HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use COLPREP KIT safely and effectively. See full prescribing information for COLPREP KIT

COLPREP KIT (sodium sulfate, potassium sulfate, and magnesium sulfate) for oral solution

Initial U.S. Approval: 2010

----------INDICATIONS AND USAGE----------

ColPrep Kit is an osmotic laxative indicated for cleansing of the colon as a preparation for colonoscopy in adults. (1)

----------DOSAGE AND ADMINISTRATION----------

- The recommended dosage of ColPrep Kit is a split-dose (2-Day) oral regimen. (2.1):
  - Dose 1: administered in the evening before colonoscopy, 10 to 12 hours before the second dose
  - Dose 2: administered the morning of colonoscopy, at least 3 ½ hours before colonoscopy
- ColPrep Kit must be reconstituted and diluted in water prior to ingestion. Direct ingestion of the undiluted reconstituted solution may increase the risk of nausea, vomiting, and dehydration. (2.2, 5.8)
- Additional fluids must be consumed after each dose of ColPrep. (2.2, 2.4)
- For complete information on dosing, instructions for use, preparation and administration, see full prescribing information. (2.1, 2.2, 2.3, 2.4).
- Do not take oral medications within 1 hour of start of each dose. (2.3, 7.2)
- Complete preparation at least 2 hours before colonoscopy or as directed by physician. (2.3)

----------DOSAGE FORMS AND STRENGTHS----------

For oral solution: Two bottles per ColPrep Kit. Each bottle contains sodium sulfate 17.5 g, potassium sulfate 3.13 g, and magnesium sulfate 1.6 g. (3)

----------CONTRAINDICATIONS----------

- Gastrointestinal obstruction. (4, 5.6)
- Bowel perforation. (4, 5.6)
- Gastric retention. (4)
- Ileus. (4)
- Toxic colitis or toxic megacolon. (4)
- Known allergies to components of the kit. (4, 11)

----------WARNINGS AND PRECAUTIONS----------

- Risk of fluid and electrolyte abnormalities, arrhythmias, seizures and renal impairment– assess concurrent medications and consider testing in some patients. (5.1, 5.2, 5.3)
- Patients with renal insufficiency – use caution, ensure adequate hydration and consider testing. (5.4)
- Suspected GI obstruction or perforation – rule out the diagnosis before administration. (4, 5.6)
- Patients at risk for aspiration – observe during administration. (5.7)

----------ADVERSE REACTIONS----------

Most common adverse reactions (≥3%) are: overall discomfort, abdominal fullness, nausea, abdominal cramping, and vomiting. (6)

To report SUSPECTED ADVERSE REACTIONS, contact KVK-Tech, Inc. at 1-215-579-1842 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------

- Some drugs increase risks due to fluid and electrolyte changes. (7.1)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 12/2016

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

ColPrep Kit is indicated for cleansing of the colon as a preparation for colonoscopy in adults.

2 DOSAGE AND ADMINISTRATION

2.1 Dosage Regimen

The recommended dosage of ColPrep Kit is one bottle administered in the evening before colonoscopy and the second bottle administered the morning of colonoscopy as follows:

Dose 1: Early in the evening prior to colonoscopy, 10 to 12 hours before the second dose.
Dose 2: The morning of colonoscopy, at least 3 ½ hours before colonoscopy.

2.2 Important Dosing Instructions

- ColPrep Kit must be reconstituted and diluted in water prior to ingestion. Direct ingestion of the undiluted reconstituted solution may increase the risk of nausea, vomiting, and dehydration *[See Warnings and Precautions (5.8)]*.
- The ColPrep Kit is comprised of two bottles of ColPrep administered as a two-day regimen. Both doses of ColPrep Kit are required for a complete preparation for colonoscopy.
- Additional fluids must be consumed after each dose of ColPrep *[See Dosage and Administration (2.4)]*.
- Do not take other laxatives while taking ColPrep Kit.

2.3 Instructions for Use

Dose 1 - On the day before colonoscopy (start 10 to 12 hours prior to Dose 2):

- A light breakfast may be consumed in the morning.
- Only clear liquids may be consumed for the rest of the day after a light breakfast. Do not drink milk.
- Do not eat solid foods for the rest of the day after breakfast until the next day after colonoscopy.
- Do not eat or drink anything colored red or purple.
- Do not drink alcohol.
- Do not take oral medications within one hour of starting the first dose of ColPrep Kit.

Dose 2 - Next morning on the day of colonoscopy (start at least 3 1/2 hours prior to colonoscopy):

- Continue to abstain from all solid food and anything to drink other than clear liquids.
- Do not take oral medications within one hour of starting the second dose of ColPrep Kit.
- Complete all ColPrep Kit and required water at least 2 hours prior to colonoscopy or as directed by physician.
- Stop drinking clear liquids at least 2 hours before colonoscopy.

2.4 Preparation and Administration

Two doses of ColPrep Kit are required for a complete preparation for colonoscopy as a split-dose (two-day regimen). The total volume of liquid required is approximately 2.8 L taken orally prior to the colonoscopy, as described below.

Dose 1: Early in the evening prior to colonoscopy, 10 to 12 hours before Dose 2:

1. Open ONE (1) bottle from the ColPrep Kit.
2. Fill the bottle with water up to the neck of the bottle. Shake well and mix thoroughly.
3. Pour the reconstituted solution from the bottle into the mixing container provided.

4. Fill the mixing container with water to the 16 ounce fill line.
5. Drink the entire amount.
6. Important: Drink two additional mixing containers filled to the 16 ounce fill line with water over the next hour (32 ounces of additional water).

