SUPREP BOWEL PREP- sodium sulfate, potassium sulfate, magnesium sulfate solution, concentrate

Braintree Laboratories, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use SUPREP Bowel Prep Kit safely and effectively. See full prescribing information for SUPREP Bowel Prep Kit

SUPREP Bowel Prep Kit (sodium sulfate, potassium sulfate, and magnesium sulfate) Oral Solution

Initial U.S. Approval: 08/2010

RECENT MAJOR CHANGES

Indications and Usage (1)	8/2020
Dosage and Administration (2.1, 2.4)	8/2020

INDICATIONS AND USAGE

SUPREP Bowel Prep Kit is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adult and pediatric patients 12 years of age and older. (1)

DOSAGE AND ADMINISTRATION

Preparation and Administration (2.2)

- Must dilute in water prior to ingestion.
- Administration of two bottles of SUPREP Bowel Prep Kit is required for a complete preparation for colonoscopy. One bottle is equivalent to one dose.
- Must consume additional water after each dose.
- Stop consumption of all fluids at least 2 hours before the colonoscopy.

Recommended Dosage and Administration

- Split-Dose (two-day) regimen consists of two doses of SUPREP Bowel Prep Kit: first dose during the evening prior to colonoscopy and second dose the next day, during the morning of colonoscopy. (2.1, 2.3, 2.4)
- Recommended SUPREP Bowel Prep Kit dosage is:
  - **Adults:** Two 6-ounce doses. (2.3)
  - **Pediatric Patients 12 Years of Age and Older:** Two 4.5-ounce doses. (2.4)
- For complete information on preparation before colonoscopy and administration of the dosage regimen, see full prescribing Information. (2.1, 2.2, 2.3, 2.4)

DOSAGE FORMS AND STRENGTHS

- SUPREP Bowel Prep Kit **(for adults)**: Two bottles each containing 6 ounces of an oral solution of 17.5 grams sodium sulfate, 3.13 grams potassium sulfate, and 1.6 grams magnesium sulfate. (3)
- SUPREP Bowel Prep Kit **(for pediatric patients 12 years of age and older)**: Two bottles each containing 4.5-ounces of an oral solution of 13.13 grams sodium sulfate, 2.35 grams potassium sulfate, and 1.2 grams magnesium sulfate. (3)

CONTRAINDICATIONS

- Gastrointestinal obstruction or ileus (4, 5.6)
- Bowel perforation (4, 5.6)
- Toxic colitis or toxic megacolon (4)
- Gastric retention (4)
- Hypersensitivity to any ingredient (4)

WARNINGS AND PRECAUTIONS

- Risk of fluid and electrolyte abnormalities: Encourage adequate hydration, assess concurrent medications, and consider laboratory assessments prior to and after each use. (5.1, 7.1)
- Cardiac arrhythmias: Consider pre-dose and post-colonoscopy ECGs in patients at increased risk. (5.2)
- Seizures: Use caution in patients with a history of seizures and patients at increased risk of seizures, including

medications that lower the seizure threshold. (5.3, 7.1)
- Patients with renal impairment or taking concomitant medications that affect renal function: Use caution, ensure adequate hydration and consider laboratory testing. (5.4, 7.1)
- Suspected GI obstruction or perforation: Rule out the diagnosis before administration. (4, 5.6)
- Patients at risk for aspiration: Observe during administration. (5.7)

ADVERSE REACTIONS

Most common adverse reactions are:
- Adults (>2%): overall discomfort, abdominal distention, abdominal pain, nausea, and vomiting. (6.1)
- Pediatric Patients (>10%): nausea, abdominal pain, abdominal bloating and vomiting. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Braintree Laboratories, Inc. at 1-800-874-6756 or FDA at 1-800-FDA-1088 or ***www.fda.gov/medwatch.***

DRUG INTERACTIONS

Drugs that increase risk of fluid and electrolyte imbalance. (7.1)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 8/2020

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

SUPREP Bowel Prep Kit is indicated for cleansing of the colon as a preparation for colonoscopy in adult and pediatric patients 12 years of age and older.

2 DOSAGE AND ADMINISTRATION

2.1 Dosage and Adminstration Overview

Administration of two bottles of SUPREP Bowel Prep Kit and additional water is required for a complete preparation for colonoscopy. One bottle of SUPREP Bowel Prep Kit is equivalent to one dose. SUPREP Bowel Prep Kit is supplied in two dosage strengths *[see Dosage Forms and Strengths (3)]* . The recommended dosage is:

- **Adults:** Two 6-ounce doses *[see Dosage and Administration (2.3)]* .
- **Pediatric patients 12 years of age and older:** Two 4.5-ounce doses *[see Dosage and Administration (2.4)]* .

2.2 Important Preparation and Administration Instructions

- Correct fluid and electrolyte abnormalities before treatment with SUPREP Bowel Prep Kit *[see Warnings and Precautions (5.1)]*
- Must dilute SUPREP Bowel Prep Kit in water before ingestion.
- Must consume additional water after each dose of SUPREP Bowel Prep Kit.
- On the day before colonoscopy, consume only a light breakfast or clear liquids (e.g., water, strained fruit juice without pulp, lemonade, plain coffee or tea, chicken broth, gelatin dessert without fruit). On the day of the colonoscopy only consume clear liquids up to two hours prior to colonoscopy.
- Do not eat solid food or drink milk or eat or drink anything colored red or purple.
- Do not drink alcohol.
- Do not take other laxatives while taking SUPREP Bowel Prep Kit.
- Do not take oral medications within one hour of starting each dose of SUPREP Bowel Prep Kit.
- If taking tetracycline or fluoroquinolone antibiotics, iron, digoxin, chlorpromazine, or penicillamine, take these medications at least 2 hours before and not less than 6 hours after administration of SUPREP Bowel Kit *[see Drug Interactions (7.2)]* .
- Stop consumption of all fluids at least 2 hours prior to the colonoscopy.

2.3 Recommended Dosage and Administration for Adults

The recommended Split-Dose (two-day) regimen for **adults** consists of two 6-ounce doses of SUPREP Bowel Prep Kit: the first dose during the evening prior to colonoscopy and the second dose the next day, during the morning of the colonoscopy.

Each dose consists of one bottle of SUPREP Bowel Prep Kit with additional water. The total volume of liquid required for colon cleansing (using two bottles) is 3 quarts. The following are recommended dosage and administration instructions for adults:

Dose 1 – On the Day Prior to Colonoscopy:

- May consume a light breakfast, or only clear liquids (no solid food).
- In the evening before the procedure, pour the contents of one bottle of SUPREP Bowel Prep Kit into the mixing container provided.
- Add cool drinking water to the 16-ounce fill line on the container, mix, and drink the entire amount.
- Drink two additional containers filled with water to the 16-ounce fill line over the next hour.

Dose 2 - Day of Colonoscopy:

- Continue to consume only clear liquids.
- In the morning (10 to 12 hours after the evening dose) on the day of the procedure, pour the contents of the second bottle of SUPREP Bowel Prep Kit into the mixing container provided.
- Add cool drinking water to the 16-ounce fill line on the container, mix, and drink the entire amount.
- Drink two additional containers filled with water to the 16-ounce fill line over the next hour.
- Complete all solution of SUPREP Bowel Prep Kit and required water at least two hours prior to colonoscopy.

2.4 Recommended Dosage and Administration for Pediatric Patients 12 Years of Age and Older

The recommended Split-Dose (two-day) regimen **for pediatric patients 12 years of age and older** consists of two 4.5-ounce doses of SUPREP Bowel Prep Kit: the first dose during the evening prior to colonoscopy and the second dose the next day, during the morning of the colonoscopy.

