SODIUM SULFATE, POTASSIUM SULFATE, AND MAGNESIUM SULFATE BOWEL PREP KIT- sodium sulfate anhydrous, potassium sulfate, and magnesium sulfate solution

Sun Pharmaceutical Industries, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use SODIUM SULFATE, POTASSIUM SULFATE, and MAGNESIUM SULFATE oral solution safely and effectively. See full prescribing information for SODIUM SULFATE, POTASSIUM SULFATE, and MAGNESIUM SULFATE oral solution.

SODIUM SULFATE, POTASSIUM SULFATE, and MAGNESIUM SULFATE oral solution

Initial U.S. Approval: 2010

INDICATIONS AND USAGE

Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adult patients. (1)

DOSAGE AND ADMINISTRATION

Preparation and Administration (2.2)

- Must dilute in water prior to ingestion.
- Administration of two bottles of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution: first dose during the evening prior to colonoscopy and second dose the next day, during the morning of colonoscopy. (2.1, 2.3)
- Recommended sodium sulfate, potassium sulfate, and magnesium sulfate oral solution dosage is:
  - **Adults:**Two 6-ounce doses. (2.3)
- For complete information on preparation before colonoscopy and administration of the dosage regimen, see full prescribing information. (2.1, 2.2, 2.3)

DOSAGE FORMS AND STRENGTHS

- Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution **(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)

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)

To report SUSPECTED ADVERSE REACTIONS, contact Sun Pharmaceutical Industries, Inc. at 1-866-923-4914 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: 6/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

Pediatric use information is approved for Braintree Laboratories, Inc.'s SUPREP BOWEL PREP KIT (sodium sulfate, potassium sulfate, and magnesium sulfate) oral solution. However, due to Braintree Laboratories, Inc.'s marketing exclusivity rights, this drug product is not labeled with that pediatric information.

1 INDICATIONS AND USAGE

Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution is indicated for cleansing of the colon as a preparation for colonoscopy in adult patients.

Pediatric use information is approved for Braintree Laboratories, Inc.'s SUPREPP® BOWEL PREP KIT (sodium sulfate, potassium sulfate, and magnesium sulfate) oral solution. However, due to Braintree Laboratories, Inc.'s marketing exclusivity rights, this drug product is not labeled with that pediatric information.

2 DOSAGE AND ADMINISTRATION

2.1 Dosage and Administration Overview

Administration of two bottles of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution and additional water is required for a complete preparation for colonoscopy. One bottle of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution is equivalent to one dose. Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution is supplied in one dosage strength *[see Dosage Forms and Strengths (3)]* . The recommended dosage is:

- **Adults:**Two 6-ounce doses *[see Dosage and Administration (2.3)]* .

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2.2 Important Preparation and Administration Instructions

- Correct fluid and electrolyte abnormalities before treatment with sodium sulfate, potassium sulfate, and magnesium sulfate oral solution *[see Warnings and Precautions (5.1)]*
- Must dilute sodium sulfate, potassium sulfate, and magnesium sulfate oral solution in water before ingestion.
- Must consume additional water after each dose of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution.
- 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution.
- Do not take oral medications within one hour of starting each dose of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution.
- 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution *[see Drug Interactions (7.2)]* .
- Stop consumption of all fluids at least 2 hours prior to the colonoscopy.

2.3 Recommended Dosage and Administration in Adults

The recommended Split-Dose (two-day) regimen for **adults**consists of two 6-ounce doses of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution: 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution and required water at least two hours prior to colonoscopy.

3 DOSAGE FORMS AND STRENGTHS

- Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution **(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.

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

Pediatric use information is approved for Braintree Laboratories, Inc.'s SUPREP BOWEL PREP KIT (sodium sulfate, potassium sulfate, and magnesium sulfate) oral solution. However, due to Braintree Laboratories, Inc.'s marketing exclusivity rights, this drug product is not labeled with that pediatric information.