Dose 2: The morning of colonoscopy, at least 3 ½ hours before colonoscopy:

1. Repeat Steps 1 through 6 from Dose 1 of the Split-Dose (2-Day Regimen).
2. Complete all ColPrep Kit solution and required water at least two hours prior to colonoscopy.

3 DOSAGE FORMS AND STRENGTHS

For oral solution: One ColPrep Kit contains two 200 mL bottles and one mixing container. Each bottle contains 22.7 g of white to off-white granular powder including sodium sulfate 17.5 g, potassium sulfate 3.13 g, and magnesium sulfate 1.6 g.

4 CONTRAINDICATIONS

- Gastrointestinal obstruction
- Bowel perforation
- Gastric retention
- Ileus
- Toxic colitis or toxic megacolon
- Known allergies to components of the kit *[See 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 ColPrep Kit. If a patient develops significant vomiting or signs of dehydration after taking ColPrep Kit, consider performing post-colonoscopy lab tests (electrolytes, creatinine, and BUN). Fluid and electrolyte disturbances can lead to serious adverse events including cardiac arrhythmias, seizures and renal impairment.

Patients with electrolyte abnormalities should have them corrected before treatment with ColPrep Kit. In addition, use caution when prescribing ColPrep Kit for 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)]*

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

5.2 Cardiac Arrhythmias

There have been rare reports of serious arrhythmias associated with the use of ionic osmotic laxative products for bowel preparation. Use caution when prescribing ColPrep Kit for patients at increased risk of arrhythmias (e.g., patients with a history of prolonged QT, uncontrolled arrhythmias, recent myocardial infarction, unstable angina, congestive heart failure, or cardiomyopathy). Pre-dose and post-colonoscopy ECGs should be considered in patients at increased risk of serious cardiac arrhythmias.

5.3 Seizures

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

Use caution when prescribing ColPrep Kit for patients with a history of seizures and in patients at increased risk of seizure, such as patients taking medications that lower the seizure threshold (e.g., tricyclic antidepressants), patients withdrawing from alcohol or benzodiazepines, or patients with known or suspected hyponatremia.

5.4 Renal Impairment

Use caution when prescribing ColPrep Kit for patients with impaired renal function or patients taking concomitant medications that may affect renal function (such as diuretics, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, or non-steroidal anti-inflammatory drugs). Advise these patients of the importance of adequate hydration, and consider performing baseline and post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN) in these patients.

5.5 Colonic Mucosal Ulcerations and Ischemic Colitis

Administration of osmotic laxative products may produce colonic mucosal aphthous ulcerations, and there have been reports of more serious cases of ischemic colitis requiring hospitalization. Concurrent use of stimulant laxatives and ColPrep Kit may increase these risks. The potential for mucosal ulcerations resulting from the bowel preparation should be considered when interpreting colonoscopy findings in patients with known or suspect inflammatory bowel disease (IBD).

5.6 Use in Patients with Significant Gastrointestinal Disease

If gastrointestinal obstruction or perforation is suspected, perform appropriate diagnostic studies to rule out these conditions before administering ColPrep Kit.
Use with caution in patients with severe active ulcerative colitis.

5.7 Aspiration

Use with caution in patients with impaired gag reflex and patients prone to regurgitation or aspiration. Such patients should be observed during administration of ColPrep Kit.

5.8 Not for Direct Ingestion

Each bottle must be reconstituted followed by dilution with water to a final volume of 16 ounces and ingestion of 32 ounces of additional water as recommended is important to patient tolerance. Direct ingestion of the undiluted solution may increase the risk of nausea, vomiting, dehydration, and electrolyte disturbances.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in clinical studies of another drug and may not reflect the rates observed in practice.
The safety of ColPrep Kit has been established from adequate and well-controlled trials of another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) *[See Clinical Studies (14)]*. Below is a display of the adverse reactions of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) in these adequate and well-controlled studies.
In a multicenter, controlled clinical trial comparing another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) with a bowel prep containing polyethylene glycol and electrolytes (PEG + E) that were administered in a split-dose (2-day) regimen, the most common adverse reactions after administration of another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) were overall discomfort, abdominal distention, abdominal pain, nausea, vomiting, and headache; See Table 1, below.
Less common adverse reactions occurring were atrioventricular (AV) block (1 case) and creatine kinase (CK) increase. In this study, patients receiving another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) were limited to a light breakfast followed by clear liquids; patients receiving the PEG + E bowel prep were allowed to have a normal breakfast and a light lunch, followed by clear liquids.

Table 1: Treatment-Emergent Adverse Reactions Observed in at Least 2% of Patients on the Split-Dose (2-Day) Regimen

Adverse Reaction	Split-Dose (2-Day) Regimen	
	Sodium sulfate (17.5 g), Potassium sulfate (3.13 g), and Magnesium sulfate (1.6 g) 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%
Headache	1.1%	0.5%

Table 2 shows the percentages of patients who developed new abnormalities of important electrolytes and uric acid after completing the bowel preparation with either another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)or PEG+E administered as a split-dose (2-day) regimen.