Each dose consists of one bottle of SUPREP Bowel Prep Kit with additional water. The total volume of liquid required for colon cleansing (using two bottles) is 2.25 quarts. The following are recommended dosage and administration instructions for pediatric patients 12 years of age and older and/or their caregivers:

Dose 1 – On the Day Prior to Colonoscopy:

• May consume a light breakfast, or only clear liquids (no solid food).
• In the evening before the procedure, pour the contents of one bottle of SUPREP Bowel Prep Kit into the mixing container provided.
• Add cool drinking water to the 12-ounce fill line on the container, mix, and drink the entire amount.
• Drink two additional containers filled with water to the 12-ounce fill line over the next hour.

Dose 2 – Day of Colonoscopy:

• Continue to consume only clear liquids.
• In the morning (10 to 12 hours after the evening dose) on the day of the procedure, pour the contents of the second bottle of SUPREP Bowel Prep Kit into the mixing container provided.
• Add cool drinking water to the 12-ounce fill line on the container, mix, and drink the entire amount.
• Drink two additional containers filled with water to the 12-ounce fill line over the next hour.
• Complete all solution of SUPREP Bowel Prep Kit solution and required water at least two hours prior to colonoscopy.

3 DOSAGE FORMS AND STRENGTHS

- SUPREP Bowel Prep Kit **(for adults)**: Two bottles each containing 6 ounces of an oral solution of 17.5 grams sodium sulfate, 3.13 grams potassium sulfate, and 1.6 grams magnesium sulfate as a clear to slightly hazy liquid.

- SUPREP Bowel Prep Kit **(for pediatric patients 12 years of age and older)**: Two bottles each containing 4.5 ounces of an oral solution of 13.13 grams sodium sulfate, 2.35 grams potassium

sulfate, and 1.2 grams magnesium sulfate as a clear to slightly hazy liquid.

When diluted as directed, the solution is clear and colorless.

4 CONTRAINDICATIONS

SUPREP Bowel Prep Kit is contraindicated in the following conditions:

- Gastrointestinal obstruction or ileus *[see Warnings and Precautions (5.6)]*
- Bowel perforation *[see Warnings and Precaution (5.6)]*
- Toxic colitis or toxic megacolon
- Gastric retention
- Hypersensitivity to any of the ingredients in SUPREP Bowel Prep Kit

5 WARNINGS AND PRECAUTIONS

5.1 Serious Fluid and Serum Chemistry Abnormalities

Advise all patients to hydrate adequately before, during, and after the use of SUPREP Bowel Prep Kit. If a patient develops significant vomiting or signs of dehydration after taking SUPREP Bowel Prep Kit, consider performing post-colonoscopy lab tests (electrolytes, creatinine, and BUN).

Fluid and electrolyte disturbances can lead to serious adverse events including cardiac arrhythmias, seizures and renal impairment. Correct fluid and electrolyte abnormalities before treatment with SUPREP Bowel Prep Kit. Use SUPREP Bowel Prep Kit with caution in patients with 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)]* .

SUPREP Bowel Prep Kit can cause temporary elevations in uric acid *[see Adverse Reactions (6.1)]* . Uric acid fluctuations in patients with gout may precipitate an acute flare. The potential for uric acid elevation should be considered before administering SUPREP Bowel Prep Kit to patients with gout or other disorders of uric acid metabolism.

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 SUPREP Bowel Prep Kit 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). Consider pre-dose and post-colonoscopy ECGs in patients at increased risk of serious cardiac arrhythmias.

5.3 Seizures

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

Use caution when prescribing SUPREP Bowel Prep Kit 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 *[see Drug Interactions (7.1)]* .

5.4 Use in Patients with Risk of Renal Injury

Use SUPREP Bowel Prep Kit with caution in 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) *[see Drug Interactions (7.1)]* . These patients may be at risk for renal injury. Advise these patients of the importance of adequate hydration with SUPREP Bowl Prep Kit and consider performing baseline and post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN) in these patients *[see Use in Specific Populations (8.6)]* .

5.5 Colonic Mucosal Ulcerations and Ischemic Colitis

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 SUPREP Bowel Prep Kit may increase these risks *[see Drug Interactions (7.3)]* . Consider the potential for mucosal ulcerations resulting from the bowel preparation 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 SUPREP Bowel Prep Kit *[see Contrandications (4)]* .

Use with caution in patients with severe active ulcerative colitis.

5.7 Aspiration

Patients with impaired gag reflex or other swallowing abnormalities are at risk for regurgitation or aspiration of SUPREP Bowel Prep Kit solution. Observe these patients during administration of SUPREP Bowel Prep Kit solution. Use with caution in these patients.

6 ADVERSE REACTIONS

The following important adverse reactions for bowel preparations 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)]*
- Use in Patients with Risk of Renal Injury *[see Warnings and Precautions (5.4)]*
- Colonic Mucosal Ulceration and Ischemic 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)]*

6.1 Clinical Studies Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in clinical studies of another drug and may not reflect the rates observed in practice.

Adults

The safety of SUPREP Bowel Prep Kit was evaluated in a multi-center, randomized, active controlled trial in 379 adult patients undergoing colonoscopy *[see Clinical Studies (14)]* .

Most Common Adverse Reactions

Table 1 shows the most common adverse reactions reported in at least 2% of patients receiving SUPREP Bowel Prep Kit or the control (a bowel prep containing polyethylene glycol and electrolytes (PEG + E)) administered in split-dose (2-day) regimens.

Table 1: Common Adverse Reactions* in Adult Patients Undergoing Colonoscopy in a Randomized, Active Controlled Trial

Symptom	Split-Dose (2-Day) Regimen	
	SUPREP % N=190	PEG + E product % N=189
Overall Discomfort	54	67
Abdominal Distension	40	52
Abdominal Pain	36	43
Nausea	36	33
Vomiting	8	4

* reported in at least 2% of patients

Laboratory Abnormalities

Table 2 shows the most common laboratory abnormalities (at least 10% in either treatment group and more than 2% difference between groups) for patients who developed new abnormalities of important electrolytes and uric acid after completing the bowel preparation with either SUPREP Bowel Prep Kit or PEG+E administered as a split-dose (2-day) regimen.

Table 2: Adult Patients with Normal Baseline Serum Chemistry with A Shift to an Abnormal Value While on the Split-Dose (2-Day) Regimen [1]

		Day of Colonoscopy N (%) [2]	Day 30 N (%) [2]
Bicarbonate (low)	SUPREP	20 (13)	7 (4)
	PEG + Electrolytes	24 (15)	4 (3)
Bilirubin, total (high)	SUPREP	14 (9)	0 (0)
	PEG + Electrolytes	20 (12)	3 (2)
BUN (high)	SUPREP	2 (2)	14 (11)
	PEG + Electrolytes	4 (3)	19 (15)
Calcium (high)	SUPREP	16 (10)	8 (5)
	PEG + Electrolytes	6 (4)	6 (4)
Chloride (high)	SUPREP	4 (2)	6 (4)
	PEG + Electrolytes	20 (12)	6 (4)
Osmolality (high)	SUPREP	8 (6)	NA
	PEG + Electrolytes	19 (13)	NA
Uric acid (high)	SUPREP	27 (24)	13 (12)
	PEG + Electrolytes	12 (10)	20 (17)

[1] The study was not designed to support comparative claims for the laboratory abnormalities reported in this table.

[2] Percent (n/N) of patients where N=number of patients with normal baseline who had abnormal values at the timepoint(s) of interest.

Less Common Adverse Reactions

AV Block (1 case) and CK increase.

Adverse Reactions with Unapproved Use

In another study of 408 adult patients, higher rates of the following adverse reactions and laboratory abnormalities were reported in patients treated with SUPREP Bowel Prep Kit as an evening-only (1-day)

regimen compared to the split-dose (2-day) regimen.

