POLYETHYLENE GLYCOL 3350, SODIUM CHLORIDE, SODIUM BICARBONATE AND POTASSIUM CHLORIDE - UNFLAVORED - polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride - unflavored powder, for solution

POLYETHYLENE GLYCOL 3350, SODIUM CHLORIDE, SODIUM BICARBONATE AND POTASSIUM CHLORIDE WITH LEMON FLAVOR - polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride with lemon flavor powder, for solution

POLYETHYLENE GLYCOL 3350, SODIUM CHLORIDE, SODIUM BICARBONATE AND POTASSIUM CHLORIDE WITH ORANGE FLAVOR - polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride with orange flavor powder, for solution

Strides Pharma Science Limited

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use POLYETHYLENE GLYCOL 3350, SODIUM CHLORIDE, SODIUM BICARBONATE and POTASSIUM CHLORIDE for Oral Solution safely and effectively. See full prescribing information for POLYETHYLENE GLYCOL 3350, SODIUM CHLORIDE, SODIUM BICARBONATE and POTASSIUM CHLORIDE for Oral Solution.

POLYETHYLENE GLYCOL 3350, SODIUM CHLORIDE, SODIUM BICARBONATE and POTASSIUM CHLORIDE for Oral Solution (UNFLAVORED, 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 combination of PEG 3350, an osmotic laxative, and electrolytes indicated for cleansing of the colon in preparation for colonoscopy in adults and pediatric patients aged 6 months or greater (1)

DOSAGE AND ADMINISTRATION

- Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution, supplied as a powder, must be reconstituted with water before its use (2.1, 5.8)
- On day prior to colonoscopy, instruct patients to:
  - Eat a light breakfast or have clear liquids (avoid red and purple liquids) (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 line (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 at a rate of 240 mL (8 oz.) every 10 minutes, until 4 liters are consumed or rectal effluent is clear. For nasogastric tube (NGT), rate is 1.2 to 1.8 liters per hour (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 for lemon flavor, acesulfame potassium 0.1 gram and flavor orange 0.6 grams for orange flavor respectively; supplied in one 5 liter disposable jug (3).

CONTRAINDICATIONS

- Gastrointestinal (GI) obstruction, ileus, or gastric retention (4, 5.6)
- Bowel perforation (4, 5.6)
- Toxic colitis or toxic megacolon (4)
- Known allergy 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 fluid and electrolyte abnormalities, arrhythmias, seizures and renal impairment – assess concurrent medications and consider testing in some patients (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)
- Patients at risk for aspiration – 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 occur less frequently (6)

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 increase risks due to fluid and electrolyte changes (7.1)
- Oral medication taken within 1 hour of start of each dose may not be absorbed properly (7.2)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 11/2022

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are 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 its use; it is not for direct ingestion *[see Dosage and Administration (2.2), Warnings and Precautions (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 4 liter reconstituted 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 lemon flavored solution contain flavoring ingredients acesulfame potassium 0.1 gram and flavor lemon 0.4 grams while orange flavored solution contains acesulfame potassium 0.1 gram and flavor orange 0.6 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 the supplied container containing the 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 reconstituted to a final volume of 4 liters.

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 following 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. The solution is more palatable if chilled prior to administration.

- **Adults:** Instruct patients to drink a total of up to 4 liters 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. 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. If pediatric patients are unable to drink the reconstituted polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution, the solution may be given by nasogastric (NGT). NGT administration is at the rate of 25 mL/kg/hour.

The first bowel movements 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 until the watery 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 USP-NF 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 g 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 the following conditions:

- Gastrointestinal (GI) obstruction, ileus, or gastric retention
- Bowel perforation
- Toxic colitis or toxic megacolon
- Known allergy 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

Advise patients to hydrate adequately before, during, and after the use of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution. Use caution in patients with congestive heart failure when replacing fluids. If a patient develops significant vomiting or signs of dehydration including signs of orthostatic hypotension after taking polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution, consider performing post-colonoscopy lab tests (electrolytes, creatinine, and BUN) and treat accordingly. Fluid and electrolyte disturbances can lead to serious adverse events including cardiac arrhythmias, seizures and renal impairment. Fluid and electrolyte abnormalities should be corrected before treatment with polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution.