Table 2: 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 (%)*
Anion Gap (high) †	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	14 (8.9)	3 (1.9)
	PEG + Electrolytes	12 (7.6)	2 (1.4)
Bicarbonate (low)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	20 (12.7)	7 (4.4)
	PEG + Electrolytes	24 (15.2)	4 (2.7)
Bilirubin, total (high)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	14 (8.5)	0 (0)
	PEG + Electrolytes	20 (11.7)	3 (1.9)
BUN (high)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	2 (1.6)	14 (11.2)
	PEG + Electrolytes	4 (2.9)	19 (14.5)
Calcium (high)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	16 (10.4)	8 (5.2)
	PEG + Electrolytes	6 (3.7)	6 (3.9)
Chloride (high)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	4 (2.4)	6 (3.7)
	PEG + Electrolytes	20 (12.2)	6 (3.8)
Creatinine (high)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and	3 (1.9)	5 (3.2)

	magnesium sulfate (1.6 g)		
	PEG + Electrolytes	2 (1.2)	8 (5.2)
Osmolality (high)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	8 (5.8)	NA
	PEG + Electrolytes	19 (12.9)	NA
Osmolality (low)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	3 (2.2)	NA
	PEG + Electrolytes	2 (1.4)	NA
Potassium (high)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	3 (1.8)	6 (3.7)
	PEG + Electrolytes	5 (2.9)	8 (4.9)
Sodium (low)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	5 (3.1)	1 (0.6)
	PEG + Electrolytes	4 (2.3)	2 (1.2)
Uric acid (high)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	27 (23.5)	13 (11.5)
	PEG + Electrolytes	12 (9.5)	20 (16.7)
*Percent (n/N) of patients where N=number of patients with normal baseline who had abnormal values at the timepoint(s) of interest.			
†Patients with normal bicarbonate at baseline who developed low bicarbonate (≤21 mEq/L) and high anion gap (≥13 mEq/L) on Day of Colonoscopy or Day 30.			

There were also 408 patients who participated in a study in which another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) or PEG+E were administered in an evening-only (1-day) regimen. Higher rates of overall discomfort, abdominal distention, and nausea were observed with the evening-only (1- day) regimen compared to the split-dose (2-day) regimen for both preparations. Patients treated with another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) had increased rates of vomiting with the evening-only (1- day) regimen. An evening-only (1-day) dosing regimen was associated with higher rates of abnormal values for some electrolytes when compared to the split-dose (2-day) regimen for both preparations. For another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g), the evening only (1-day) regimen was associated with higher rates of total bilirubin (high), BUN (high), creatinine (high), osmolality (high), potassium (high) and uric acid (high) than the split dose (2-day) regimen. Administration of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) in an evening-only (1-day) dosing regimen is *not* recommended.

7 DRUG INTERACTIONS

7.1 Drugs That May Increase Risks Due to Fluid and Electrolyte Abnormalities

Use caution when prescribing ColPrep Kit for 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 prolonged QT in the setting of fluid and electrolyte abnormalities. Consider additional patient evaluations as appropriate *[See Warnings (5)]* in patients taking these concomitant medications.

7.2 Potential for Altered Drug Absorption

Oral medication administered within one hour of the start of each ColPrep Kit dose may be flushed from the gastrointestinal tract, and the medication may not be absorbed properly.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic effects: Pregnancy Category C. Animal reproduction studies have not been conducted with ColPrep Kit. It is also not known whether ColPrep Kit can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. ColPrep Kit should be given to a pregnant woman only if clearly needed.

8.3 Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ColPrep Kit is administered to a nursing woman.

8.4 Pediatric Use

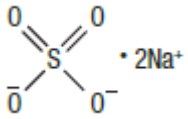
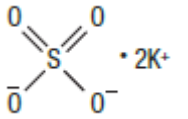
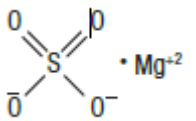
The safety and effectiveness of ColPrep Kit have not been established in pediatric patients.

8.5 Geriatric Use

Of the 375 patients who received another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) 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 (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) administered as a split-dose (2-day) regimen were observed between geriatric patients and younger patients. Geriatric patients reported more vomiting when sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) was given as a one- day preparation.

11 DESCRIPTION

ColPrep Kit (sodium sulfate, potassium sulfate and magnesium sulfate) for oral solution is an osmotic laxative that includes two 200 mL bottles and one 20-ounce mixing container. Each bottle contains 22.7 g of white to off-white granular powder including sodium sulfate 17.5 g, potassium sulfate 3.13 g, and magnesium sulfate 1.6 g and the following inactive ingredients: citric acid anhydrous, sucralose, and lemon flavor.

Component	Structural Formula	Molecular Formula	Molecular Weight
Sodium Sulfate		Na_2SO_4	142.04
Potassium Sulfate		K_2SO_4	174.26
Magnesium Sulfate		$MgSO_4$	120.37

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

The osmotic effect of the unabsorbed ions, when ingested with a large volume of water, produces a copious watery diarrhea.

12.3 Pharmacokinetics

Absorption

After administration of another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) in six healthy subjects, the time at which serum sulfate reached its highest point (T_{max}) was approximately 17 hours after the first half dose or approximately 5 hours after the second dose.

Elimination

Serum sulfate concentrations declined with a half-life of 8.5 hours. The mean sulfate levels returned to baseline level by Day 6 after dose initiation. Fecal excretion was the primary route of sulfate elimination in healthy subjects.

Specific Populations

Hepatic and Renal Impairment

The disposition of sulfate after administration of another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) was studied in patients (N=6) with mild-moderate hepatic impairment (Child-Pugh grades A and B) and in patients (N=6) with moderate renal impairment (creatinine clearance of 30 to 49 mL/min). The renal impairment group had the highest serum sulfate AUC and Cmax, followed by the hepatic impairment group, and then by healthy subjects. The mean sulfate levels of all three groups returned to their respective baseline levels by Day 6 after dose initiation.