- overall discomfort, abdominal distention, nausea, and vomiting
- total bilirubin (high), BUN (high), creatinine (high), osmolality (high), potassium (high) and uric acid (high)

Administration of SUPREP Bowel Prep Kit in an evening-only (1-day) dosing regimen is not recommended.

Pediatrics 12 Years to 16 Years of Age

The safety of SUPREP Bowel Prep Kit was evaluated in a single dose-ranging clinical trial of 89 pediatric patients aged 12 years to 16 years *[see Clinical Studies (14)]* . In 26 pediatric patients who received SUPREP Bowel Prep Kit (two 4.5-ounce doses), the most common adverse reactions (> 10%) were nausea, abdominal pain, abdominal bloating, and vomiting.

7 DRUG INTERACTIONS

7.1 Drugs That May Increase Risks of Fluid and Electrolyte Abnormalities

Use caution when prescribing SUPREP Bowel Prep Kit to patients taking medications that increase the risk of 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 *[see Warnings and Precautions (5.1, 5.2, 5.3, 5.4)]*.

7.2 Potential for Reduced Drug Absorption

SUPREP Bowel Prep Kit can reduce the absorption of other co-administered drugs *[see Dosage and Administration (2.1)]* .

- Administer oral medications at least one hour before starting each dose of SUPREP Bowel Prep Kit.
- Administer tetracycline and fluoroquinolone antibiotics, iron, digoxin, chlorpromazine, and penicillamine at least 2 hours before and not less than 6 hours after administration of SUPREP Bowel Prep Kit to avoid chelation with magnesium.

7.3 Stimulant Laxatives

Concurrent use of stimulant laxatives and SUPREP Bowel Prep Kit may increase the risk of mucosal ulceration or ischemic colitis. Avoid use of stimulant laxatives (e.g., bisacodyl, sodium picosulfate) while taking SUPRPEP Bowel Prep Kit *[see Warnings and Precautions (5.5)]* .

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on SUPREP Bowel Prep Kit use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Animal reproductive studies have not been conducted with sodium sulfate, potassium sulfate, and magnesium sulfate (SUPREP Bowel Prep Kit).

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major bi rth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

8.2 Lactation

Risk Summary

There are no data available data on the presence of SUPREP Bowel Prep Kit in human or animal milk, the effects on the breastfed child, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for SUPREP Bowel Prep Kit and any potential adverse effects on the breastfed child from SUPREP Bowel Prep Kit or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness of SUPREP Bowel Prep Kit (two 4.5-ounce doses) have been established for cleansing of the colon as a preparation for colonoscopy in pediatric patients 12 years of age and older. Use of SUPPREP Bowel Prep Kit in this age group is supported by evidence from an adequate and well-controlled trial of SUPREP Bowel Prep Kit in adults and a single, dose-ranging, controlled trial in 89 pediatric patients 12 years to 16 years of age *[see Clinical Studies (14)]* . In the pediatric trial, SUPREP Bowel Prep Kit (two 6-ounce doses) did not demonstrate additional treatment benefit and more patients reported gastrointestinal adverse reactions compared to SUPREP Bowel Prep Kit (two 4.5-ounce doses). Therefore, SUPREP Bowel Prep Kit (two 6-ounce doses) is not recommended for pediatric patients 12 years of age and older *[see Dosage and Administration (2.3)]* . The safety profile of SUPREP Bowel Prep Kit (two 4.5-ounce doses) in this pediatric population was similar to that seen in adults *[see Adverse Reactions (6.1)]* .

The safety and effectiveness of SUPREP Bowel Prep Kit in pediatric patients less than 12 years of age have not been established.

8.5 Geriatric Use

Of the 375 patients who received SUPREP Bowel Prep Kit in clinical trials, 94 (25%) were 65 years of age or older, and 25 (7%) were 75 years of age or older. No overall differences in safety or effectiveness of SUPREP Bowel Prep Kit, administered as the recommended split-dose (2-day) regimen, were observed between geriatric patients and younger patients. Geriatric patients reported more vomiting when SUPREP Bowel Prep Kit was given as a one-day preparation (not a recommended regimen). Elderly patients are more likely to have decreased hepatic, renal or cardiac function and may be more susceptible to adverse reactions resulting from fluid and electrolyte abnormalities *[see Warnings and Precautions (5.1)]* .

8.6 Renal Impairment

Use SUPREP Bowel Prep Kit with caution in patients with renal impairment or patients taking concomitant medications that may affect renal function. These patients may be at risk for renal injury. Advise these patients of the importance of adequate hydration before, during and after use of SUPREP Bowel Prep Kit and consider performing baseline and post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN) in these patients *[see Warnings and Precautions (5.4)]* .

10 OVERDOSAGE

Overdosage of more than the recommended dose of SUPREP Bowel Prep Kit may lead to severe electrolyte disturbances, as well as dehydration and hypovolemia, with signs and symptoms of these disturbances. *[see Warnings and Precautions (5.1, 5.2, 5.3)].* Monitor for fluid and electrolyte disturbances and treat symptomatically.

11 DESCRIPTION

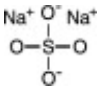
SUPREP Bowel Prep Kit (sodium sulfate, potassium sulfate, and magnesium sulfate) oral solution **(for adults)** is an osmotic laxative and is provided as two bottles each containing 6 ounces of solution. Each

bottle contains: 17.5 grams sodium sulfate, 3.13 grams potassium sulfate, and 1.6 grams magnesium sulfate. Inactive ingredients include: citric acid USP, flavoring ingredients, malic acid FCC, sodium benzoate, NF, sucralose, purified water, USP.

SUPREP Bowel Prep Kit (sodium sulfate, potassium sulfate, and magnesium sulfate) oral solution **(for pediatric patients 12 years of age and older)** is an osmotic laxative and is provided as two bottles each containing 4.5 ounces of solution. Each bottle contains: 13.13 grams sodium sulfate, 2.35 grams potassium sulfate, and 1.2 grams magnesium sulfate. Inactive ingredients include: citric acid USP, flavoring ingredients, malic acid FCC, sodium benzoate, NF, sucralose, purified water, USP.

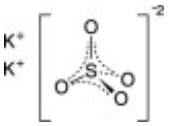
Sodium Sulfate, USP

The chemical name is Na_2SO_4. The average Molecular Weight is 142.04. The structural formula is:



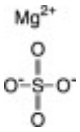
Potassium Sulfate, FCC, purified

The chemical name is K_2SO_4. The average Molecular Weight is 174.26. The structural formula is:



Magnesium Sulfate, USP

The chemical name is $MgSO_4$. The average Molecular Weight: 120.37. The structural formula is:



Each SUPREP Bowel Prep Kit also contains a polypropylene mixing container.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Sulfate salts provide sulfate anions, which are poorly absorbed. The osmotic effect of unabsorbed sulfate anions and the associated cations causes water to be retained within the gastrointestinal tract.

12.2 Pharmacodynamics

No formal pharmacodynamic studies have been conducted with SUPREP Bowel Prep Kit.

12.3 Pharmacokinetics

Absorption and Elimination

After administration of SUPREP Bowel Prep Kit in six healthy subjects, the time at which serum sulfate reached its highest point (Tmax) was approximately 17 hours after the first dose or approximately 5 hours after the second dose, and then declined with a half-life of 8.5 hours.

Excretion

Fecal excretion was the primary route of sulfate elimination.

Specific Populations

Patients with Renal Impairment

The disposition of sulfate after ingestion of SUPREP Bowel Prep Kit was studied in patients (N=6)

with moderate renal impairment (creatinine clearance of 30 to 49 mL/min). In patients with moderate renal impairment, mean AUC was 54% higher and mean Cmax was 44% higher, than healthy subjects.