4 CONTRAINDICATIONS

Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution is contraindicated in the following conditions:

- Gastrointestinal obstruction or ileus *[see Warnings and Precautions (5.6)]*
- Bowel perforation *[see Warnings and Precautions (5.6)]*
- Toxic colitis or toxic megacolon
- Gastric retention
- Hypersensitivity to any of the ingredients in sodium sulfate, potassium sulfate, and magnesium sulfate oral solution

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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution. If a patient develops significant vomiting or signs of dehydration after taking sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution. Use sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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)]* .

Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate 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). 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 sodium sulfate, potassium sulfate, and magnesium sulfate 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 *[see Drug Interactions (7.1)]* .

5.4 Use in Patients with Risk of Renal Injury

Use sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution *[see Contraindications (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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution. Observe these patients during administration of sodium sulfate, potassium sulfate, and magnesium sulfate oral 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 Trials 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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

	Split-Dose (2-Day) Regimen	
Symptom	**Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution % 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 *

		Day of Colonoscopy N (%) †	**Day 30 N (%) †**
Bicarbonate (low)	Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution	20 (13)	7(4)
	PEG + Electrolytes	24 (15)	4 (3)
Bilirubin, total (high)	Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution	14 (9)	0 (0)
	PEG + Electrolytes	20 (12)	3 (2)
BUN (high)	Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution	2 (2)	14 (11)
	PEG + Electrolytes	4(3)	19 (15)
Calcium (high)	Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution	16 (10)	8 (5)
	PEG + Electrolytes	6 (4)	6 (4)
Chloride (high)	Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution	4 (2)	6 (4)
	PEG + Electrolytes	20 (12)	6 (4)
Osmolality (high)	Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution	8 (6)	NA

	PEG + Electrolytes	19 (13)	NA
Uric acid (high)	Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution	27 (24)	13 (12)
	PEG + Electrolytes	12 (10)	20 (17)

* The study was not designed to support comparative claims for the laboratory abnormalities reported in this table.
† Percent (n/N) of patients where N=number of patients with normal baseline who had abnormal values at the time-point(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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution in an evening-only (1-day) dosing regimen is not recommended.

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7 DRUG INTERACTIONS

7.1 Drugs That May Increase Risk of Fluid and Electrolyte Abnormalities

Use caution when prescribing sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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

Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution.
- Administer tetracycline and fluoroquinolone antibiotics, iron, digoxin, chlorpromazine, and penicillamine at least 2 hours before and not less than 6 hours after administration of sodium sulfate, potassium sulfate, and magnesium sulfate oral

solution to avoid chelation with magnesium.

7.3 Stimulant Laxatives

Concurrent use of stimulant laxatives and sodium sulfate, potassium sulfate, and magnesium sulfate oral solution may increase the risk of mucosal ulceration or ischemic colitis. Avoid use of stimulant laxatives (e.g., bisacodyl, sodium picosulfate) while taking sodium sulfate, potassium sulfate, and magnesium sulfate oral solution *[see Warnings and Precautions (5.5)]* .

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 oral solution.

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 birth 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution and any potential adverse effects on the breastfed child from sodium sulfate, potassium sulfate, and magnesium sulfate oral solution or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution in pediatric patients less than 12 years of age have not been established.

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8.5 Geriatric Use

Of the 375 patients who received sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution, administered as the recommended split-dose (2-day) regimen, were observed between geriatric patients and younger patients. Geriatric patients reported more vomiting when sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution and consider performing baseline and post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN) in these patients *[see Warnings and Precautions (5.4)]* .

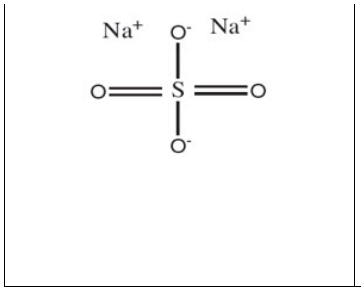
10 OVERDOSAGE

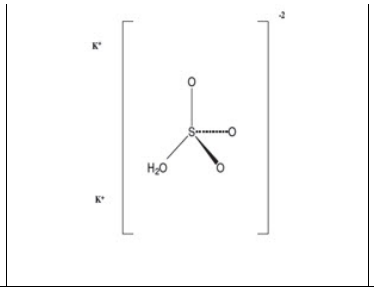
Overdosage of more than the recommended dose of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution may lead to severe electrolyte disturbances, as well as dehydration and hypovolemia, with signs and symptoms of these disturbances *[see Warnings and Precautions (5.1, 5.2, 5.3)]* .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