The systemic exposure of serum sulfate (AUC and C_{max}) was similar between healthy subjects and patients with mild to moderate hepatic impairment. Urinary excretion of sulfate over 30 hours, starting after the first half dose, was similar between hepatically impaired patients and healthy subjects.

In patients with moderate renal impairment, mean AUC and C_{max} were 54% and 44% higher than those in healthy subjects, respectively. Urinary excretion of sulfate over 30 hours, starting after the first half dose, was approximately 16% lower in moderate renal impairment patients than in healthy subjects.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of ColPrep Kit. Studies to evaluate the possible impairment of fertility or mutagenic potential of ColPrep Kit have not been performed.

13.2 Animal Toxicology and/or Pharmacology

The sulfate salts of sodium, potassium, and magnesium contained in ColPrep Kit were administered orally (gavage) to rats and dogs up to 28 days up to a maximum daily dose of 5 g/kg/day (approximately 0.9 and 3 times for rats and dogs, respectively, the recommended human dose of 44 g/day or 0.89 g/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

The safety and efficacy of ColPrep Kit has been established based on an adequate, controlled study of another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g). Below is a display of the results of this adequate and well-controlled study.

The colon cleansing efficacy of another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) was evaluated in a randomized, single-blind, active-controlled, multicenter study. In this study, 363 adult patients were 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: another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) or a marketed polyethylene glycol (PEG) bowel prep. In the Study, another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) was administered according to a split-dose preparation regimen *[See Dosage and Administration (2.1)]*. The PEG bowel prep was also given as a split-dose preparation according to its labeled instructions. Patients receiving another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) 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. In the study, no clinically or statistically significant differences were seen between the group treated with another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) and the group treated with the PEG bowel prep. See Table 3 below.

Table 3: Colon Cleansing Response Rates

Treatment Group	**Regimen**	**N**	**Responders[1] % (95% C.I.)**	**sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) - PEG Difference (95% CI)**
sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) (with light breakfast)	Split-Dose	180	**97%** (94%, 99%)	**2%**[2] (-2%, 5%)
PEG bowel prep (with normal breakfast & light lunch)	Split-Dose	183	**96%** (92%, 98%)	

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

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

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied:
Each ColPrep Kit contains:

- Two 200 mL round white high density polyethylene bottles with 38 mm white plastic caps. Each bottle contains sodium sulfate 17.5 g, potassium sulfate 3.13 g, and magnesium sulfate 1.6 g and the following inactive ingredients: citric acid anhydrous, sucralose, and lemon flavor.
- One 20-ounce polypropylene mixing container with a 16 ounce fill line.

ColPrep Kit NDC 10702-283-23

Storage:
Store at 20º to 25°C (68º to 77°F). Excursions permitted between 15ºC and 30°C (59ºF and 86°F). [See USP controlled room temperature]

Keep out of reach of children.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide and Instructions for Use)

Instruct patients:

- Two doses of ColPrep Kit are required for a complete preparation for colonoscopy as a split-dose (two-day regimen).
    - Dose 1: administered in the evening before colonoscopy, 10 to 12 hours before the second dose
    - Dose 2: administered the morning of colonoscopy, at least 3 ½ hours before colonoscopy
- To reconstitute each bottle of ColPrep Kit and to dilute the reconstituted solution in water before ingestion.
- To drink additional water, as described in the Instructions for Use.
- Direct ingestion of the undiluted reconstituted solution may increase the risk of nausea, vomiting, and dehydration *[See Warnings and Precautions (5.8)]*.
- Not to take other laxatives while they are taking ColPrep Kit.
- On the day before colonoscopy: A light breakfast may be consumed. Only clear liquids may be consumed after a light breakfast. Examples of clear liquids are found in the Instructions for Use.
- To avoid red and purple liquids, milk, and alcoholic beverages.
- Not to take oral medications within one hour of starting each dose of ColPrep Kit.
- The first bowel movement may occur approximately 1 hour after the start of ColPrep Kit administration. Abdominal bloating and distention may occur before the first bowel movement. If severe abdominal discomfort or distention occurs, stop drinking ColPrep Kit temporarily or drink each portion at longer intervals until these symptoms diminish. If severe symptoms persist, notify their healthcare provider.
- To notify their healthcare provider, if they develop significant vomiting or signs of dehydration after taking ColPrep Kit or if they experience seizures or loss of consciousness *[See Warnings and Precautions (5.1, 5.3)]*.

Manufactured for: **GATOR PHARMACEUTICALS, INC. ST. AUGUSTINE, FL 32080**

Item ID # 6190/07
Rev 12/2016

Dispense the enclosed Medication Guide to each patient.

ColPrep Kit

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

(17.5 g/3.13 g/1.6 g) per bottle

Patient Instructions for Use

Booklet Includes:

1- Medication Guide

2- Instructions for Use

3- Package Insert

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

ColPrep Kit is indicated for cleansing of the colon as a preparation for colonoscopy in adults.

2 DOSAGE AND ADMINISTRATION

2.1 Dosage Regimen

The recommended dosage of ColPrep Kit is one bottle administered in the evening before colonoscopy and the second bottle administered the morning of colonoscopy as follows:

Dose 1: Early in the evening prior to colonoscopy, 10 to 12 hours before the second dose.

Dose 2: The morning of colonoscopy, at least 3 ½ hours before colonoscopy.

2.2 Important Dosing Instructions

- ColPrep Kit must be reconstituted and diluted in water prior to ingestion. Direct ingestion of the undiluted reconstituted solution may increase the risk of nausea, vomiting, and dehydration *[see Warnings and Precautions (5.8)]*.
- The ColPrep Kit is comprised of two bottles of ColPrep administered as a two-day regimen. Both doses of ColPrep Kit are required for a complete preparation for colonoscopy.
- Additional fluids must be consumed after each dose of ColPrep *[see Dosage and Administration (2.4)]*.
- Do not take other laxatives while taking ColPrep Kit.

