenic potential of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution. Studies to evaluate the potential for mutagenicity of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution have not been performed.

16 HOW SUPPLIED/STORAGE AND HANDLING
In powdered form, for oral administration as a solution following reconstitution.
Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is available in a disposable jug in powdered form containing:
Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution in following flavors: 420 grams, sodium bicarbonate 5.72 grams, sodium chloride 11.2 grams, potassium chloride 1.48 g and flavoring ingredients acesulfame potassium 0.1 gram and flavor lemon 0.4 grams while orange flavor powder contains acesulfame potassium 0.1 gram and flavor orange 0.6 grams respectively. The following inactive ingredients are added during reconstitution: sodium chloride USP, potassium chloride USP, Polyethylene Glycol 3350, NF.

Drug product	NDC	Package
Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution	64380-768-21	5 L disposable jug with a 4 L fill line
Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution with lemon flavor	64380-769-21	
Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution with orange flavor	64380-770-21	

17 PATIENT COUNSELING INFORMATION
See FDA-Approved Patient Labeling (Medication Guide) Instructions:
- Inform patients of the potential benefits and risks of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and of the importance of adequate hydration, and consider performing baseline and post-colonoscopy electrolyte determinations with subsequent follow-up as needed.
- Not to take other laxatives while they are taking polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution.
- That the product should be used for bowel preparation and after completion of the bowel preparation up until 2 hours before the time of the colonoscopy.
- That if they experience severe bloating, distention or abdominal pain, the administration of the solution should be discontinued until the symptoms abate. Advise patients to report these events to their health care provider.
- That if they have hives, rashes, or any allergic reaction, they should discontinue the medication and notify their healthcare provider immediately. Advise patients to report any signs of angioedema such as swelling of the face, eyes, lips, tongue, or throat, difficulty breathing or swallowing.
- To contact their healthcare provider if they develop signs and symptoms of dehydration *[see Warnings and Precautions (5.1)]*.
- That the product is administered within one hour of the start of administration of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution may be flushed from the GI tract and the medication may not be absorbed completely.

Manufactured by:
Strides Pharma Science Limited
Bengaluru - 562106, India.
Distributed by:
Strides Pharma Inc.
Bridgewater, NJ 08807
Revised: 09/2025

15 MM BLANK FOR GLUE AREA

NDC 64380-769-21
FILL TO THE TOP OF THE LINE ON BOTTLE

To Pharmacist: Patient instructions are on base label.
Package insert may be removed before dispensing.
Dispense the Medication Guide available at www.strides.com/peg-os/, separately to each patient.

PEG 3350, Sodium Chloride, Sodium Bicarbonate and Potassium Chloride for Oral Solution

With Lemon Flavor

When reconstituted with water to a volume of 4 liters, this 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.

Each disposable jug contains in powdered form: Polyethylene glycol 3350 USPNF 420 g, sodium bicarbonate USP 5.72 g, sodium chloride USP 11.2 g, potassium chloride USP 1.48 g, flavor Lemon 0.4 g.

Rx Only

Code No.:
KR/DRUGS/KTK/25/415/98

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

Distributed by:
Strides Pharma Inc.
Bridgewater, NJ 08807

Strides Pharma Inc.

1052535

PULL DOWN TO OPEN

110 mm

574 mm

PAGE 03

PAGE 04

TITLE TOP

IP PART - 1 BACK

14MM BLANK FOR GLUE AREA

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to prescribe PEG 3350, SODIUM CHLORIDE, SODIUM BICARBONATE and POTASSIUM CHLORIDE for Oral Solution safely and effectively. See full prescribing information for PEG 3350, SODIUM CHLORIDE, SODIUM BICARBONATE and POTASSIUM CHLORIDE for Oral Solution.

