

POLYETHYLENE GLYCOL-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE AND SODIUM BICARBONATE - polyethylene glycol-3350, sodium chloride, potassium chloride and sodium bicarbonate powder, for solution
Novel Laboratories, Inc.

PEG-3350, Sodium Chloride, Sodium Bicarbonate and Potassium Chloride for Oral Solution with Flavor pack

Rx Only

DESCRIPTION

PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE is a white powder for reconstitution containing 420 g polyethylene glycol 3350, 5.72 g sodium bicarbonate, 11.2 g sodium chloride, 1.48 g potassium chloride and one 2 g flavor pack (optional). When dissolved in water to a volume of 4 liters, PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution) is an isosmotic solution, for oral administration, having a pleasant mineral water taste. PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE is administered orally or via nasogastric tube as a gastrointestinal lavage. PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE Flavor Pack is available in lemon flavor. This preparation can be used without the addition of a PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE Flavor Pack.

CLINICAL PHARMACOLOGY

PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE induces a diarrhea which rapidly cleanses the bowel, usually within four hours. The osmotic activity of polyethylene glycol 3350 and the electrolyte concentration result in virtually no net absorption or excretion of ions or water. Accordingly, large volumes may be administered without significant changes in fluid or electrolyte balance.

INDICATIONS AND USAGE

PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE for Oral Solution is indicated for bowel cleansing prior to colonoscopy.

CONTRAINDICATIONS

PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE is contraindicated in patients known to be hypersensitive to any of the components. PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE is contraindicated in patients with ileus, gastrointestinal obstruction, gastric retention, bowel perforation, toxic colitis or toxic megacolon.

WARNINGS

PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE Flavor Pack is for use only in combination with the contents of the accompanying 4 liter container. No additional ingredients, e.g. flavorings, should be added to the solution. PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE should be used with caution in

patients with severe ulcerative colitis. Use of PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, and SODIUM BICARBONATE 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 1 child and hypokalemia has been reported in 3 children.

PRECAUTIONS

General

Patients with impaired gag reflex, unconscious, or semiconscious patients, and patients prone to regurgitation or aspiration should be observed during the administration of PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE, especially if it is administered via nasogastric tube. If a patient experiences severe bloating, distention or abdominal pain, administration should be slowed or temporarily discontinued until the symptoms abate. If gastrointestinal obstruction or perforation is suspected, appropriate studies should be performed to rule out these conditions before administration of PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE.

Information for Patients

PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE produces a watery stool which cleanses the bowel before examination. Prepare the solution according to the instructions on the bottle. It is more palatable if chilled. For best results, no solid food should be consumed during the 3 to 4 hour period before drinking the solution, but in no case should solid foods be eaten within 2 hours of taking PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE.

Adults drink 240 mL (8 oz.) every 10 minutes. Continue drinking until the watery stool is clear and free of solid matter. This usually requires at least 3 liters. Any unused portion should be discarded. Pediatric patients (aged 6 months or greater) drink 25 mL/kg/hour. Continue drinking until the watery stool is clear and free of solid matter. Any unused portion should be discarded. Rapid drinking of each portion is better than drinking small amounts continuously. The first bowel movement should occur approximately one hour after the start of PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE administration. You may experience some abdominal bloating and distention before the bowels start to move. If severe discomfort or distention occur, stop drinking temporarily or drink each portion at longer intervals until these symptoms disappear.

Use of PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, and SODIUM BICARBONATE 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 1 child and hypokalemia has been reported in 3 children.

Drug Interactions

Oral medication administered within one hour of the start of administration of PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE may be flushed from the gastrointestinal tract and not absorbed.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenic and reproductive studies with animals have not been performed.

Pregnancy

Category C. Animal reproduction studies have not been conducted with PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE. It is also not known whether PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE can cause

fetal harm when administered to a pregnant woman or can affect reproductive capacity. PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness of PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE in pediatric patients aged 6 months and older is supported by evidence from adequate and well-controlled clinical trials of PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE in adults with additional safety and efficacy data from published studies of similar formulations.

ADVERSE REACTIONS

Nausea, abdominal fullness and bloating are the most common adverse reactions (occurring in up to 50% of patients) to administration of PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE. Abdominal cramps, vomiting and anal irritation occur less frequently. These adverse reactions are transient and subside rapidly. Isolated cases of urticaria, rhinorrhea, dermatitis and (rarely) anaphylactic reaction have been reported which may represent allergic reactions. Published literature contains isolated reports of serious adverse reaction following the administration of PEG-ELS products in patients over 60 years of age. These adverse events include upper GI bleeding from Mallory-Weiss Tear, esophageal perforation, asystole, sudden dyspnea with pulmonary edema, and "butterfly-like" infiltrate on chest X-ray after vomiting and aspirating PEG.