2.3 Instructions for Use

Dose 1 - On the day before colonoscopy (start 10 to 12 hours prior to Dose 2):

- A light breakfast may be consumed in the morning.

- Only clear liquids may be consumed for the rest of the day after a light breakfast. Do not drink milk.
- Do not eat solid foods for the rest of the day after breakfast until the next day after colonoscopy.
- Do not eat or drink anything colored red or purple.
- Do not drink alcohol.
- Do not take oral medications within one hour of starting the first dose of ColPrep Kit.

Dose 2 - Next morning on the day of colonoscopy (start at least 3 ½ hours prior to colonoscopy):

- Continue to abstain from all solid food and anything to drink other than clear liquids.
- Do not take oral medications within one hour of starting the second dose of ColPrep Kit.
- Complete all ColPrep Kit and required water at least 2 hours prior to colonoscopy or as directed by physician.
- Stop drinking clear liquids at least 2 hours before colonoscopy.

2.4 Preparation and Administration

Two doses of ColPrep Kit are required for a complete preparation for colonoscopy as a split-dose (two-day regimen). The total volume of liquid required is approximately 2.8 L taken orally prior to the colonoscopy, as described below.

Dose 1: Early in the evening prior to colonoscopy, 10 to 12 hours before Dose 2:

1. Open ONE (1) bottle from the ColPrep Kit.
2. Fill the bottle with water up to the neck of the bottle. Shake well and mix thoroughly.
3. Pour the reconstituted solution from the bottle into the mixing container provided.

Medication Guide

ColPrep (kō-l Prep) Kit
(sodium sulfate, potassium sulfate, and magnesium sulfate)
for oral solution

What is the most important information I should know about ColPrep Kit?

ColPrep Kit 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 risk of having fluid loss and changes in body salts with ColPrep Kit is higher if you:

- have heart problems
- have kidney problems
- take water pills, high blood pressure medicine, 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 ColPrep Kit:

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

Tell your healthcare provider right away if you have a seizure or faint (lose consciousness).

See "What are the possible side effects of ColPrep Kit?" for more information about side effects.

What is ColPrep Kit?

ColPrep Kit is a prescription medicine used by adults to clean the colon before a colonoscopy. ColPrep Kit cleans your colon by causing you to have diarrhea. Cleaning your colon helps your healthcare provider see the inside of your colon more clearly during your colonoscopy.

It is not known if ColPrep Kit is safe and effective in children.

Do not take ColPrep Kit if your healthcare provider has told you that you have:

- a blockage in your bowel (obstruction).
- an opening in the wall of your stomach or intestine (bowel perforation).
- a problem with food and fluid emptying from your stomach (gastric retention).
- a problem with food moving too slowly through your intestines (ileus).
- a very dilated intestine (toxic megacolon).
- an allergy to any of the ingredients in ColPrep Kit. See the end of this leaflet for a complete list of ingredients in ColPrep Kit.

4. Fill the mixing container with water to the 16 ounce fill line.
5. Drink the entire amount.
6. Important: Drink two additional mixing containers filled to the 16 ounce fill line with water over the next hour (32 ounces of additional water).

Dose 2: The morning of colonoscopy, at least 3 ½ hours before colonoscopy:

1. Repeat Steps 1 through 6 from Dose 1 of the Split-Dose (2-Day Regimen).
2. Complete all ColPrep Kit solution and required water at least two hours prior to colonoscopy.

3 DOSAGE FORMS AND STRENGTHS

For oral solution: One ColPrep Kit contains two 200 mL bottles and one mixing container. Each bottle contains 22.7 g of white to off-white granular powder including sodium sulfate 17.5 g, potassium sulfate 3.13 g, and magnesium sulfate 1.6 g.

4 CONTRAINDICATIONS

- Gastrointestinal obstruction
- Bowel perforation
- Gastric retention
- Ileus
- Toxic colitis or toxic megacolon
- Known allergies to components of the kit *[see 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 ColPrep Kit. If a patient develops significant vomiting or signs of dehydration after taking ColPrep Kit, consider performing post-colonos-

copy lab tests (electrolytes, creatinine, and BUN). Fluid and electrolyte disturbances can lead to serious adverse events including cardiac arrhythmias, seizures and renal impairment.

Patients with electrolyte abnormalities should have them corrected before treatment with ColPrep Kit. In addition, use caution when prescribing ColPrep Kit for 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)]*

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

5.2 Cardiac Arrhythmias

There have been rare reports of serious arrhythmias associated with the use of ionic osmotic laxative products for bowel preparation. Use caution when prescribing ColPrep Kit for patients at increased risk of arrhythmias (e.g., patients with a history of prolonged QT, uncontrolled arrhythmias, recent myocardial infarction, unstable angina, congestive heart failure, or cardiomyopathy). Pre-dose and post-colonoscopy ECGs should be considered in patients at increased risk of serious cardiac arrhythmias.

5.3 Seizures

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

Medication Guide

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

- have heart problems.
- have stomach or bowel problems, including ulcerative colitis.
- have problems with swallowing, gastric reflux, or if you inhale food or fluid into your lungs when eating or drinking (aspirate).
- have gout.
- have a history of seizures.
- are withdrawing from drinking alcohol.
- have a low blood salt (sodium) level.
- have kidney problems.
- are pregnant. It is not known if ColPrep Kit can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ColPrep Kit passes into your breast milk. You and your healthcare provider should decide if you will take ColPrep Kit while breastfeeding.