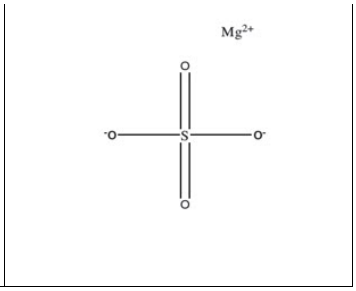
11 DESCRIPTION

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, grape flavor, malic acid, mixed berry flavor natural, purified water, sodium benzoate and sucralose.

Sodium Sulfate, USP	Potassium Sulfate, FCC, purified	Magnesium Sulfate, USP
The chemical name is Na_2SO_4. The average Molecular Weight is 142.04. The structural formula is:	The chemical name is K_2SO_4. The average Molecular Weight is 174.26. The structural formula is:	The chemical name is $MgSO_4$. The average Molecular Weight: 120.37. The structural formula is:







Each sodium sulfate, potassium sulfate, and magnesium sulfate oral solution also contains a polypropylene mixing container.

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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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution.

12.3 Pharmacokinetics

Absorption and Elimination

After administration of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution in six healthy subjects, the time at which serum sulfate reached its highest point (T_{max}) 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 $C_{max}$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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 C_{max}) 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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: sodium sulfate, potassium sulfate, and magnesium sulfate oral solution or a marketed polyethylene glycol (PEG) plus electrolytes bowel preparation. In the Study sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate,

potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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* % (95% C. I.)**	**Sodium sulfate, potassium sulfate, and magnesium sulfate – PEG Difference (95% CI)**
Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution (with light breakfast)	Split-Dose	180	**97%** (94%, 99%)	**2%**† (-2%, 5%)
PEG bowel prep (with normal breakfast & light lunch)	Split-Dose	183	**96%** (92%, 98%)	

* 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.

† Does not equal difference in tabled responder rates due to rounding effects.

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16 HOW SUPPLIED/STORAGE AND HANDLING

Each Sodium Sulfate, Potassium Sulfate, and Magnesium Sulfate Oral Solution **(for**

adults)(NDC 51672-4170-5) contains:

- 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. When diluted as directed, the solution is clear and colorless.
- One (1) mixing container with a 16-ounce fill line.

Store at 20° to 25°C (68° to 77°F)[see USP Controlled Room Temperature].

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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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution before ingestion.
- Must consume additional water after each dose of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution.
- 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution are required for a complete preparation for colonoscopy .One bottle of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution is equivalent to one dose.
- Do not to take other laxatives while taking sodium sulfate, potassium sulfate, and magnesium sulfate oral solution.
- 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution.
- 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution *[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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution or if they experience cardiac arrhythmias or seizures *[see Warnings and Precautions (5.1, 5.2, 5.3)]* .

Mfd. by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel 2624761
Dist. by: **Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512**

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Dispense with Mediation Guide available at https://www.sunpharma.com/usa/products

MEDICATION GUIDE
Sodium Sulfate, Potassium Sulfate, and Magnesium Sulfate
(soe' dee um sul' fate, poe tas' ee um sul' fate, mag nee' zee um sul' fate)
Oral Solution

Read and understand this Medication Guide instructions **at least 2 days**before your colonoscopy and again before you start taking sodium sulfate, potassium sulfate, and magnesium sulfate oral solution..

What is the most important information I should know about sodium sulfate, potassium sulfate, and magnesium sulfate oral solution?
Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution? 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 sodium sulfate, potassium sulfate, and magnesium sulfate 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution:
o vomiting o urinating less often than normal
o dizziness o headache

See " What are the possible side effects ofsodium sulfate, potassium sulfate, and magnesium sulfate oral solution? for more information about side effects.

