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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.

Initial U.S. Approval: 2010

RECENT MAJOR CHANGES

Warnings and Precautions, Hypersensitivity Reactions (5.8) 11/2025

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.
• 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, 2.2)
• Recommended sodium sulfate, potassium sulfate, and magnesium sulfate oral solution dosage is:
o 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)

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FULL PRESCRIBING 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 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.

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)].

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.

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 for 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 dose 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.

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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 Precaution (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 [see Warnings and Precautions (5.8) and Description (11)].

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 ionic cations 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 sphincter 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 suspected 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.

5.8 Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis, angioedema, dyspnea, rash, pruritus and urticaria have been reported with sodium sulfate, potassium sulfate, and magnesium sulfate oral solution [see Adverse Reactions (6.2)]. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should signs and symptoms occur.

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)]
• Hypersensitivity Reactions [see Warnings and Precautions (5.8)]

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

* reported in at least 2% of patients

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, 5, 8)

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: 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)
• Hypersensitivity reactions, including anaphylaxis: Inform patients to seek immediate medical care if symptoms occur. (5.8)

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.

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7.2 Potential for Reduced Drug Absorption

7.3 Specific Laxatives

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

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 ionic cations 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 sphincter 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 suspected 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.

5.8 Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis, angioedema, dyspnea, rash, pruritus and urticaria have been reported with sodium sulfate, potassium sulfate, and magnesium sulfate oral solution [see Adverse Reactions (6.2)]. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should signs and symptoms occur.

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)]
• Hypersensitivity Reactions [see Warnings and Precautions (5.8)]

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:
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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

* 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*

Table with 3 columns: Parameter, Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution, Day of Colonoscopy N (%), Day 30 N (%).

* 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 timepoint(s) of interest.

Less Common Adverse Reactions

All 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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6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Hypersensitivity: anaphylaxis, angioedema, dyspnea, rash, pruritus, urticaria [see Warnings and Precautions (5.8)].

7 DRUG INTERACTIONS

7.1 Drugs That May Increase Risks 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 372 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

Overdose 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 Sulf

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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:

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

See "What are the possible side effects of sodium 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 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 not take 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 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)
- chlorpromazine
- 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 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 away if 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:
 - vomiting
 - nausea
 - bloating
 - dizziness
 - stomach area (abdomen) cramping
 - headache
 - urinate less than usual
 - trouble drinking clear liquid
 - trouble swallowing
 - seizures
 - heart problems
 - 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.
- **Serious allergic reactions.** Get medical help right away if you have any signs and symptoms of a serious allergic reaction while taking SUPREP Bowel Prep Kit, including:
 - difficulty breathing
 - itching
 - swelling of the face, lips, tongue or throat
 - raised red patches on your skin (hives)
 - skin rash

The most common side effects of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution in adults include:

- overall discomfort
- stomach bloating
- stomach pain
- nausea
- 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 health 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 strength. 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.

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

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