DOSAGE AND ADMINISTRATION

PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE is usually administered orally, but may be given via nasogastric tube to patients who are unwilling or unable to drink the solution. Ideally, the patient should fast for approximately three or four hours prior to PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE administration, but in no case should solid food be given for at least two hours before the solution is given.

Oral administration

Adults: At a rate of 240 mL (8 oz.) every 10 minutes, until the rectal effluent is clear or 4 liters are consumed. **Pediatric Patients (aged 6 months or greater):** At a rate of 25 mL/kg/hour, until the rectal effluent is clear. Rapid drinking of each portion is preferred to drinking small amounts continuously. **Nasogastric tube administration: Adults:** At a rate of 20 to 30 mL per minute (1.2 to 1.8 liters per hour). **Pediatric Patients (aged 6 months or greater):** At a rate of 25 mL/kg/hour, until the rectal effluent is clear.

The first bowel movement should occur approximately one hour after the start of PEG-3350, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE administration. Ingestion of 4 liters of PEG-3350, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE solution prior to gastrointestinal examination produces satisfactory preparation in over 95% of patients.

Various regimens have been used. One method is to schedule patients for examination in midmorning or later, allowing the patients three hours for drinking and an additional one hour period for complete bowel evacuation. Another method is to administer PEG 3350, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE on the evening before the examination.

Preparation of the solution: PEG 3350, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE solution is prepared by filling the container to the 4 liter mark with water and shaking vigorously several times to insure that the ingredients are dissolved. Dissolution is facilitated by using lukewarm water. The solution is more palatable if chilled before administration. However,

chilled solution is not recommended for infants. The reconstituted solution should be refrigerated and used within 48 hours. Discard any unused portion.

HOW SUPPLIED

PEG 3350, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE with Flavor Pack is supplied in a disposable jug, in powdered form, for oral administration as a solution following reconstitution. Each jug has an attached lemon flavor pack, in powdered form, for the addition of the flavor pack by the pharmacist prior to dispensing.

PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, AND SODIUM BICARBONATE FOR ORAL SOLUTION with Flavor Pack: PEG 3350 420 g, sodium bicarbonate 5.72 g, sodium chloride 11.2 g, potassium chloride 1.48 g and lemon flavor pack 2 g (optional). When made up to 4 liters volume with water, the solution contains PEG-3350 31.3 mmol/L, sodium 65 mmol/L, chloride 53 mmol/L, bicarbonate 17 mmol/L and potassium 5 mmol/L.

STORAGE: Store in sealed container at 25°C. When reconstituted, keep solution refrigerated. Use within 48 hours. Discard unused portion.

NDC 40032-050-19

Manufactured by:

Novel Laboratories, Inc.

Somerset, NJ 08873

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

↑ ↑ ↑
FILL TO THE TOP OF THE LINE ON BOTTLE

EXP:

LOT:

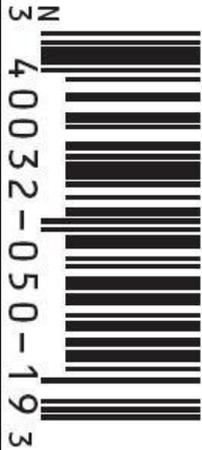
**PEG-3350, Sodium Chloride, Sodium Bicarbonate and Potassium Chloride
for Oral Solution with Flavor Pack**

1. PEG-3350, Sodium Chloride, Sodium Bicarbonate and Potassium Chloride for Oral Solution with Flavor Pack is available in Lemon flavor. This preparation can be used with or without lemon flavor pack. The pharmacist will add lemon flavor pack prior to dispensing (See packet instructions).
2. Add lukewarm drinking water to the fill mark (4 liters) on the bottle. Do not add any other ingredients, flavors, etc.
3. Cap bottle securely and shake vigorously several times to ensure that the ingredients are dissolved.
4. For best results, no solid food should be consumed for the 3 to 4 hour period before drinking the solution, but in no case should food be eaten within two hours of taking PEG-3350, Sodium Chloride, Sodium Bicarbonate and Potassium Chloride for Oral Solution.
5. **Adults** drink one 8 ounce (240 mL) cup of the solution rapidly every 10 minutes. Continue drinking until the watery stool is clear and free of solid matter. This usually requires at least 3 liters. **Pediatric Patients (aged 6 months or greater)** drink at a rate of 25 mL/kg/hour. A loose watery bowel movement should result in approximately one hour. Continue drinking until the watery stool is clear and free of solid matter.

NOTE: The solution is more palatable if chilled in the refrigerator before drinking. However, chilled solution is not recommended for infants. Keep reconstituted solution refrigerated. Use within 48 hours. Discard unused portion.