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

ColPrep Kit may affect how other medicines work. Medicines taken by mouth may not be absorbed properly when taken within 1 hour before the start of each dose of ColPrep Kit.

Especially tell your healthcare provider if you take:

- medicines for blood pressure or heart problems
- medicines for kidney problems
- medicines for seizures
- water pills (diuretics)
- non-steroidal anti-inflammatory drugs (NSAIDs)
- laxatives
- medicines for depression or mental health problems

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 ColPrep Kit?

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

- Take ColPrep Kit exactly as your healthcare provider tells you to take it.
- **Do not take ColPrep Kit powder that has not been mixed with water, it may increase your risk of nausea, vomiting and fluid loss (dehydration).**
- Each bottle of ColPrep Kit powder must be mixed with water and diluted with additional water 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).
- You may eat a light breakfast in the morning on the day before your colonoscopy.
- Do not take other laxatives while taking ColPrep Kit.
- Do not take any medicine by mouth within 1 hour of starting each dose of ColPrep Kit.
- Do not eat solid foods or drink milk or alcohol while taking ColPrep Kit and until after your colonoscopy. Drink only clear liquids:
  - after eating a light breakfast in the morning on the day before your colonoscopy
  - while taking ColPrep Kit
  - after taking ColPrep Kit and until 2 hours before your colonoscopy

osmolality. The neurologic abnormalities resolved with correction of fluid and electrolyte abnormalities.

Use caution when prescribing ColPrep Kit for patients with a history of seizures and in patients at increased risk of seizure, such as patients taking medications that lower the seizure threshold (e.g., tricyclic antidepressants), patients withdrawing from alcohol or benzodiazepines, or patients with known or suspected hyponatremia.

5.4 Renal Impairment

Use caution when prescribing ColPrep Kit for patients with impaired renal function or patients taking concomitant medications that may affect renal function (such as diuretics, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, or non-steroidal anti-inflammatory drugs). Advise these patients of the importance of adequate hydration, and consider performing baseline and post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN) in these patients.

5.5 Colonic Mucosal Ulcerations and Ischemic Colitis

Administration of osmotic laxative products may produce colonic mucosal aphthous ulcerations, and there have been reports of more serious cases of ischemic colitis requiring hospitalization. Concurrent use of stimulant laxatives and ColPrep Kit may increase these risks. The potential for mucosal ulcerations resulting from the bowel preparation should be considered when interpreting colonoscopy findings in patients with known or suspect inflammatory bowel disease (IBD).

5.6 Use in Patients with Significant Gastrointestinal Disease

If gastrointestinal obstruction or perforation is suspected, perform appropriate diagnostic studies to rule out these conditions before administering ColPrep Kit.

Use with caution in patients with severe active ulcerative colitis.

5.7 Aspiration

Use with caution in patients with impaired gag reflex and patients prone to regurgitation or aspiration. Such patients should be observed during administration of ColPrep Kit.

5.8 Not for Direct Ingestion

Each bottle must be reconstituted followed by dilution with water to a final volume of 16 ounces and ingestion of 32 ounces of additional water as recommended is important to patient tolerance. Direct ingestion of the undiluted solution may increase the risk of nausea, vomiting, dehydration, and electrolyte disturbances.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

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

The safety of ColPrep Kit has been established from adequate and well-controlled trials of another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) *[see Clinical Studies (14)]*. Below is a display of the adverse reactions of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) in these adequate and well-controlled studies.

In a multicenter, controlled clinical trial comparing another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) with a bowel prep containing polyethylene glycol and electrolytes (PEG + E) that were administered in a split-dose (2-day) regimen, the most common adverse reactions after administration of another oral formulation of sodium sulfate (17.5 g),

Medication Guide

Do not eat or drink anything at least 2 hours before your colonoscopy.

- Drink clear liquids before, during, and after you take ColPrep Kit to avoid fluid loss (dehydration). See the Instructions for Use for examples of clear liquids.

Do not eat or drink anything colored red or purple.

- You may have stomach-area (abdomen) bloating before you have your first bowel movement.
- Stop drinking ColPrep Kit for a short time or wait a longer time between each dose of ColPrep Kit if you have severe stomach-area (abdomen) discomfort or bloating until your symptoms improve. If these symptoms continue, tell your healthcare provider.
- Your first bowel movement may happen about 1 hour after you start taking ColPrep Kit.

What are the possible side effects of ColPrep Kit?

ColPrep Kit can cause serious side effects, including:

- **See "What is the most important information I should know about ColPrep Kit?"**
- **Changes in certain blood tests.** Your healthcare provider may do blood tests after you take ColPrep Kit 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

- **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 ColPrep Kit include:

- discomfort
- stomach-area (abdomen) bloating
- stomach-area (abdomen) cramping
- nausea
- vomiting

These are not all of the possible side effects of ColPrep Kit.

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

How should I store ColPrep Kit?

- Store ColPrep Kit at room temperature between 68ºF to 77°F (20ºC to 25°C).

Keep ColPrep Kit and all medicines out of the reach of children.

General information about the safe and effective use of ColPrep Kit.

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

What are the ingredients in ColPrep Kit?

Active ingredients: sodium sulfate, potassium sulfate, and magnesium sulfate

Inactive ingredients: citric acid anhydrous, sucralose, and lemon flavor

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Issued: 12/2016

potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) were overall discomfort, abdominal distention, abdominal pain, nausea, vomiting, and headache; see Table 1, below.