PEG 3350, SODIUM CHLORIDE, SODIUM BICARBONATE and POTASSIUM CHLORIDE for Oral Solution (LEMON FLAVOR, LEMON AND ORANGE FLAVORS)

Initial U.S. Approval: 1991

----------INDICATIONS AND USAGE----------
Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is a polyethylene glycol (PEG)-based osmotic laxative, and electrolytes indicated for cleansing of the colon in preparation for colonoscopy in adults, and for bowel preparation in adults and children aged 6 months and older. (1)

----------DOSAGE AND ADMINISTRATION----------
- Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is supplied as a powder; must be reconstituted with water before use. (2.1, 5.8)
- On day prior to colonoscopy, instruct patients to:
  - Eat only clear liquids during the day. Clear liquids include broth, coffee and tea, fruit juice without pulp, gelatin, water, and sports drinks. (2.2)
  - Early in the evening prior to colonoscopy, fill container containing polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution's powder with lukewarm water to 4 liter fill mark. (2.2)
  - After capping container, shake vigorously several times. (2.2)
  - Instruct patients to consume water or clear liquids during and after bowel preparation up until 2 hours before time of colonoscopy. (2.3).
- Adults: Drink 4 liters (1 gallon) of the solution rapidly over 1 hour. Continue drinking until watery stool is clear and free of solid matter. (2.3)
- **Pediatric Patients (aged 6 months or greater):** Drink 25 mL/kg/hour orally or administer by NGT. Continue drinking until watery stool is clear and free of solid matter. (2.3)

----------DOSAGE FORMS AND STRENGTHS----------
For oral solution: Polyethylene glycol 3350 420 grams, sodium bicarbonate 5.72 grams, sodium chloride 11.2 grams, potassium chloride 1.48 grams and flavoring ingredients acesulfame potassium 0.1 gram and flavor lemon 0.4 grams while orange flavor powder contains acesulfame potassium 0.1 gram and flavor orange 0.6 grams respectively. The following inactive ingredients are added during reconstitution: sodium chloride USP, potassium chloride USP, Polyethylene Glycol 3350, NF.

----------CONTRAINDICATIONS----------
- Gastrointestinal (GI) obstruction, ileus, or gastric retention (4)
- Bowel perforation (4, 5.6)
- Toxic colitis or toxic megacolon (4)
- Known allergic or hypersensitivity to components of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution (4, 11)

----------WARNINGS AND PRECAUTIONS----------
- Risk of Severe Acute Hypersensitivity Reactions, arrhythmias, seizures and renal impairment – assess concurrent medications and consider monitoring electrolytes (5.1, 5.2, 5.3, 5.4)
- Patients with renal insufficiency – use caution, ensure adequate hydration and consider testing (5.4)
- Suspected GI obstruction or perforation – rule out the diagnosis before administration (4, 5.6)
- Aspiration – use caution during administration – observe during administration (5.7)
- Not for direct ingestion – dilute and take with additional water (5.8)

----------ADVERSE REACTIONS----------
Most common adverse reactions (≥3%) are nausea, abdominal fullness and bloating. Abdominal cramps, vomiting and anal irritation are most common in children.

To report SUSPECTED ADVERSE REACTIONS, contact Strides Pharma Inc. at 1-877-244-9825 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------
- Some drugs may interact with data to fluid and electrolyte changes (7.1)
- Oral medication taken within 1 hour of start of administration may be flushed from the GI tract (7.2)

See 17 for PATIENT COUNSELING INFORMATION and MEDICATION GUIDE

Revised: 09/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
2.1 Dosage Overview
2.2 Administration Instructions Prior to Dosage
2.3 Dosage
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
5.1 Severe Acute Hypersensitivity
5.2 Cardiac Arrhythmias
5.3 Seizures
5.4 Renal Impairment
5.5 Colonic Mucosal Ulcerations and Ischemic Colitis
5.6 Use in Patients with Significant Gastrointestinal Disease
5.7 Aspiration
5.8 Not for Direct Ingestion
6 ADVERSE REACTIONS
7 DRUG INTERACTIONS
7.1 Drugs that May Lead to Fluid and Electrolyte Abnormalities
7.2 Potential for Altered Drug Absorption
7.3 Stimulant Laxatives
8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
8.2 Lactation
8.3 Nursing Mothers
8.4 Pediatric Use
8.5 Geriatric Use
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
12.2 Pharmacodynamics
12.3 Pharmacokinetics
13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION
*Patient information is separated from the full prescribing information not listed.