In addition, 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, arrhythmias, and renal impairment *[see Drug Interactions (7.1)].*

5.2 Cardiac Arrhythmias

There have been rare reports of serious arrhythmias associated with the use of ionic osmotic laxative products for bowel preparation. Use caution when prescribing polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution for patients at increased risk of arrhythmias (e.g., patients with a history of prolonged QT, uncontrolled arrhythmias, recent myocardial infarction, unstable angina, congestive heart failure, or cardiomyopathy). Pre-dose and post-colonoscopy ECGs should be considered 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., hyponatremia, hypokalemia, hypocalcemia, and hypomagnesemia) and low serum osmolality. The neurologic abnormalities resolved with correction of fluid and electrolyte abnormalities.

Use caution when prescribing polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution for patients with a history of seizures and in patients at increased risk 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 hyponatremia.

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 concomitant medications that may affect renal function (such as diuretics, 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 laboratory tests (electrolytes, creatinine, and BUN) in these patients.

5.5 Colonic Mucosal 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, sodium chloride, sodium bicarbonate and potassium chloride for oral solution may increase this risk. The potential for mucosal ulcerations resulting from the bowel preparation should be considered when interpreting colonoscopy findings in patients with known or suspect inflammatory bowel disease (IBD).

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, sodium chloride, sodium bicarbonate and potassium chloride for oral solution. 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, sodium chloride, sodium bicarbonate and potassium chloride for oral solution.

Use with caution in patients with severe active ulcerative colitis.

5.7 Aspiration

Use with caution in patients with impaired gag reflex, unconscious, or semiconscious patients, and patients prone to regurgitation or aspiration. Such patients should be observed during administration of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution, especially if it is administered via nasogastric tube.

Do not combine polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution, with starch-based thickeners [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, 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 pre-thickened liquids used in patients with dysphagia, thinning of the liquid occurred and cases of choking and potential aspiration were reported.

5.8 Not for Direct Ingestion

The contents of each jug must be diluted with water to a final volume of 4 liters (4 L) 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.

6 ADVERSE REACTIONS

The following serious or otherwise important adverse reactions are described elsewhere in the labeling:

- Serious Fluid and Serum Chemistry Abnormalities *[see Warnings and Precautions (5.1)].*
- Cardiac Arrhythmias *[see Warnings and Precautions (5.2)].*
- Seizures *[see Warnings and Precautions (5.3)].*
- Renal Impairment *[see Warnings and Precautions (5.4)]*
- Colonic Mucosal Ulcerations, Ischemic Colitis and Ulcerative Colitis *[see Warnings and Precautions (5.5)].*
- Patients with Significant Gastrointestinal Disease *[see Warnings and Precautions (5.6)].*
- Aspiration *[see Warnings and Precautions (5.7)].*
- Direct Ingestion *[see Warnings and Precautions (5.8)].*

The following adverse reactions have been identified during post-approval use 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. Abdominal cramps, vomiting and anal irritation occur less frequently. 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.

Published literature contains isolated reports of serious adverse reactions following the 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 "butterfly-like" infiltrates on chest X-ray after vomiting and aspirating PEG.

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 prolonged QT in the setting of fluid and electrolyte abnormalities. Consider additional patient evaluations 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 medication 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 gastrointestinal tract and the medication may

not be absorbed properly.

7.3 Stimulant Laxatives

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 of stimulant laxatives (e.g., bisacodyl, sodium picosulfate) while taking polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Animal reproduction studies have not been conducted with polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution. It is also not known whether polyethylene glycol 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. Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution should be given to a pregnant woman only if clearly needed.