NDC 40032-050-19

Manufactured by Novel Laboratories, Inc. Somerset, NJ 08873



ADVERSE REACTIONS: Nausea, abdominal fullness and bloating are the most common adverse reactions (occurring in up to 50% of patients) to administration of PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE. Abdominal cramps, vomiting and anal irritation occur less frequently. These adverse reactions are transient and subside rapidly. Isolated cases of urticaria, rhinitis, dermatitis and (rarely) anaphylactic reaction have been reported which may represent allergic reactions. Published literature contains isolated reports of serious adverse reaction following the administration of PEG-ELS products in patients over 60 years of age. These adverse events include upper GI bleeding from Mallory-Weiss Tear, esophageal perforation, ascites, sudden dyspnea with pulmonary edema, and "butterfly-like" infiltrate on chest X-ray after vomiting and aspirating PEG.

DOSE AND ADMINISTRATION: PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE is usually administered orally, but may be given via nasogastric tube to patients who are unwilling or unable to drink the solution. Ideally, the patient should fast for approximately 12 hours prior to PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE administration, but in no case should solid food be given for at least 2 hours prior to administration. The solution is given over a 4-hour period. **Oral administration:** Adults: At a rate of 240 mL (8 oz.) every 10 minutes, until the total volume of 240 mL (8 oz.) is administered. **Pediatric Patients (aged 6 months or greater):** At a rate of 25 mL/kg/hour, until the total volume of 25 mL/kg/hour is administered. **Nasogastric tube administration:** Adults: At a rate of 20 to 30 mL (up to 1.8 mL/kg/hour) until the total volume is clear. (aged 6 months or greater): At a rate of 25 mL/kg/hour until the total volume is clear.

The first bowel movement should occur approximately one hour after the start of PEG-3350, SODIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE administration. If no bowel movement occurs within 24 hours, a physician should be consulted. Various regimens have been used. One method is to schedule patients for examination in the morning or later, allowing the patients three hours for drinking and an additional one hour period for complete bowel evacuation. Another method is to administer PEG-3350, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE on the evening before the examination.

Preparation of the solution: PEG-3350, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE solution is prepared by filling the container to the 4 liter mark with water and shaking vigorously several times to insure that the ingredients are dissolved. Dissolution is facilitated by using lukewarm water. The solution is more palatable if chilled before administration. However, chilled solution is not recommended for infants. The reconstituted solution should be refrigerated and used within 48 hours. Discard any unused portion.

HOW SUPPLIED: PEG-3350, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE with Flavor Pack is supplied in a disposable jug, in powdered form, for oral administration as a solution following reconstitution. Each jug has an attached lemon flavor pack, in powdered form, for the addition of the flavor pack by the pharmacist prior to dispensing.

ATE FOR ORAL SOLUTION WITH FLAVOR PACK: PEG-3350, 420 g, sodium bicarbonate 5.72 g, sodium chloride 11.2 g, potassium chloride 1.48 g and lemon flavor pack 2 g (optional). When made up to 4 liters volume with water, the solution contains PEG-3350 31.3 mmol/L, sodium 85 mmol/L, chloride 53 mmol/L, bicarbonate 17 mmol/L, and potassium 5 mmol/L.

STORAGE: Store in sealed container at 25°C. When reconstituted, keep solution refrigerated. Use within 48 hours. Discard unused portion.

Manufactured by: Novel Laboratories, Inc. Somerset, NJ 08873

NLB-059-4L-01

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

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

| Product Information | | | |
|-------------------------|-------------------------|--------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:40032-050 |
| 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 438.4 g |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698) | SODIUM CHLORIDE | 11.2 g in 438.4 g |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:L4YR4M0NH37) | SODIUM BICARBONATE | 5.72 g in 438.4 g |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152) | POTASSIUM CHLORIDE | 1.48 g in 438.4 g |

| Inactive Ingredients | |
|----------------------|----------|
| Ingredient Name | Strength |
| | |

PEG-3350, Sodium Chloride, Sodium Bicarbonate and Potassium Chloride for Oral Solution with Flavor pack, Rx Only

DESCRIPTION: PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE is a white powder for oral administration. Each 4 liter polyethylene glycol 3350, 5.72 g, sodium chloride, 11.2 g, potassium chloride, 1.48 g, and sodium bicarbonate (one 2 g lemon flavor pack) when dissolved in water to a volume of 4 liters, PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE (PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE) is an isotonic solution, for oral administration, having a pleasant mineral water taste.

PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE is administered orally or via nasogastric tube as a gastrointestinal lavage. PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE Flavor Pack is available in lemon flavor. This preparation can be used without the addition of a PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE Flavor Pack.

CLINICAL PHARMACOLOGY: PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE induces a diarrhea which rapidly clears the bowel, usually within four hours. The osmotic activity of polyethylene glycol 3350 and the electrolyte concentration result in virtually no net absorption of ions or water. Accordingly, large volumes may be administered without significant changes in fluid or electrolyte balance.