FULL PRESCRIBING INFORMATION
1 INDICATIONS AND USAGE
Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is indicated for bowel cleansing prior to colonoscopy in adults and pediatric patients aged 6 months or greater.

2 DOSAGE AND ADMINISTRATION
2.1 Dosage Overview
- Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution, supplied as a powder; must be reconstituted with water before use; it is not for direct ingestion. Dilute and take with additional water before use. (5.8)
- Do not reconstitute with other liquids and/or add starch-based thickeners to the mixing container *[see Warnings and Precautions (5.7)]*.
- The recommended dose of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution contains: 420 grams of polyethylene glycol (PEG) 3350, 5.72 grams of sodium bicarbonate, 11.2 grams of sodium chloride, and 1.48 grams of potassium chloride. Besides these, the following inactive ingredients are added during reconstitution: sodium chloride USP, potassium chloride USP, Polyethylene Glycol 3350, NF. Flavored products contain acesulfame potassium 0.1 gram and flavor orange 0.6 grams respectively, or acesulfame potassium 0.1 gram and flavor lemon 0.4 grams respectively.

2.2 Administration Instructions Prior to Dosage
On the day prior to the colonoscopy, instruct patients to:
a) Take only clear liquids, but avoid red and purple liquids. Patients may consume a light breakfast.
b) Early in the evening prior to colonoscopy, fill container containing polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution's powder with lukewarm water (to facilitate dissolution) to the 4 liter fill line. The solution is clear and colorless when the powder is completely dissolved in water.
c) After capping the container, shake vigorously several times to ensure that the ingredients are dissolved. When reconstituted use within 48 hours.

2.3 Dosage
The dose of PEG 3350 is the recommended dose of reconstituted polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution for adults and pediatric patients ≥ 6 months. Instruct patients they may consume water or clear liquids during the bowel preparation and after completion of the bowel preparation up until 2 hours before the time of the colonoscopy. Administer the solution in a manner most palatable (chilled prior to administration).
- **Adults:** Instruct patients to drink 4 liters (1 gallon) of the solution rapidly over 1 hour (10 minutes until 4 liters is consumed). Rapid drinking (2 liters in 1 hour) is preferred to drinking small amounts continuously. For NGT, rate is 20 to 30 mL per minute (1.2 to 1.8 liters per hour).
- **Pediatric Patients ≥ 6 Months:** Pediatric patients should drink 25 mL/kg/hour until the stool is watery, clear and free of solid matter. Administer by nasogastric tube (NGT) if unable to drink the solution. Administer polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution, the recommended dose, in a single day. Administer the entire dose over a period of 2 hours. Discard unused portion. Keep out of reach of children.

The first bowel movement should occur approximately one hour after the start of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution administration. Continue drinking the solution until the stool is clear and free of solid matter.

3 DOSAGE FORMS AND STRENGTHS
For oral solution: One 5 liter jug with powder for reconstitution with water.
Each 5 liter jug contains polyethylene glycol 3350 USPNF 420 g, sodium bicarbonate USP 5.72 g, sodium chloride USP 11.2 g, potassium chloride USP 1.48 g and flavoring ingredients acesulfame potassium 0.1 gram and flavor lemon 0.4 g for lemon flavor or acesulfame potassium 0.1 gram and flavor orange 0.6 g for orange flavor). 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.