8.3 Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is administered to a nursing woman.

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 clinical trials 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 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 3 children.

8.5 Geriatric Use

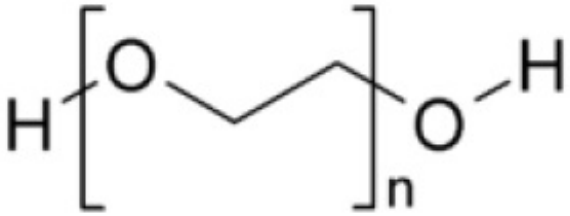
Clinical studies of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified 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 jug contains a white powder for reconstitution. 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, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is available in unflavored, lemon and orange flavors.

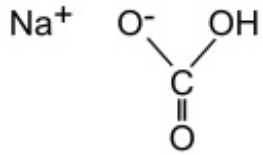
Each 5 liter jug contains: polyethylene glycol 3350 USP-NF 420 g, sodium bicarbonate USP 5.72 g, sodium chloride USP 11.2 g, potassium chloride USP 1.48 g. Besides these, the lemon flavored powder contains flavoring ingredients acesulfame potassium 0.1 gram and flavor lemon 0.4 grams while orange flavor powder contains acesulfame potassium 0.1 gram and flavor orange 0.6 grams respectively. The solution is clear and colorless when reconstituted to a final volume of 4 liters with water.

Polyethylene Glycol 3350, NF



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 primary mode of action 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 as 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 were not assessed. 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 possible impairment of fertility or mutagenic potential 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 with Flavor Packs: polyethylene glycol 3350 420 g, sodium bicarbonate 5.72 g, sodium chloride 11.2 g, potassium chloride 1.48 g and flavoring ingredients acesulfame potassium 0.1 gram and flavor lemon 0.4 grams for lemon flavor and acesulfame potassium 0.1 gram and flavor orange 0.6 grams 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.

Storage:

Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. When reconstituted, keep solution refrigerated. Use within 48 hours. Discard unused portion.

Keep out of reach of children.

Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is available in following flavors:

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). Instruct patients:

- To let you know if they have trouble swallowing or are prone to regurgitation or aspiration.
- Not to take other laxatives while they are taking polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution.
- To 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.
- That if they experience severe bloating, distention or abdominal pain, the administration of the solution should be slowed or temporarily 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 contact their health care provider. Medication should be discontinued until they speak to their physician.
- To contact their healthcare provider if they develop signs and symptoms of dehydration *[see Warnings and Precautions (5.1)]* .
- That oral medication 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.

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MEDICATION GUIDE

Polyethylene Glycol 3350, Sodium Chloride, Sodium Bicarbonate and Potassium Chloride for Oral Solution

(pol" ee eth' i leen glye' kol 3350, soe' dee um klor' ide, soe' dee um bye kar' bo nate and poe tas' ee um klor' ide**)**

Read this Medication Guide before you start taking polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution?

Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and other osmotic bowel preparations can cause serious side effects, including:

Serious loss of body fluid (dehydration) and changes in blood salts (electrolytes) in your blood.

These changes can cause:
- **abnormal heartbeats that can cause death**
- **seizures** . This can happen even if you have never had a seizure.
- **kidney problems**

Your chance of having fluid loss and changes in body salts with polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is higher if you:
- have heart problems
- have kidney problems
- take water pills or non-steroidal anti-inflammatory drugs (NSAIDS)

Tell your healthcare provider right away if you have any of these symptoms of a loss of too much body fluid (dehydration) while taking polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution:
- vomiting that prevents you from keeping down the solution
- dizziness
- urinating less often than normal
- headache

See Section "What are the possible side effects of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution" for more information about side effects.

What is polyethylene glycol 3350, sodium chloride, sodium bicarbonate and

potassium chloride for oral solution?

Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is a prescription medicine used by adults to clean the colon before a colonoscopy. Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution cleans your colon by causing you to have diarrhea. Cleaning your colon helps your healthcare provider see the inside of your colon more clearly during your colonoscopy.

Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution is safe and effective for use in pediatric patients aged 6 months and older.

Who should not take polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution?

Do not take polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution if your healthcare provider has told you that you have:

- a blockage in your bowel (obstruction)
- an opening in the wall of your stomach or intestine (bowel perforation)
- problems with food and fluid emptying from your stomach (gastric retention)
- a very dilated intestine (bowel)
- an allergy to any of the ingredients in polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution. See the end of this leaflet for a complete list of ingredients in polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution.

What should I tell my healthcare provider before taking polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution?

Before you take polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution, tell your healthcare provider if you:

- have heart problems
- have stomach or bowel problems
- have ulcerative colitis
- have problems with swallowing or gastric reflux
- have a history of seizures
- are withdrawing from drinking alcohol
- have a low blood salt (sodium) level
- have kidney problems
- any other medical conditions
- are pregnant. It is not known if polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution passes into your breast milk. You and your healthcare provider should decide if you will take polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution while breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution may affect how other medicines work. Medicines taken by mouth may not be absorbed properly when taken within 1 hour before the start of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution.

Especially tell your healthcare provider if you take:

- medicines for blood pressure or heart problems
- medicines for kidney problems
- medicines for seizures
- water pills (diuretics)
- non-steroidal anti-inflammatory medicines (NSAID) pain medicines
- laxatives
- starch-based thickeners. For patients who have trouble swallowing, do not mix polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution, with starch-based thickeners

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure if you are taking any of the medicines listed above.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution?

You must read, understand, and follow these instructions to take polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution the right way.

- Take polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution exactly as your healthcare provider tells you to take it.
- Drink 240 mL (8 oz.) every 10 minutes. Rapid drinking of each portion is better than drinking small amounts.
- The first bowel movement should occur approximately one hour after you start drinking the solution.
- 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 the discomfort goes away.
- Continue drinking until the watery stool is clear and free of solid matter. This usually requires 3 liters and it is best to drink all of the solution.
- **Do not take undissolved polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution's powder that has not been mixed with water (diluted), it may increase your risk of nausea, vomiting and fluid loss (dehydration).**
- Each jug of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution must be reconstituted with water (diluted) to 4 liters total volume before drinking.
- Do not take other laxatives while taking polyethylene glycol 3350, sodium chloride,

sodium bicarbonate and potassium chloride for oral solution.

- **Do not eat solid foods on the day before your colonoscopy and until after your colonoscopy** . Drink only clear liquids:
  - the day before your colonoscopy
  - while taking polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution
  - after taking polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution until 2 hours before your colonoscopy

What are the possible side effects of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution?

Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution can cause serious side effects, including:

- **See Section "What is the most important information I should know about polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution?"**
- **changes in certain blood tests.** Your healthcare provider may do blood tests after you take polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution to check your blood for changes. Tell your healthcare provider if you have any symptoms of too much fluid loss, including:
  - vomiting
  - nausea
  - bloating
  - dizziness
  - stomach (abdominal) cramping
  - headache
  - urinate less than usual
  - trouble drinking clear liquid
- **heart problems. Polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution may cause irregular heartbeats.**
- **seizures**
- **ulcers of the bowel or bowel problems (ischemic colitis).** Tell your healthcare provider right away if you have severe stomach-area (abdomen) pain or rectal bleeding.

The most common side effects of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution include:

- nausea
- stomach (abdominal) fullness
- bloating
- stomach (abdominal) cramps
- vomiting
- anal irritation

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of polyethylene glycol 3350, sodium chloride,

sodium bicarbonate and potassium chloride for oral solution. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution?

- Store polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution at room temperature, between 59ºF to 86ºF (15ºC to 30ºC).