The mean sulfate concentrations in healthy subjects and in patients with moderate renal impairment returned to their respective baselines by Day 6 after dose initiation. Urinary excretion of sulfate over 30 hours after the first dose was approximately 16% lower in patients with moderate renal impairment than in healthy subjects. These differences are not considered clinically meaningful.

Patients with Hepatic Impairment

The disposition of sulfate after ingestion of SUPREP Bowel Prep Kit was studied in patients (N=6) with mild to moderate hepatic impairment (Child-Pugh grades A and B). Systemic exposure of serum sulfate (AUC and Cmax) was similar between healthy subjects and patients with hepatic impairment. The mean sulfate concentrations in healthy subjects and in patients with mild to moderate hepatic impairment returned
to their respective baselines by Day 6 after dose initiation. Urinary excretion of sulfate over 30 hours after the first dose was similar between patients with hepatic impairment and healthy subjects.

13 NONCLINICAL TOXICOLOGY

13.2 Animal Toxicology and/or Pharmacology

The sulfate salts of sodium, potassium, and magnesium contained in SUPREP Bowel Prep Kit were administered orally (gavage) to rats and dogs up to 28 days up to a maximum daily dose of 5 grams/kg/day (approximately 0.9 and 3 times for rats and dogs, respectively, the recommended human dose of 44 grams/day or 0.89 grams/kg based on the body surface area). In rats, the sulfate salts caused diarrhea and electrolyte and metabolic changes, including hypochloremia, hypokalemia, hyponatremia, lower serum osmolality, and high serum bicarbonate. Significant renal changes included increased fractional sodium excretion, increased urinary sodium and potassium excretion, and alkaline urine in both males and females. In addition, creatinine clearance was significantly decreased in females at the highest dose. No microscopic renal changes were seen. In dogs, the sulfate salts caused emesis, excessive salivation, excessive drinking of water, and abnormal excreta (soft and/or mucoid feces and/or diarrhea) and increased urine pH and sodium excretion.

14 CLINICAL STUDIES

Adults

The colon cleansing efficacy of SUPREP Bowel Prep Kit was evaluated in a randomized, single-blind, active-controlled, multicenter study in adult patients scheduled to have a colonoscopy. There were 363 adult patients included in the efficacy analysis. Patients ranged in age from 20 to 84 years (mean age 55 years) and 54% were female. Race distribution was 86% Caucasian, 9% African-American, and 5% other.

Patients were randomized to one of the following two colon preparation regimens: SUPREP Bowel Prep Kit or a marketed polyethylene glycol (PEG) plus electrolytes bowel preparation. In the Study SUPREP Bowel Prep Kit was administered as a split-dose (two-day) regimen. The PEG bowel prep was also given as a split-dose preparation according to its labeled instructions. Patients receiving SUPREP Bowel Prep Kit were limited to a light breakfast followed by clear liquids on the day prior to the day of colonoscopy; patients receiving the PEG bowel prep were allowed to have a normal breakfast and a light lunch, followed by clear liquids.

The primary efficacy endpoint was the proportion of patients with successful colon cleansing as assessed by the colonoscopists, who were not informed about the type of preparation received, as shown in Table 3. In the study, no clinically or statistically significant differences were seen between the group treated with SUPREP Bowel Prep Kit and the group treated with the PEG bowel prep.

Table 3: Proportion of Adult Patients with Successful Colon Cleansing Response Rates

Treatment Group	Regimen	N	Responders[1] % (95% C. I.)	SUPREP – PEG Difference (95% CI)
SUPREP Bowel Prep Kit (with light breakfast)	Split-Dose	180	**97%** (94%, 99%)	**2%**[2] (-2%, 5%)
PEG bowel prep (with normal breakfast & light lunch)	Split-Dose	183	**96%** (92%, 98%)	

[1] Responders were patients whose colon preparations were graded excellent (no more than small bits of adherent feces/fluid) or good (small amounts of feces or fluid not interfering with the exam) by the colonoscopist.

[2] Does not equal difference in tabled responder rates due to rounding effects.

Pediatric Patients 12 Years to 16 Years of Age

SUPREP Bowel Prep Kit was evaluated for colon cleansing in a randomized, single-blind, multicenter, doseranging, active-controlled study in 89 pediatric patients 12 years to 16 years of age. The majority of patients were female (57%), white (78%), and of non-Hispanic or non-Latino ethnicity (91%). The mean age was 14 years. The median body weight was 60 kg (range 32 to 155 kg).

Patients were randomized to SUPREP Bowel Prep Kit (two 6-ounce doses), SUPREP Bowel Prep Kit (two 4.5-ounce doses) or oral PEG solution. SUPREP Bowel Prep Kit (two 6-ounce doses) did not demonstrate additional treatment benefit and more patients reported gastrointestinal adverse reactions compared to SUPREP Bowel Prep Kit (two 4.5-ounce doses); therefore, SUPREP Bowel Prep Kit (two 6-ounce doses) is not recommended for pediatric patients 12 years of age and older *[see Dosage and Administration (2.4)]* .

Patients in the SUPREP Bowel Prep Kit (two 4.5-ounce doses) group took the preparation in a "split-dose" regimen, where the first dose was taken the evening before colonoscopy, with the second dose taken the morning of the exam. Patients in the control group took the preparation according to its approved labeling on the evening before colonoscopy.

Patients in the SUPREP Bowel Prep Kit group (two 4.5-ounce doses) were allowed to have a light breakfast on the day before colonoscopy, followed by clear liquids until the colonoscopy is completed the following day. Patients in the control group subjects were permitted only clear liquids on the day prior to colonoscopy until completion of the colonoscopy the following day.

The primary efficacy endpoint was the proportion of patients with successful colon cleansing as assessed by the colonoscopists, who were not informed about the type of preparation received.

The percentage of responders and the associated 95% confidence intervals for the SUPREP Bowel Prep Kit (two 4.5-ounce doses) and Oral PEG solution are shown in Table 4. Efficacy was similar between patients who weighed 65 kg or more (n=12) and those patients who weighed less than 65 kg (n=15) in the SUPREP Bowel Prep Kit (two 4.5-ounce doses) arm.

Table 4: Proportion of Pediatric Patients 12 Years to 16 Years of Age with Successful Colon Cleansing Response Rates

Treatment Group	Regimen	N	Responders[1] % (95% C. I.)	SUPREP – PEG Difference (95% CI)
SUPREP Bowel Prep Kit 4.5 ounces per dose (with light breakfast)	Split-Dose	26	**85%** (71%, 99%)	**25%**[2] (3%, 47%)
Oral PEG Solution	Evening	22	**59%**	

(with clear liquids only)	Dosing	32	(42%, 76%)	

[1] Responders were patients whose colon preparations were graded excellent (no more than small bits of adherent feces/fluid) or good (small amounts of feces or fluid not interfering with the exam) by the colonoscopist.

[2] Does not equal difference in tabled responder rates due to rounding effects.

16 HOW SUPPLIED/STORAGE AND HANDLING

Each SUPREP Bowel Prep Kit (sodium sulfate, potassium sulfate, and magnesium sulfate) oral solution **(for adults)** (NDC 52268-012-01) contains:

- Two bottles (NDC 52268-011-01) each containing 6-ounces of an oral solution of 17.5 grams sodium sulfate, 3.13 grams potassium sulfate, and 1.6 grams magnesium sulfate as a clear to slightly hazy liquid. When diluted as directed, the solution is clear and colorless.
- One (1) mixing container with a 16-ounce fill line.

Each SUPREP Bowel Prep Kit (sodium sulfate, potassium sulfate, and magnesium sulfate) oral solution **(for pediatric patients 12 years of age and older)** (NDC 52268-112-01) contains:

- Two bottles (NDC 52268-111-01) each containing 4.5-ounces of an oral solution of 13.13 grams sodium sulfate, 2.35 grams potassium sulfate, and 1.2 grams magnesium sulfate as a clear to slightly hazy liquid. When diluted as directed, the solution is clear and colorless.
- One (1) mixing container with a 12-ounce fill line.