Less common adverse reactions occurring were atrioventricular (AV) block (1 case) and creatine kinase (CK) increase. In this study, patients receiving another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) were limited to a light breakfast followed by clear liquids; patients receiving the PEG + E bowel prep were allowed to have a normal breakfast and a light lunch, followed by clear liquids.

Table 1: Treatment-Emergent Adverse Reactions Observed in at Least 2% of Patients on the Split-Dose (2-Day) Regimen

Adverse Reaction	Split-Dose (2-Day) Regimen	
	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) 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%
Headache	1.1%	0.5%

Table 2 shows the percentages of patients who developed new abnormalities of important electrolytes and uric acid after completing the bowel preparation with either another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) or PEG+E administered as a split-dose (2-day) regimen.

Table 2: 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 (%)*
Anion gap (high)†	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	14 (8.9)	3 (1.9)
	PEG + Electrolytes	12 (7.6)	2 (1.4)
Bicarbonate (low)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	20 (12.7)	7 (4.4)
	PEG + Electrolytes	24 (15.2)	4 (2.7)
Bilirubin, total (high)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	14 (8.5)	0 (0)
	PEG + Electrolytes	20 (11.7)	3(1.9)
BUN (high)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	2 (1.6)	14 (11.2)
	PEG + Electrolytes	4 (2.9)	19 (14.5)
Calcium (high)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	16 (10.4)	8 (5.2)
	PEG + Electrolytes	6 (3.7)	6 (3.9)
Chloride (high)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	4 (2.4)	6 (3.7)
	PEG + Electrolytes	20 (12.2)	6 (3.8)
Creatinine (high)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	3 (1.9)	5 (3.2)
	PEG + Electrolytes	2 (1.2)	8 (5.2)
Osmolality (high)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	8 (5.8)	NA
	PEG + Electrolytes	19 (12.9)	NA
Osmolality (low)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	3 (2.2)	NA
	PEG + Electrolytes	2 (1.4)	NA
Potassium (high)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	3 (1.8)	6 (3.7)
	PEG + Electrolytes	5 (2.9)	8 (4.9)
Sodium (low)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	5 (3.1)	1 (0.6)
	PEG + Electrolytes	4 (2.3)	2 (1.2)
Uric acid (high)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g)	27 (23.5)	13 (11.5)
	PEG + Electrolytes	12 (9.5)	20 (16.7)

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

†Patients with normal bicarbonate at baseline who developed low bicarbonate (≤21 mEq/L) and high anion gap (≥13 mEq/L) on Day of Colonoscopy or Day 30.

Instructions for Use

On the day before your colonoscopy:

- You may eat a light breakfast.
- **Do not** eat solid foods or drink milk or alcohol while taking ColPrep Kit and until after your colonoscopy.
- **Do not** eat or drink anything colored red or purple.

Drink only clear liquids:

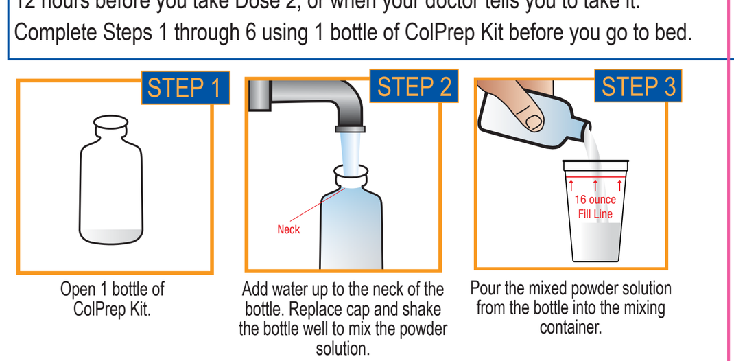
- after eating a light breakfast in the morning on the day before your colonoscopy.
- while taking ColPrep Kit.
- after taking ColPrep Kit and until 2 hours before your colonoscopy.

Do not eat or drink anything at least 2 hours before your colonoscopy.

Two doses of ColPrep Kit are required for a complete bowel prep.

Split-Dose (2 Day) ColPrep Kit Instructions

Dose 1: Take this dose early in the evening before your colonoscopy, about 10 to 12 hours before you take Dose 2, or when your doctor tells you to take it. Complete Steps 1 through 6 using 1 bottle of ColPrep Kit before you go to bed.



Open 1 bottle of ColPrep Kit. — Add water up to the neck of the bottle. Replace cap and shake the bottle well to mix the powder solution. — Pour the mixed powder solution from the bottle into the mixing container.

This Instructions for Use has been approved by the U.S. Food and Drug Administration

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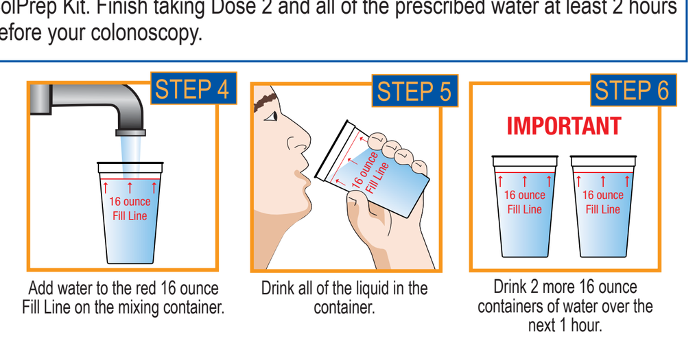
You may eat or drink any of the following clear liquids:

- water
- clear fruit juices without pulp including apple, white grape, or white cranberry
- strained limeade or lemonade
- coffee or tea (**Do not** use any dairy or non-dairy creamer)
- clear broth
- clear soda
- gelatin (without added fruit or topping)
- popsicles (without pieces of fruit or fruit pulp)

Do not eat or drink anything colored red or purple.