What is sodium sulfate, potassium sulfate, and magnesium sulfate oral solution?
Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution is a prescription medicine used by adults and children 12 years of age and older to clean the colon before a colonoscopy. Sodium sulfate, potassium sulfate, and magnesium sulfate 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.

It is not known if sodium sulfate, potassium sulfate, and magnesium sulfate oral solution is safe and effective in children under 12 years of age.

Do nottake sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution. See the end of <"background-color: transparent;">this Medication Guide for a complete list of ingredients in sodium sulfate, potassium sulfate, and magnesium sulfate oral solution.

Before taking sodium sulfate, potassium sulfate, and magnesium sulfate oral solution, 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution passes into your breast milk. You and your healthcare provider should decide if you will take sodium sulfate, potassium sulfate, and magnesium sulfate oral solution while breastfeeding.

Tell your healthcare provider about all the medicines you take,including prescription and over-the-counter medicines, vitamins, and herbal supplements. Sodium sulfate, potassium sulfate, and magnesium sulfate 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 each dose of sodium sulfate, potassium sulfate, and magnesium sulfate 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 (pain medicines).
• medicines for depression or mental health problems.
• laxatives. **Do not**take other laxatives while taking sodium sulfate, potassium sulfate, and magnesium sulfate oral solution.
The following medicines should be taken at least 2 hours before starting sodium sulfate, potassium sulfate, and magnesium sulfate oral solution and not less than 6 hours after taking sodium sulfate, potassium sulfate, and magnesium sulfate oral solution:
• 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution?
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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution the right way.

• Take sodium sulfate, potassium sulfate, and magnesium sulfate oral solution exactly as your healthcare provider tells you to take it.
• Each bottle of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution is equal to one dose.
• Two doses of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution are required for complete colonoscopy preparation.
• All people taking sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution, do not:**
• take any other laxatives.
• take any medicines by mouth (oral) within 1 hour of starting sodium sulfate, potassium sulfate, and magnesium sulfate oral solution.
• eat solid foods, drink dairy (such as milk), or drink alcohol while taking sodium sulfate, potassium sulfate, and magnesium sulfate oral solution and until after your colonoscopy
• eat or drink anything colored red or purple.
Contact your healthcare provider right awayif after taking sodium sulfate, potassium sulfate, and magnesium sulfate oral solution you have severe vomiting, signs of dehydration, changes in consciousness such as feeling confused, delirious or fainting (loss of consciousness) or seizures after taking sodium sulfate, potassium sulfate, and

magnesium sulfate oral solution.

What are the possible side effects of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution.?

Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution can cause serious side effects, including:

• See **What is the most important information I should know about sodium sulfate, potassium sulfate, and magnesium sulfate oral solution?**

• **Changes in certain blood tests.** Your healthcare provider may do blood tests after you take sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution in adults include:

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

The most common side effects of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution.

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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution?

• Store sodium sulfate, potassium sulfate, and magnesium sulfate oral solution at room temperature, between 68°F to 77°F (20°C to 25°C).

Keep sodium sulfate, potassium sulfate, and magnesium sulfate oral solution and all medicines out of the reach of children.

General information about the safe and effective use of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use sodium sulfate, potassium sulfate, and magnesium sulfate oral solution for a condition for which it was not prescribed. Do not give sodium sulfate, potassium sulfate, and magnesium sulfate oral solution 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 sodium sulfate, potassium sulfate, and magnesium sulfate oral solution that is written for healthcare professionals.