Keep polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and all medicines out of the reach of children.

General information about the safe and effective use of polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution for a condition for which it was not prescribed. Do not give polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution to other people, even if they are going to have the same procedure you are. It may harm them.

This Medication Guide summarizes important information about polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information that is written for healthcare professionals.

For more information go to www.strides.com or call Strides Pharma Inc. at 1-877-244-9825.

What are the ingredients in polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution?

Active ingredients: polyethylene glycol 3350 USP-NF, sodium bicarbonate USP, sodium chloride USP and potassium chloride USP.

Inactive ingredients: Flavor lemon or flavor orange (in its respective flavor pack) with acesulfame potassium

Manufactured by:

Strides Pharma Science Limited

Bengaluru – 562106, India.

Distributed by:

Strides Pharma Inc.

East Brunswick, NJ 08816

This Medication Guide has been approved by the U.S. Food and Drug Administration.

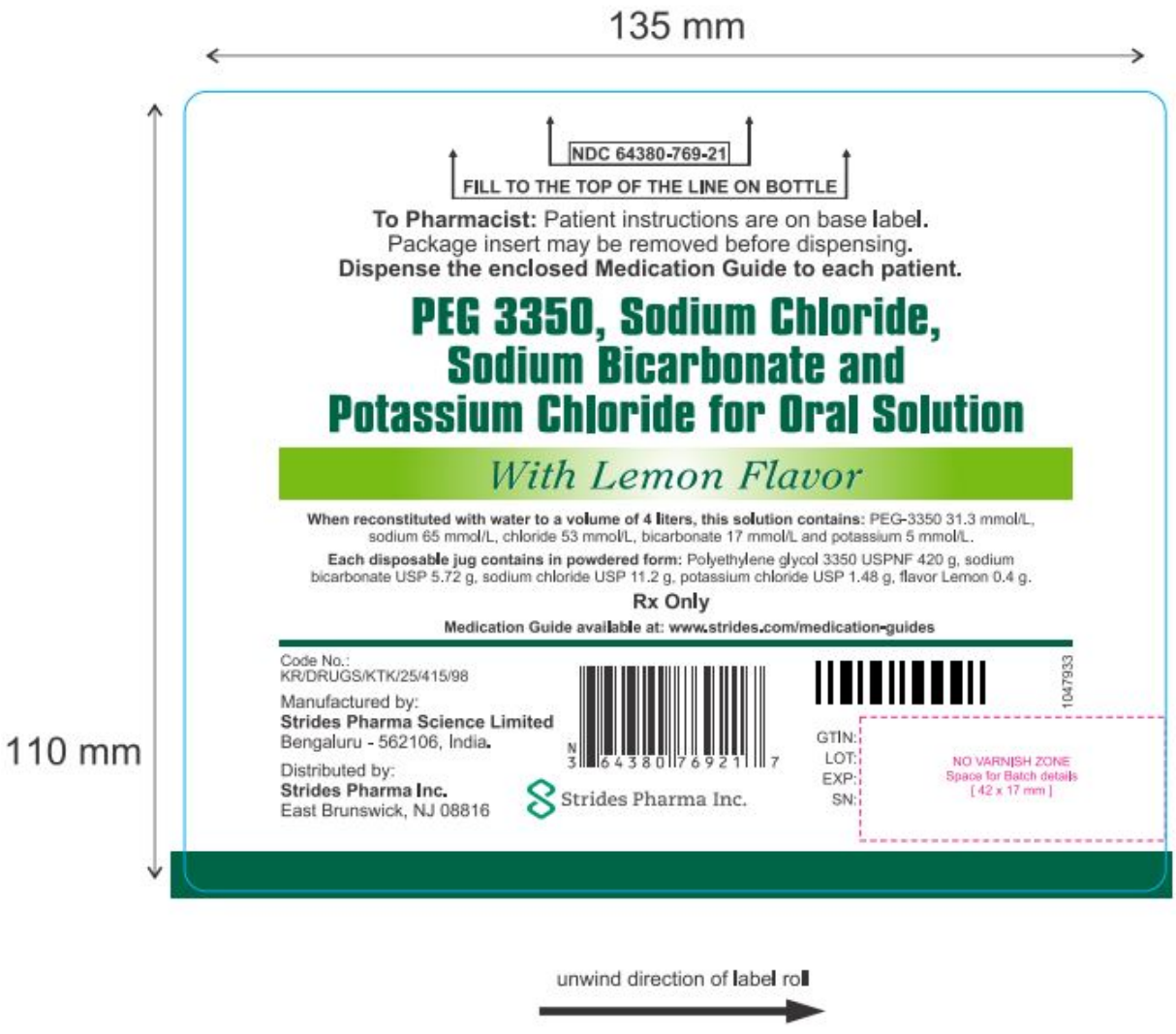
Revised: 10/2022

Medication Guide available at:

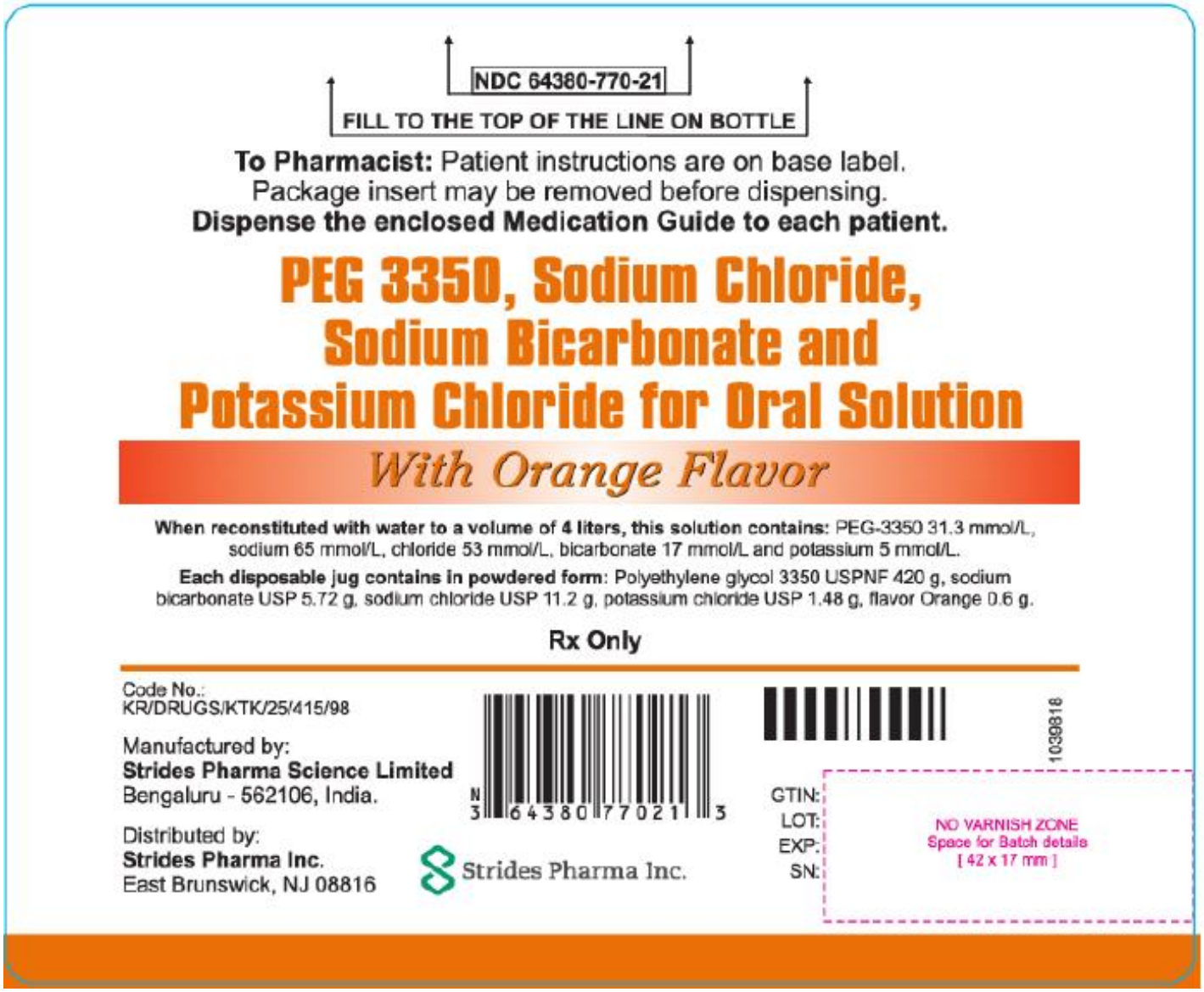
www.strides.com/medication-guides

PRINCIPAL DISPLAY PANEL - UNFLAVORED PACK

PRINCIPAL DISPLAY PANEL - LEMON FLAVORED PACK



PRINCIPAL DISPLAY PANEL - ORANGE FLAVORED PACK



POLYETHYLENE GLYCOL 3350, SODIUM CHLORIDE, SODIUM BICARBONATE AND POTASSIUM CHLORIDE - UNFLAVORED

polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride - unflavored powder, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:64380-768
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL 3350 - UNII:G2M7P15E5P)	POLYETHYLENE GLYCOL 3350	420 g in 4 L
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	11.2 g in 4 L

SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	5.72 g in 4 L
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	1.48 g in 4 L

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64380-768-21	4 L in 1 JUG; Type 0: Not a Combination Product	04/14/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204559	04/14/2015	

POLYETHYLENE GLYCOL 3350, SODIUM CHLORIDE, SODIUM BICARBONATE AND POTASSIUM CHLORIDE WITH LEMON FLAVOR

polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride with lemon flavor powder, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:64380-769
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL 3350 - UNII:G2M7P15E5P)	POLYETHYLENE GLYCOL 3350	420 g in 4 L
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	11.2 g in 4 L
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM BICARBONATE	5.72 g in 4 L
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (CHLORIDE ION - UNII:Q32ZN48698, POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	1.48 g in 4 L

Inactive Ingredients	
Ingredient Name	**Strength**