4 CONTRAINDICATIONS
Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is contraindicated in patients with:
- Gastrointestinal (GI) obstruction, ileus, or gastric retention
- Bowel perforation
- Toxic megacolon

Known allergic or hypersensitivity to any component of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution *[see How Supplied/Storage and Handling (16)]*.

5 WARNINGS AND PRECAUTIONS
5.1 Serious Fluid and Serum Chemistry Abnormalities
Use caution when prescribing polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution for patients who are using medications that increase the risk for fluid and electrolyte disturbances or may increase the risk of adverse events of seizure, arrhythmias, and renal impairment. Fluid and electrolyte abnormalities should be corrected before initiation of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution.
Use caution when prescribing polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution for patients with renal insufficiency, because renal impairment, fluid and electrolyte abnormalities (e.g., hyponatremia, hypokalemia, hypocalcemia, and hypomagnesemia) and low serum osmolality. The neurologic abnormalities resolved with correction of electrolyte and fluid disturbances.
Use caution when prescribing polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution for patients who have conditions, or who are using medications, that increase the risk for fluid and electrolyte disturbances or may increase the risk of adverse events of seizure, such as patients taking medications that lower the seizure threshold (e.g., tricyclic antidepressants), patients withdrawing from alcohol or benzodiazepines, or patients with known or suspected seizure disorders.

5.4 Renal Impairment
Use caution when prescribing polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution for patients with impaired renal function or patients taking medications that may adversely affect renal function (e.g., angiotensin converting enzyme inhibitors, angiotensin receptor blockers, or non-steroidal anti-inflammatory drugs). Advise these patients of the importance of adequate hydration, and consider performing baseline and post-colonoscopy electrolyte determinations with subsequent follow-up as needed.

5.5 Colonic Mucosal Ulcerations and Ischemic Colitis
Administration of osmotic laxative products may produce colonic mucosal aphthous ulcerations, and ischemic colitis. Use caution when prescribing polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution for patients who are using medications that increase the risk of stimulant laxatives and polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution may increase this risk. The potential for mucosal ulcerations and ischemic colitis may be increased by administration with interpreting colonoscopy findings in patients with known or suspect inflammatory bowel disease (IBD).

5.6 Use in Patients with Significant Gastrointestinal Disease
If a gastrointestinal obstruction or perforation is suspected, perform appropriate diagnostic studies to rule out these conditions before administration of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution, especially if administered via nasogastric tube.
Do not use polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution *[see Dosage and Administration (2.1)]* Polyethylene glycol (PEG), a component of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution, has been associated with fatal bowel perforation when administered as a thickened liquid. When a PEG-based product used for another indication was mixed in starch-based prethickened liquids used in patients with dysphagia, thinning of the liquid occurred and cases of choking and aspiration pneumonia occurred.

5.8 Not for Direct Ingestion
The contents of each jug must be diluted with water to a final volume of 4 liters (4L) and ingestion of additional water is important to patient tolerance. Direct ingestion of the undissolved powder may increase the risk of nausea, vomiting, dehydration, and electrolyte disturbances.

14MM BLANK FOR GLUE AREA

110 mm

574 mm

PAGE 01

TEXT MATTER START FROM HERE
TEXT READ THIS WAY

PAGE 02

MFG. LOCATION: KRSG

NON PRINTING COLOUR

ARTWORK DETAIL LABEL

Product	**PEG-3350, Sodium Chloride, Sodium Bicarbonate and Potassium Chloride for Oral Solution - WITH LEMON FLAVOR**				
Buyer/Country	STRIDES PHARMA INC	Component	FIX-A-FORM - CAN LABELS		
Dimension	**135 x 110mm (open size: 574 x 110mm)**			Pack	5 LTR
New Item Code	1052535	Old Item Code	1047934		
Colour Shades	PANTONE 342 C, BLACK, PANTONE 368 C, PANTONE 340 C			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	Colour shades to be matched as per Pantone Shade only. 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.**

RD/PD/003/F-08/R0