What are the ingredients in sodium sulfate, potassium sulfate, and

magnesium sulfate oral solution?
Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution is supplied in one dosage strengths. Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution comes in a carton containing two 6-ounce bottles, along with a 16-ounce polypropylene mixing container.
Each bottle contains:
Active ingredients:sodium sulfate, potassium sulfate and magnesium sulfate.
Inactive ingredients:citric acid, grape flavor, malic acid, mixed berry flavor natural, purified water, sodium benzoate and sucralose
Pediatric use information is approved for Braintree Laboratories, Inc.'s SUPREP BOWEL PREP KIT (sodium sulfate, potassium sulfate, and magnesium sulfate) oral solution. However, due to Braintree Laboratories, Inc.'s marketing exclusivity rights, this drug product is not labeled with that pediatric information.
Mfd. by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel 2624761
Dist by: **Sun Pharmaceutical Industries, Inc.,**Cranbury, NJ 08512
For more information go to https://www.sunpharma.com/usa/products or call 1-866-923-4914.

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

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Patient Instructions for Use

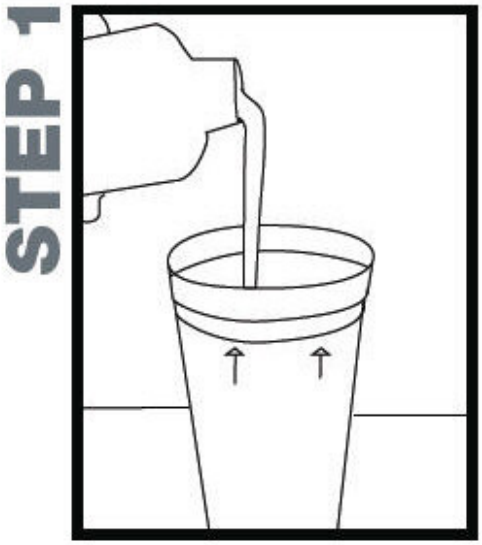
On the day before your procedure
- You may have a light breakfast or have clear liquids ONLY; please have nothing for dinner
- **DO NOT**drink milk
- **DO NOT**eat or drink anything colored red or purple
- **DO NOT**drink alcoholic beverages

Any of the following clear liquids are OK
- Water
- Strained fruit juices (without pulp) including apple, orange, white grape, or white cranberry
- Limeade or lemonade
- Coffee or tea (**DO NOT**use any dairy or non-dairy creamer)
- Chicken broth
- Gelatin desserts without added fruit or topping (**NO RED OR PURPLE**)

Split-Dose (2-Day) Regimen (Both 6 oz bottles are required for a complete prep.)
• In the evening before the procedure complete steps 1 through 4 using one (1) 6-ounce bottle before going to bed • In the morning or the day of the procedure, repeat steps 1 through 4 using the other 6-ounce bottle

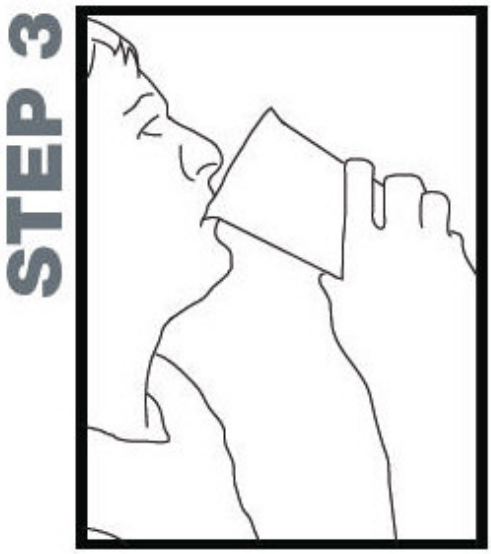
NOTE: You must finish drinking the final glass of water at least 2 hours before your procedure or as directed by physician

NOTE: Dilute the solution concentrate as directed prior to use.



Pour **ONE**(1) 6-ounce bottle of Sodium Sulfate, Potassium Sulfate, and Magnesium Sulfate liquid into the mixing container.

Add cool drinking water to the 16-ounce line on the container and mix.



Drink **ALL**the liquid in the container.

You **must**drink two (2) more 16-ounce containers of water over the next 1 hour.