Store at 20° to 25°C (68° to 77°F). Excursions permitted between 15° to 30°C (59° to 86°F). See USP controlled room temperature.

17 PATIENT COUNSELING INFORMATION

Advise the patient and/or caregiver to read the FDA-approved patient labeling (Medication Guide).

Instruct patients or caregivers:

- Must dilute SUPREP Bowel Prep Kit before ingestion.
- Must consume additional water after each dose of SUPREP Bowel Prep Kit.
- On the day before colonoscopy, consume only a light breakfast or clear liquids (e.g., water, apple or orange juice without pulp, lemonade, coffee, tea, or chicken broth). On the day of the colonoscopy only consume clear liquids up to two hours prior to colonoscopy.
- Two doses of SUPREP Bowel Prep Kit are required for a complete preparation for colonoscopy. One bottle of SUPREP Bowel Prep Kit is equivalent to one dose.
- Do not to take other laxatives while taking SUPREP Bowel Prep Kit.
- Do not eat solid food or drink milk or eat or drink anything colored red or purple.
- Do not drink alcohol.
- Do not take oral medications within one hour of starting each dose of SUPREP Bowel Prep Kit.
- If taking tetracycline or fluoroquinolone antibiotics, iron, digoxin, chlorpromazine, or penicillamine, take these medications at least 2 hours before and not less than 6 hours after administration of SUPREP Bowel Prep Kit *[see Drug Interactions (7.2)]* .
- Stop consumption of all fluids at least 2 hours prior to colonoscopy.
- Contact their healthcare provider if they develop significant vomiting or signs of dehydration after taking SUPREP Bowel Prep Kit or if they experience cardiac arrhythmias or seizures *[see Warnings and Precautions (5.1, 5.2, 5.3)]* .

Distributed by Braintree Laboratories, Inc.

Braintree, MA 02185
U.S. Patent 6,946,149

MEDICATION GUIDE
SUPREP ® (Soo-prep) Bowel Prep Kit
(sodium sulfate, potassium sulfate and magnesium sulfate)
oral solution

Read and understand this Medication Guide instructions **at least 2 days** before your colonoscopy and again before you start taking SUPREP Bowel Prep Kit.

What is the most important information I should know about SUPREP Bowel Prep Kit?
SUPREP Bowel Prep Kit and other 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 SUPREP Bowel Prep Kit 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 SUPREP Bowel Prep Kit:

o vomiting
o dizziness
o urinating less often than normal
o headache

See What are the possible side effects of SUPREP Bowel Prep Kit? for more information about side effects.

What is SUPREP Bowel Prep Kit?
SUPREP Bowel Prep Kit is a prescription medicine used by adults and children 12 years of age and older to clean the colon before a colonoscopy. SUPREP Bowel Prep Kit 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.

It is not known if SUPREP Bowel Prep Kit is safe and effective in children under 12 years of age.

Do not take SUPREP Bowel Prep Kit if your healthcare provider has told you that you have:

- a blockage in your intestine (bowel obstruction)
- an opening in the wall of your stomach or intestine (bowel perforation)
- a very dilated intestine (toxic megacolon)
- problems with the emptying of food and fluid from your stomach (gastric retention)
- an allergy to any of the ingredients in SUPREP Bowel Prep Kit. See the end of this Medication Guide for a complete list of ingredients in SUPREP Bowel Prep Kit.

Before taking SUPREP Bowel Prep Kit, tell your healthcare provider about all of your medical conditions, including if you:

- have problems with serious loss of body fluid (dehydration) and changes in blood salts (electrolytes).
- have gout
- have heart problems including an irregular heartbeat, especially a condition called "QT prolongation".
- have a history of seizures or take medicines for seizures.
- are withdrawing from drinking alcohol or from taking benzodiazepines.
- have a low blood salt (sodium) level.
- have kidney problems or take medicines for kidney problems.

• have stomach or bowel problems including ulcerative colitis.
• have problems with swallowing or gastric reflux.
• are pregnant or plan to become pregnant. It is not known if SUPREP Bowel Prep Kit will harm your unborn baby. Talk to your healthcare provider if you are pregnant.
• are breastfeeding or plan to breastfeed. It is not known if SUPREP Bowel Prep Kit passes into your breast milk. You and your healthcare provider should decide if you will take SUPREP Bowel Prep Kit while breastfeeding.

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

SUPREP Bowel Prep Kit may affect how other medicines work. Medicines taken by mouth may not be absorbed properly when taken within 1 hour before the start of each dose of SUPREP Bowel Prep Kit.
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 (pain medicines).
• medicines for depression or mental health problems.
• laxatives. **Do not** take other laxatives while taking SUPREP Bowel Prep Kit.

The following medicines should be taken at least 2 hours before starting SUPREP Bowel Prep Kit and not less than 6 hours after taking SUPREP Bowel Prep Kit:
• tetracycline
• fluoroquinolone antibiotics
• iron
• digoxin (Lanoxin)
• chloropromazine
• penicillamine (Cuprimine. Depen)

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 SUPREP Bowel Prep Kit?
See the Instructions for Use in the Patient Instructions for Use Booklet for dosing instructions. You must read, understand, and follow these instructions to take SUPREP Bowel Prep Kit the right way.

• Take SUPREP Bowel Prep Kit exactly as your healthcare provider tells you to take it.
• Each bottle of SUPREP Bowel Prep Kit must be mixed with water (diluted) before drinking.
• It is important for you to drink the additional prescribed amount of water listed in the Instructions for Use to prevent fluid loss (dehydration).
• One bottle of SUPREP Bowel Prep Kit is equal to one dose.
• Two doses of SUPREP Bowel Prep Kit are required for complete colonoscopy preparation.
• All people taking SUPREP Bowel Prep Kit should follow these general instructions starting 1 day **before** your colonoscopy:
  • eat only a light breakfast or clear liquids (for example: water, strained fruit juice without pulp, lemonade, plain coffee or tea, chicken broth, gelatin dessert without fruit) on the day before your procedure.
  • only drink clear liquids the rest of the day and the next day until 2 hours before your colonoscopy. **Stop** drinking all fluids at least 2

hours before your colonoscopy.

• after taking SUPREP Bowel Prep Kit if you have any bloating or feeling like your stomach is upset, wait to take your second dose until your stomach feels better.

• **While taking SUPREP Bowel Prep Kit, do not:**

• take any other laxatives.

• take any medicines by mouth (oral) within 1 hour of starting SUPREP Bowel Prep Kit.

• eat solid foods, drink dairy (such as milk), or drink alcohol while taking SUPREP Bowel Prep Kit and until after your colonoscopy

• eat or drink anything colored red or purple.

Contact your healthcare provider right away if after taking SUPREP Bowel Prep Kit you have severe vomiting, signs of dehydration, changes in consciousness such as feeling confused, delirious or fainting (loss of consciousness) or seizures after taking SUPREP Bowel Prep Kit.

What are the possible side effects of SUPREP Bowel Prep Kit?

SUPREP Bowel Prep Kit can cause serious side effects, including:

• See **What is the most important information I should know about SUPREP Bowel Prep Kit?**

• **Changes in certain blood tests.** Your healthcare provider may do blood tests after you take SUPREP Bowel Prep Kit to check your blood for changes. Tell your healthcare provider if you have any symptoms of too much fluid loss, including:

o vomiting	o nausea	o bloating
o dizziness	o stomach area (abdomen) cramping	o headache
o urinate less than usual	o trouble drinking clear liquid	o trouble swallowing
o seizures	o heart problems	o worsening gout

• **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 SUPREP Bowel Prep Kit in adults include:

o overall discomfort	o stomach bloating
o stomach pain	o nausea
o vomiting	

The most common side effects of SUPREP Bowel Prep Kit in children 12 to 16 years of age include:

o nausea	o stomach pain
o stomach bloating	o vomiting

These are not all the possible side effects of SUPREP Bowel Prep Kit.