INDICATIONS AND USAGE: PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE for Oral Solution is indicated for bowel cleansing prior to colonoscopy.

CONTRAINDICATIONS: PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE is contraindicated in patients known to be hypersensitive to any of the components. PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE is contraindicated in patients with ileus, gastrointestinal obstruction, gastric retention, bowel perforation, toxic colitis or toxic megacolon.

WARNINGS: PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE Flavor Pack is for use only in combination with the contents of the accompanying instruction insert. PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE should be used with caution in patients with severe ulcerative colitis. Use of PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, and SODIUM BICARBONATE in children younger than 2 years of age should be carefully monitored for occurrence of possible hyponatremia, as this solution has no cationic substrate. Dehydration has been reported in 1 child and hypokalemia has been reported in 3 children.

PRECAUTIONS: Patients with impaired gag reflex, unconscious, or semiconscious patients, and patients prone to regurgitation or aspiration should be observed during the administration of PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE, especially if it is administered via nasogastric tube. If a patient experiences severe bloating, distention or abdominal pain, administration should be slowed or temporarily discontinued until the symptoms abate. If gastrointestinal obstruction or perforation is suspected, appropriate studies should be performed to rule out these conditions before administration of PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE.

Information for patients: PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE produces a watery stool which cleanses the bowel before examination. Prepare the solution according to the instructions on the bottle. It is more palatable if chilled. For best results, no solid food should be consumed during the 3 to 4 hour period before drinking the solution, but in no case should solid foods be eaten within 2 hours of taking PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE.

Adults drink 240 mL (8 oz.) every 10 minutes. Continue drinking until the watery stool is clear and free of solid matter. This usually requires at least 3 liters. Any unused portion should be discarded. Pediatric patients (aged 6 months or greater) drink 25 mL/kg/hour. Continue drinking until the watery stool is clear and free of solid matter. Any unused portion should be discarded. Rapid drinking of each portion is better than drinking small amounts continuously. The first bowel movement should occur approximately one hour after the start of administration. You may experience some abdominal bloating and distention before the bowels start to move. If severe discomfort or distention occurs, stop drinking temporarily or discontinue drinking until the discomfort subsides. Use of PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, and SODIUM BICARBONATE in children younger than 2 years of age should be carefully monitored for occurrence of possible hyponatremia, as this solution has no cationic substrate. Dehydration has been reported in 1 child and hypokalemia has been reported in 3 children.

Drug Interactions: Oral medication administered within one hour of the start of administration of PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE may be less effective. PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE may not be absorbed. **Concomitant Use:** Medication administered prior to, during, or after administration of PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE and reproductive studies with animals have not been performed.

Pregnancy: Category C. Animal reproduction studies have not been conducted with PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE. It is also not known whether PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE should be given to a pregnant woman only if clearly needed.

Pediatric Use: Safety and effectiveness of PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE in pediatric patients aged 6 months and older is supported by evidence from adequate and well-controlled clinical trials of PEG-3350, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM BICARBONATE in adults with additional safety and efficacy data from published studies of similar formulations.

NDC 40032-050-19

↑ FILL TO THE TOP OF THE LIME ON BOTTLE ↓

TO PREPARE: Patient instructions on on base label. Discard unused flavor pack. Package insert may be removed before dispensing.

PEG-3350 (420 g), Sodium Chloride (11.2 g), Sodium Bicarbonate (5.72 g) and Potassium Chloride (1.48 g) for Oral Solution

With Flavor Pack

When reconstituted with water to a volume of 4 liters, this solution contains PEG-3350 31.3 mmol/L, sodium 85 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 420 g, sodium bicarbonate 5.72 g, sodium chloride 11.2 g, potassium chloride 1.48 g.

Novel Laboratories Inc. NJ 08873

PULL DOWN TO OPEN

| | |
|--|--|
| ALPHA-TOCOPHEROL, DL- (UNII: 7QWA1RIO01) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) | |
| ACACIA (UNII: 5C5403N26O) | |

Product Characteristics

| | | | |
|----------|-------|--------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | LEMON | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:40032-050-19 | 438.4 g in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA090019 | 05/28/2009 | |

Labeler - Novel Laboratories, Inc. (793518643)

Registrant - Novel Laboratories, Inc. (793518643)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|---------------------|
| Novel Laboratories, Inc. | | 793518643 | MANUFACTURE, REPACK |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|---------------------|
| Dow Chemical Company | | 801038019 | API MANUFACTURE |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| Mallinckrodt Baker Inc. | | 001213481 | API MANUFACTURE |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|---------------------|
| Church and Dwight Co, Inc. | | 001211952 | API MANUFACTURE |