PRINCIPAL DISPLAY PANEL - 2 Bottles (177 mL) Carton

NDC 51672-4170-5

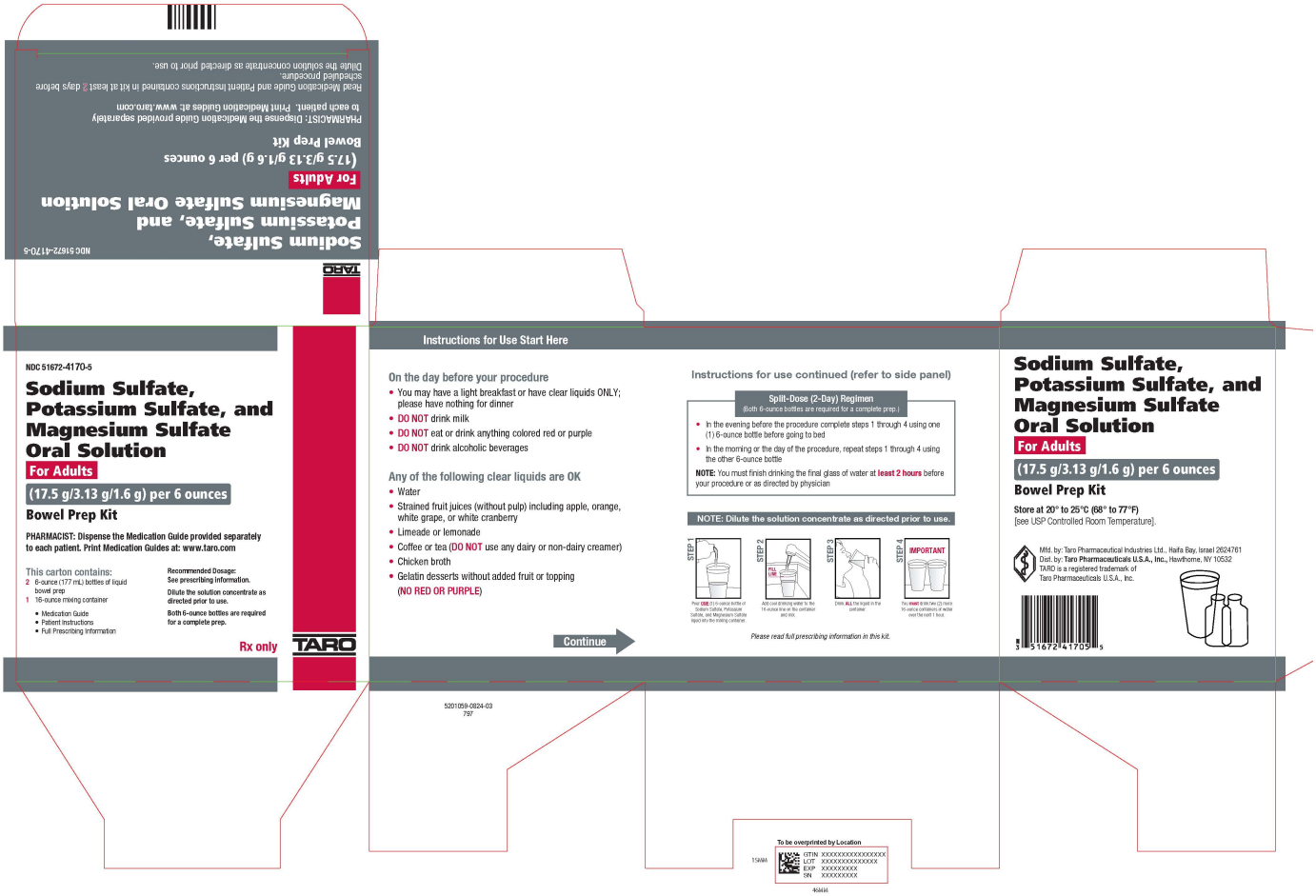
Sodium Sulfate,
Potassium Sulfate, and
Magnesium Sulfate