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 SUPREP Bowel Prep Kit?

• Store SUPREP Bowel Prep Kit at room temperature, between 68°F to 77°F (20°C to 25°C).

Keep SUPREP Bowel Prep Kit and all medicines out of the reach of children.

General information about the safe and effective use of SUPREP Bowel Prep Kit.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use SUPREP Bowel Prep Kit for a condition for which it was not prescribed. Do not give SUPREP Bowel Prep Kit to other people, even if they are going to have the same procedure you are. It may harm them. You can ask your pharmacist or healthcare provider for information about SUPREP Bowel Prep Kit that is written for healthcare professionals.

What are the ingredients in SUPREP Bowel Prep Kit?

SUPREP Bowel Prep Kit is supplied in two dosage strengths. SUPREP Bowel Prep Kit comes in a

carton containing two 6-ounce bottles, along with a 16-ounce polypropylene mixing container.
SUPREP Pediatric Bowel Prep Kit comes in a carton containing two bottles containing 4.5 ounces of oral solution, along with a 12-ounce polypropylene mixing container.
Each bottle contains:
Active ingredients: sodium sulfate, potassium sulfate and magnesium sulfate.
Inactive ingredients: citric acid, USP, flavoring ingredients, malic acid, FCC, sodium benzoate, NF, sucralose, purified water, USP.
Distributed by Braintree Laboratories, Inc.
60 Columbian Street West
Braintree, MA 02185, USA
For more information go to www.braintreelabs.com or call 1-800-874-6756.

This Medication Guide has been approved by the U.S. Food and Drug Administration.
Revised 08/2020

Principal Display Panel – Adult Carton Label

NDC 52268-012-01 U.S. Patent 6,946,149

Dispense the enclosed Medication Guide to each patient.

SUPREP
BOWEL PREP KIT
(sodium sulfate, potassium
sulfate and magnesium sulfate)
Oral Solution
For Adults
(17.5g/3.13g/1.6g) per 6 ounces

This carton contains:

2 6-ounce (177 mL) bottles of liquid bowel prep
1 16-ounce mixing container
1 Patient booklet. Booklet includes:
1- Medication Guide
2- Patient Instructions
3- Full Prescribing Information

Recommended Dosage:
See prescribing information

Dilute the solution concentrate as directed prior to use.

Both 6-ounce bottles are required for a complete prep.

Rx only

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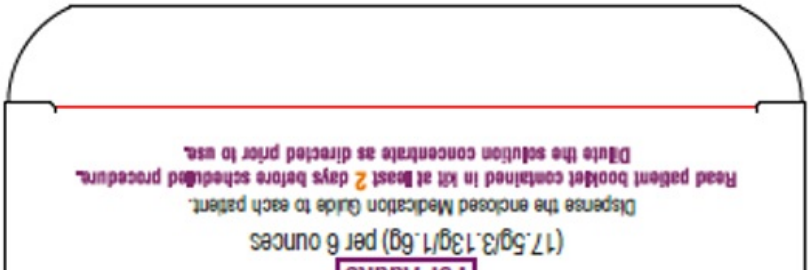
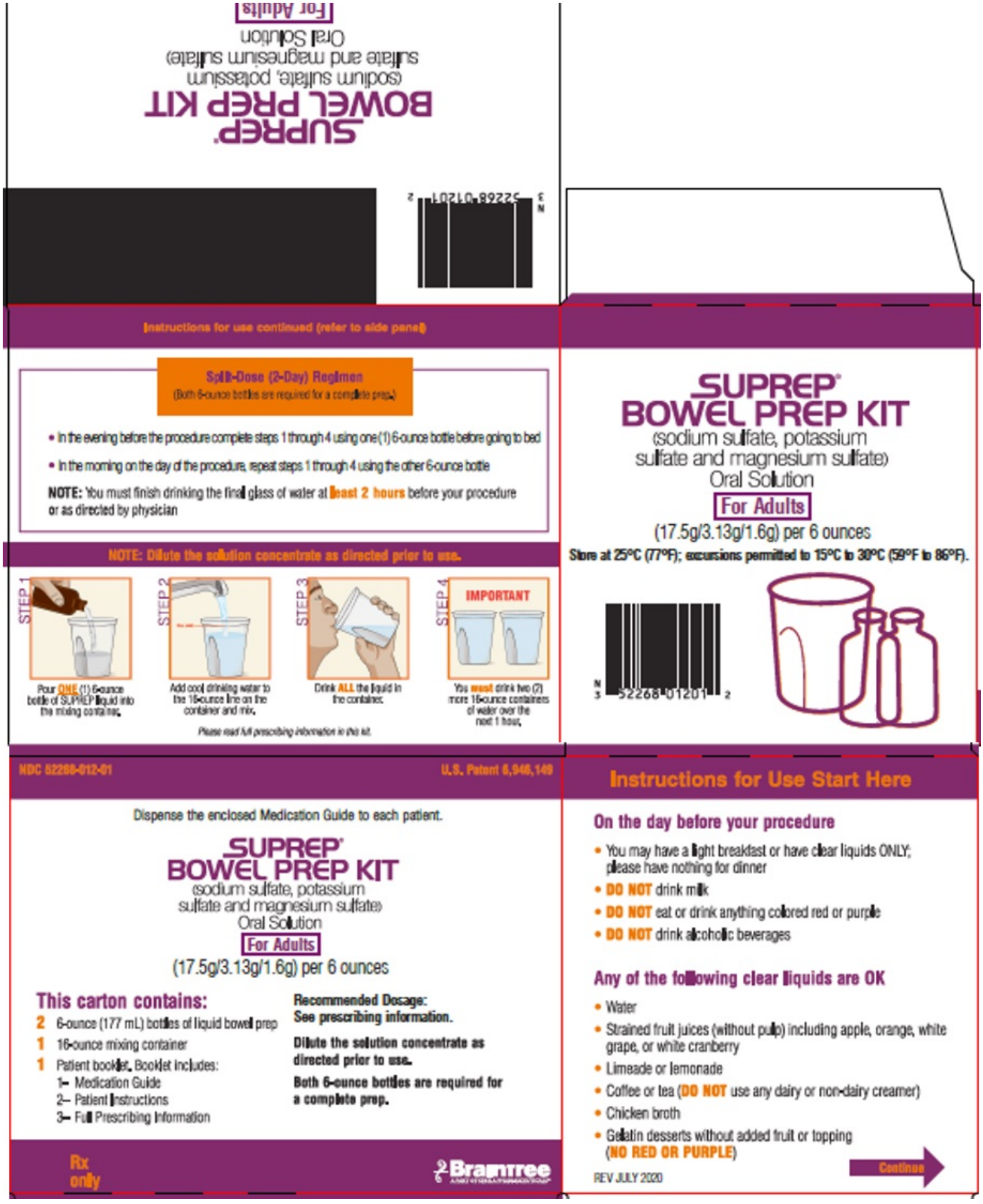




Principal Display Panel – Adult Bottle Label

NDC 52268-011-01

SUPREP
BOWEL PREP KIT

(sodium sulfate, potassium
sulfate and magnesium sulfate)
Oral Solution
For Adults
(17.5g/3.13g/1.6g) per 6 ounces