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
LEMON (UNII: 24RS0A988O)	
LIME (CITRUS) (UNII: 8CZS546954)	

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor	LEMON	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:64380-769-21	4 L in 1 JUG; Type 0: Not a Combination Product	04/14/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204559	04/14/2015	

POLYETHYLENE GLYCOL 3350, SODIUM CHLORIDE, SODIUM BICARBONATE AND POTASSIUM CHLORIDE WITH ORANGE FLAVOR

polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride with orange flavor powder, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:64380-770
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL 3350 - UNII:G2M7P15E5P)	POLYETHYLENE GLYCOL 3350	420 g in 4 L
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	11.2 g in 4 L
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM BICARBONATE	5.72 g in 4 L
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (CHLORIDE ION - UNII:Q32ZN48698, POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	1.48 g in 4 L

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ORANGE (UNII: 5EVU04N5QU)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor	ORANGE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64380-770-21	4 L in 1 JUG; Type 0: Not a Combination Product	04/14/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204559	04/14/2015	

Labeler - Strides Pharma Science Limited (650738743)

Registrant - Strides Pharma Science Limited (650738743)

Establishment

Name	Address	ID/FEI	Business Operations
Strides Pharma Science Limited		918513263	ANALYSIS(64380-768, 64380-769, 64380-770) , MANUFACTURE(64380-768, 64380-769, 64380-770)

Revised: 11/2022 Strides Pharma Science Limited