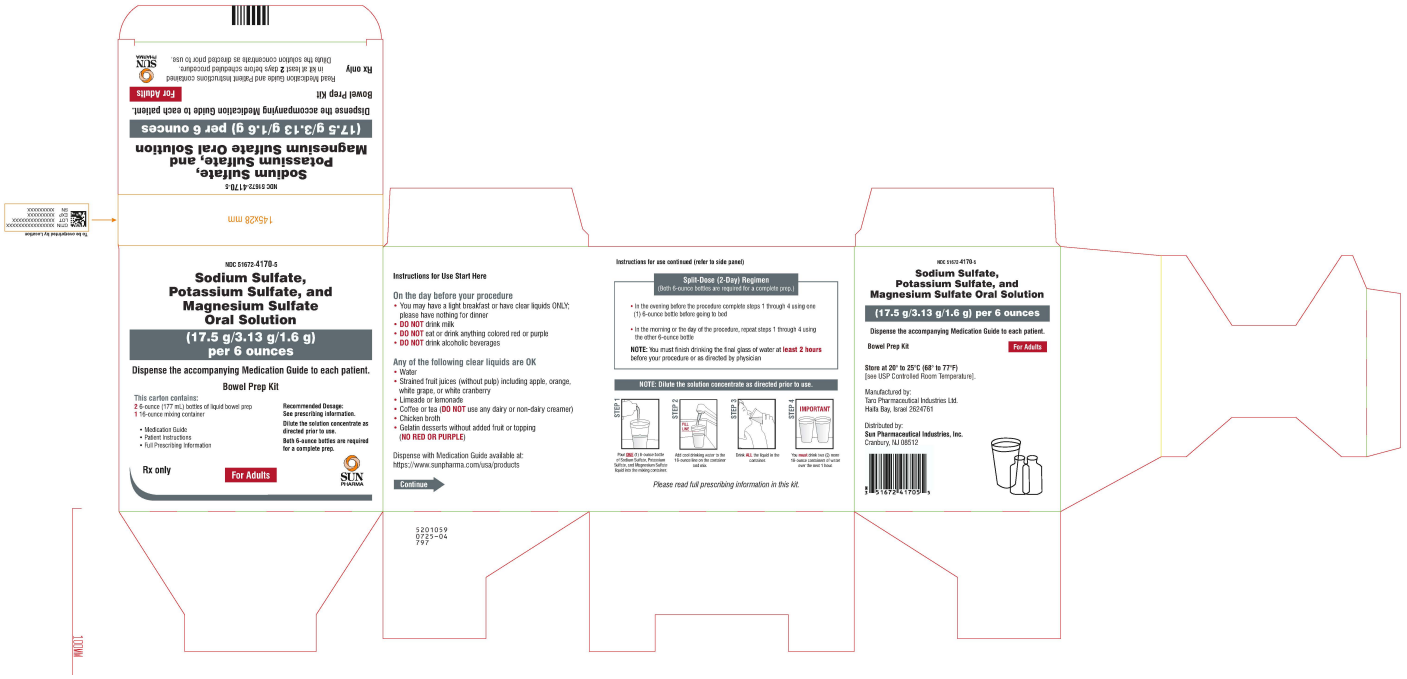
Oral Solution

For Adults

(17.5 g/3.13 g/1.6 g) per 6 ounces

Bowel Prep Kit





SODIUM SULFATE, POTASSIUM SULFATE, AND MAGNESIUM SULFATE BOWEL PREP KIT

sodium sulfate anhydrous, potassium sulfate, and magnesium sulfate solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51672-4170
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM SULFATE ANHYDROUS (UNII: 36KCS0R750) (SODIUM SULFATE ANHYDROUS - UNII:36KCS0R750)	SULFATE ION	17.5 g in 177 mL
POTASSIUM SULFATE (UNII: 1K573LC5TV) (SULFATE ION - UNII:7IS9N8KPMG)	POTASSIUM SULFATE	3.13 g in 177 mL
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM SULFATE, UNSPECIFIED FORM	1.6 g in 177 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
MALIC ACID (UNII: 817L1N4CKP)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	GRAPE, BERRY (mixed berry)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-4170-5	2 in 1 CARTON	03/27/2024	
1		177 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206431	03/27/2024	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries, Ltd.		600072078	manufacture(51672-4170)

Revised: 7/2025 Sun Pharmaceutical Industries, Inc.