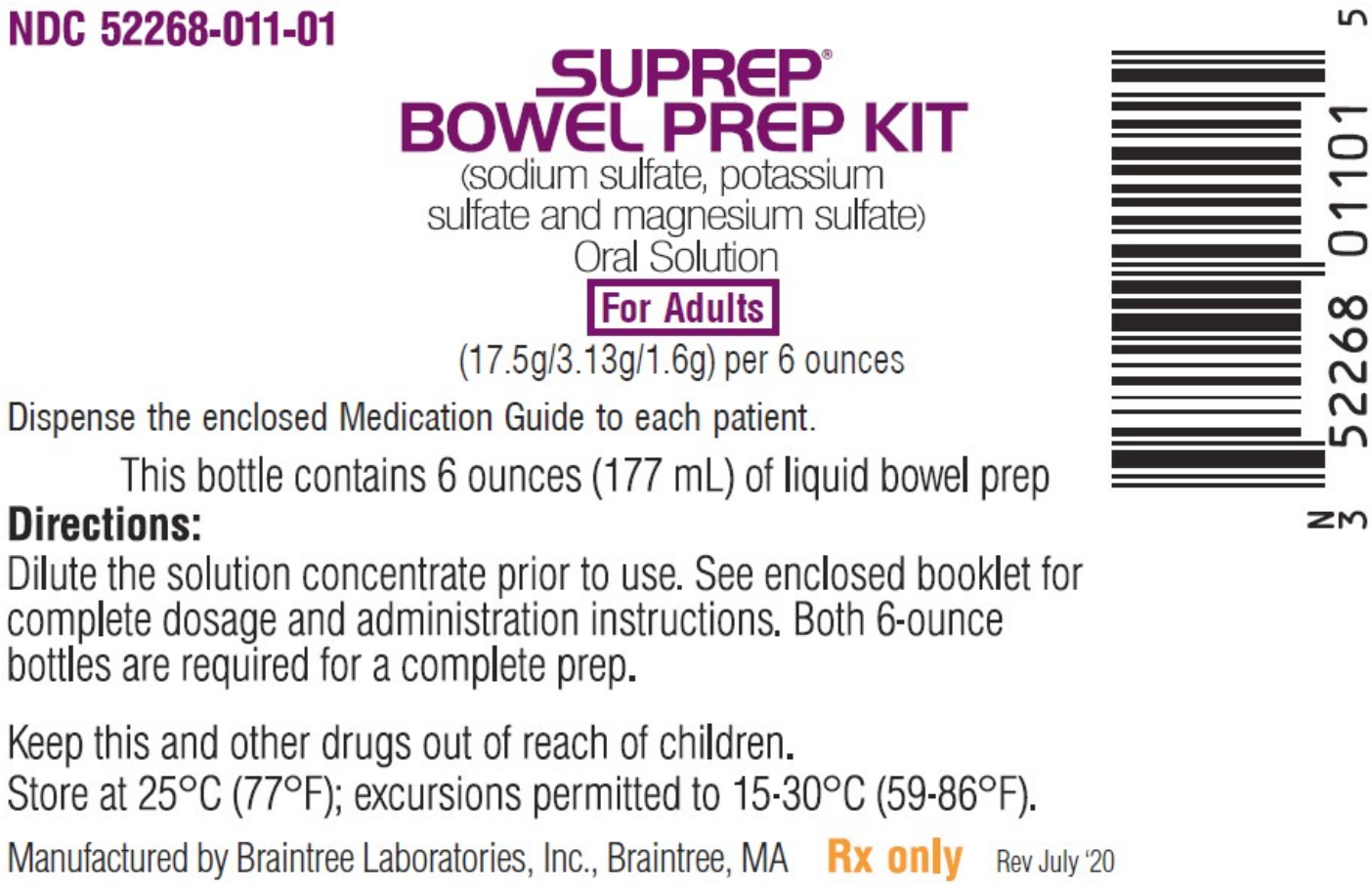
Dispense the enclosed Medication Guide to each patient.

This bottle contains 6 ounces (177 mL) of liquid bowel prep

Directions:
Dilute the solution concentrate prior to use. See enclosed booklet for complete dosage and administration instructions. Both 6-ounce bottles are required for a complete prep.

Keep this and other drugs out of reach of children.
Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

Manufactured by Braintree Laboratories, Braintree, MA **Rx only** Rev July '20



Principal Display Panel – Pediatric Carton Label

NDC 52268-112-01 U.S. Patent 6,946,149

Dispense the enclosed Medication Guide to each patient.

SUPREP®
BOWEL PREP KIT
(sodium sulfate, potassium
sulfate and magnesium sulfate)
Oral Solution
For pediatric patients 12 years of age and older
(13.13g/2.35g/1.2g) per 4.5 ounces

This carton contains:

2 Bottles containing 4.5 ounces
of liquid bowel prep
1 12-ounce mixing container
1 Patient booklet. Booklet includes:
1- Medication Guide
2- Patient Instructions
3- Full Prescribing Information

Recommended Dosage:
See prescribing information

Dilute the solution concentrate as directed prior to use.

Both bottles containing 4.5 ounces of oral solutions are required for a complete prep.

Rx only

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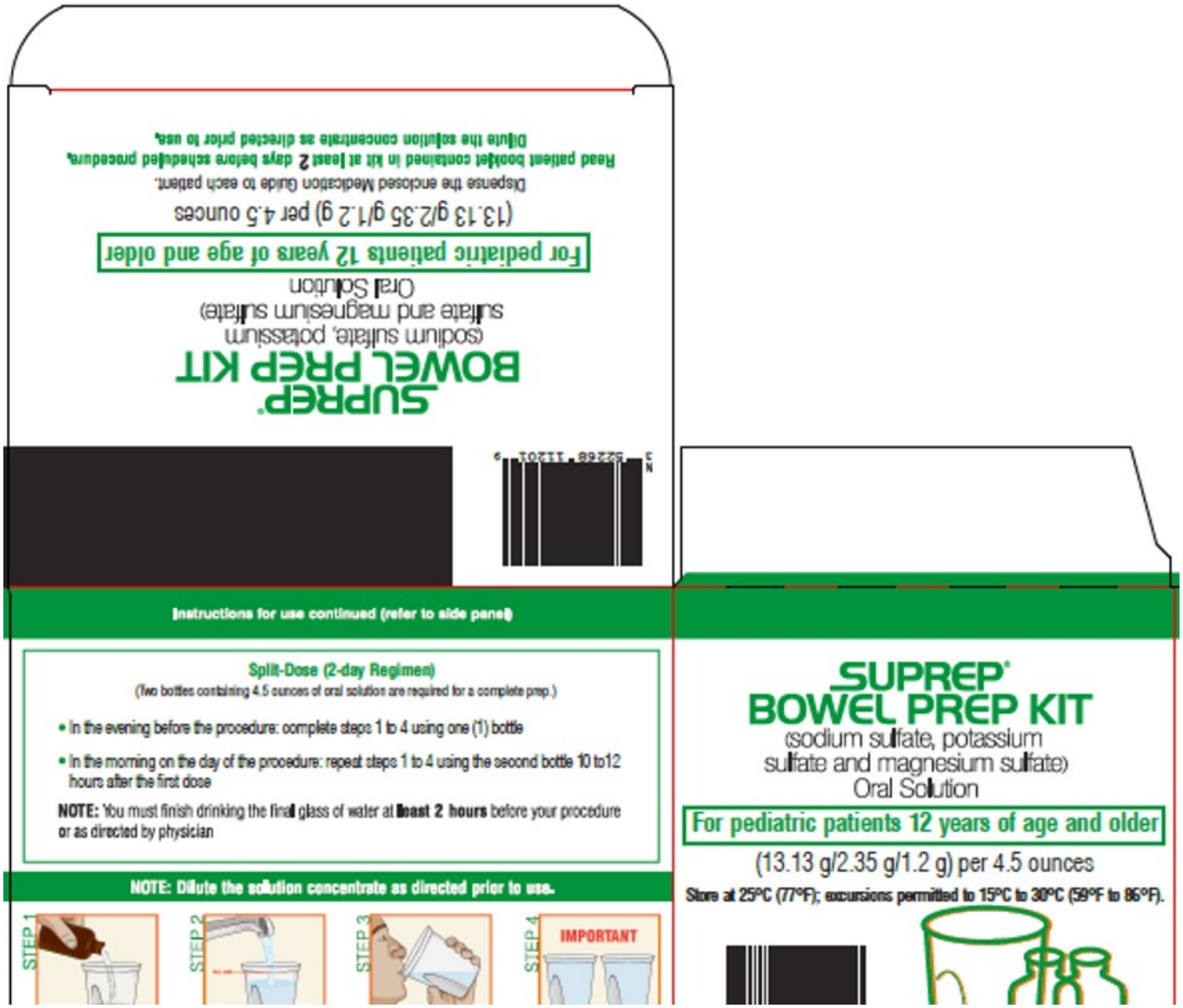

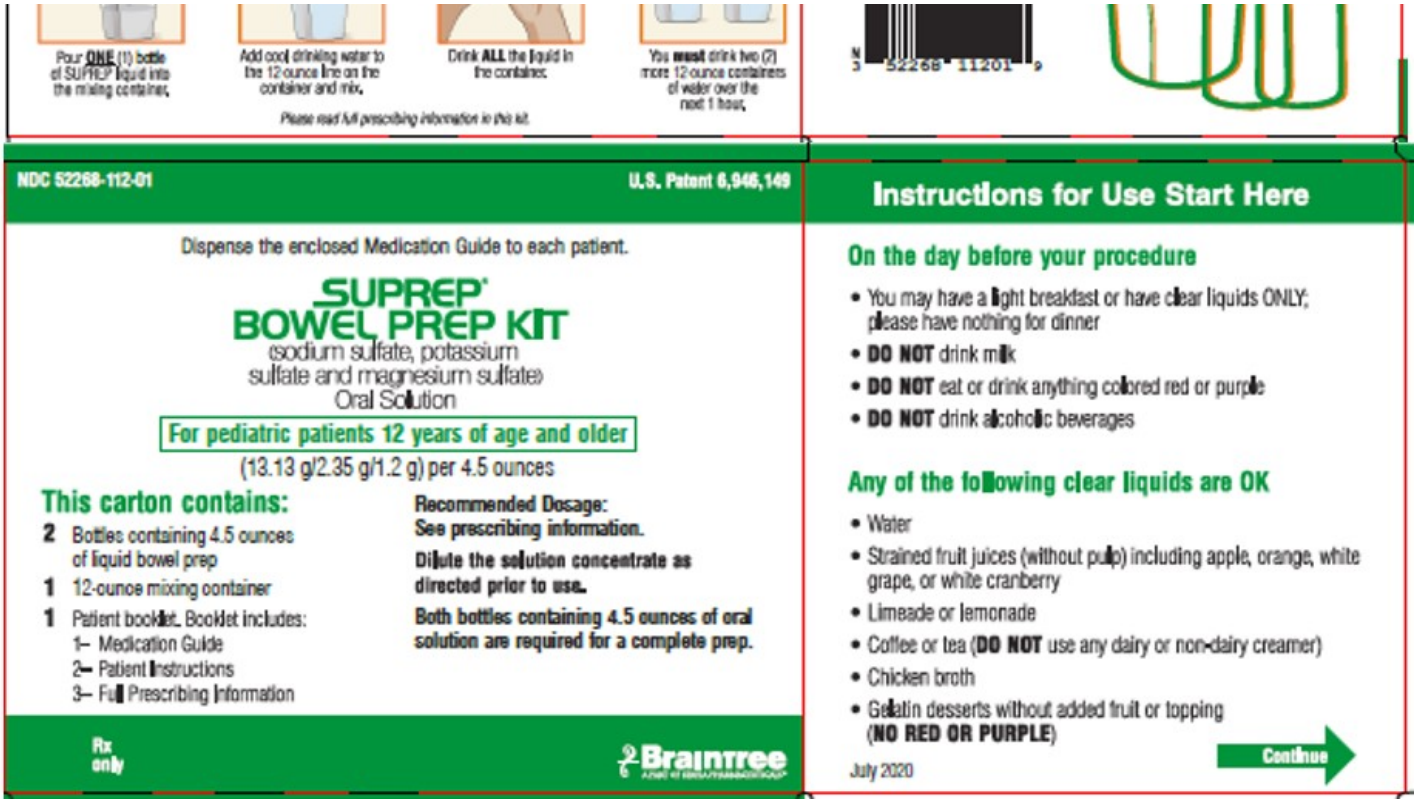

Principal Display Panel – Pediatric Bottle Label

NDC 52268-111-01

SUPREP®
BOWEL PREP KIT
(sodium sulfate, potassium
sulfate and magnesium sulfate)
Oral Solution
For pediatric patients 12 years of age and older
(13.13g/2.35g/1.2g) per 6 ounces

Dispense the enclosed Medication Guide to each patient.

This bottle contains 4.5 ounces of liquid bowel prep

Directions:
Dilute the solution concentrate prior to use. See enclosed booklet for complete dosage and administration instructions. Both 6 bottles containing 4.5 ounces of oral soultion are required for a complete prep.

Keep this and other drugs out of reach of children.
Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

Manufactured by Braintree Laboratories, Braintree, MA **Rx only** July 2020

NDC 52268-111-01

SUPREP® BOWEL PREP KIT

(sodium sulfate, potassium sulfate and magnesium sulfate) Oral Solution

For pediatric patients 12 years of age and older

(13.13 g/2.35 g/1.2 g) per 4.5 ounces

Dispense the enclosed Medication Guide to each patient.

This bottle contains 4.5 ounces of liquid bowel prep

Directions:

Dilute the solution concentrate prior to use. See enclosed booklet for complete dosage and administration instructions. Both bottles containing 4.5 ounces of oral solution are required for a complete prep.

Keep this and other drugs out of reach of children.

Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).

Manufactured by Braintree Laboratories, Inc., Braintree, MA **Rx only** July 2020

SUPREP BOWEL PREP

sodium sulfate, potassium sulfate, magnesium sulfate solution, concentrate

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:52268-012
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM SULFATE (UNII: 0YPR65R21J) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM SULFATE	17.5 g in 1 mL
POTASSIUM SULFATE (UNII: 1K573LC5TV) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM SULFATE	3.13 g in 1 mL
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM SULFATE, UNSPECIFIED FORM	1.6 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
MALIC ACID (UNII: 817L1N4CKP)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	BERRY (BERRY)	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52268-012-01	2 in 1 CARTON	08/05/2010	
1		177.4 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022372	08/05/2010	

SUPREP BOWEL PREP

sodium sulfate, potassium sulfate, magnesium sulfate solution, concentrate

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52268-112
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM SULFATE (UNII: 0YPR65R21J) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM SULFATE	13.13 g in 133.1 mL
POTASSIUM SULFATE (UNII: 1K573LC5TV) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM SULFATE	2.35 g in 133.1 mL
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM SULFATE, UNSPECIFIED FORM	1.2 g in 133.1 mL

Inactive Ingredients	
Ingredient Name	Strength
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
MALIC ACID (UNII: 817L1N4CKP)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	BERRY (BERRY)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52268-112-01	2 in 1 CARTON	01/05/2021	
1		133.1 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022372	08/05/2010	

Labeler - Braintree Laboratories, Inc. (107904591)

Establishment

Name	Address	ID/FEI	Business Operations
BrainTree Laboratories, Inc.		617357954	manufacture(52268-012, 52268-112) , analysis(52268-012, 52268-112)

Revised: 8/2020 Braintree Laboratories, Inc.