Each bottle of ColPrep Kit powder must be mixed with water and diluted with additional water according to instructions.

Dose 2: Take this dose on the morning of your colonoscopy, at least 3 ½ hours before your colonoscopy. Repeat Steps 1 through 6 using the remaining bottle of ColPrep Kit. Finish taking Dose 2 and all of the prescribed water at least 2 hours before your colonoscopy.



Add water to the red 16 ounce Fill Line on the mixing container. — Drink all of the liquid in the container. — Drink 2 more 16 ounce containers of water over the next 1 hour.

There were also 408 patients who participated in a study in which another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) or PEG+E were administered in an evening-only (1-day) regimen. Higher rates of overall discomfort, abdominal distention, and nausea were observed with the evening-only (1-day) regimen compared to the split-dose (2-day) regimen for both preparations. Patients treated with another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) had increased rates of vomiting with the evening-only (1-day) regimen. An evening-only (1-day) dosing regimen was associated with higher rates of abnormal values for some electrolytes when compared to the split-dose (2-day) regimen for both preparations. For another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) , the evening only (1-day) regimen was associated with higher rates of total bilirubin (high), BUN (high), creatinine (high), osmolality (high), potassium (high) and uric acid (high) than the split dose (2-day) regimen. Administration of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) in an evening-only (1-day) dosing regimen is *not* recommended.

7 DRUG INTERACTIONS

7.1 Drugs That May Increase Risks Due to Fluid and Electrolyte Abnormalities

Use caution when prescribing ColPrep Kit for 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 prolonged QT in the setting of fluid and electrolyte abnormalities. Consider additional patient evaluations as appropriate *[see Warnings (5)]* in patients taking these concomitant medications.

7.2 Potential for Altered Drug Absorption

Oral medication administered within one hour of the start of each ColPrep Kit dose may be flushed from the gastrointestinal tract, and the medication may not be absorbed properly.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic effects: Pregnancy Category C. Animal reproduction studies have not been conducted with ColPrep Kit. It is also not known whether ColPrep Kit can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. ColPrep Kit should be given to a pregnant woman only if clearly needed.

8.3 Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ColPrep Kit is administered to a nursing woman.

8.4 Pediatric Use

The safety and effectiveness of ColPrep Kit have not been established in pediatric patients.

8.5 Geriatric Use

Of the 375 patients who received another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) 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 another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) administered as a split-dose (2-day) regimen were observed between geriatric patients and younger patients. Geriatric patients reported more vomiting when sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) was given as a one-day preparation.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use COLPREP KIT safely and effectively. See full prescribing information for COLPREP KIT

COLPREP KIT (sodium sulfate, potassium sulfate, and magnesium sulfate) for oral solution
Initial U.S. Approval: 2010

----------------------INDICATIONS AND USAGE----------------------

ColPrep Kit is an osmotic laxative indicated for cleansing of the colon as a preparation for colonoscopy in adults. (1)

--------------------DOSAGE AND ADMINISTRATION------------------

- The recommended dosage of ColPrep Kit is a split-dose (2-Day) oral regimen. (2.1):
  - Dose 1: administered in the evening before colonoscopy, 10 to 12 hours before the second dose
  - Dose 2: administered the morning of colonoscopy, at least 3 ½ hours before colonoscopy
- ColPrep Kit must be reconstituted and diluted in water prior to ingestion. Direct ingestion of the undiluted reconstituted solution may increase the risk of nausea, vomiting, and dehydration. (2.2, 5.8)
- Additional fluids must be consumed after each dose of ColPrep. (2.2, 2.4)
- For complete information on dosing, instructions for use, preparation and administration, see full prescribing information. (2.1, 2.2, 2.3, 2.4)
- Do not take oral medications within 1 hour of start of each dose. (2.3, 7.2)
- Complete preparation at least 2 hours before colonoscopy or as directed by physician. (2.3)

-----------------DOSAGE FORMS AND STRENGTHS------------------

- For oral solution: Two bottles per ColPrep Kit. Each bottle contains sodium sulfate 17.5 g, potassium sulfate 3.13 g, and magnesium sulfate 1.6 g. (3)

------------------------CONTRAINDICATIONS-------------------------

- Gastrointestinal obstruction. (4, 5.6)
- Bowel perforation. (4, 5.6)
- Gastric retention. (4)
- Ileus. (4)
- Toxic colitis or toxic megacolon. (4)
- Known allergies to components of the kit (4, 11)

---------------------WARNINGS AND PRECAUTIONS------------------

- Risk of fluid and electrolyte abnormalities, arrhythmias, seizures and renal impairment – assess concurrent medications and consider testing in some patients (5.1, 5.2, 5.3)
- Patients with renal insufficiency – use caution, ensure adequate hydration and consider testing. (5.4)
- Suspected GI obstruction or perforation – rule out the diagnosis before administration. (4, 5.6)
- Patients at risk for aspiration – observe during administration. (5.7)

------------------------ADVERSE REACTIONS-------------------------

Most common adverse reactions (≥3%) are: overall discomfort, abdominal fullness, nausea, abdominal cramping, and vomiting. (6)

To report SUSPECTED ADVERSE REACTIONS, contact KVK-Tech, Inc. at 1-215-579-1842 or FDA at 1-800-FDA-1088 or www.fda.gov-/medwatch.

-------------------------DRUG INTERACTIONS-------------------------

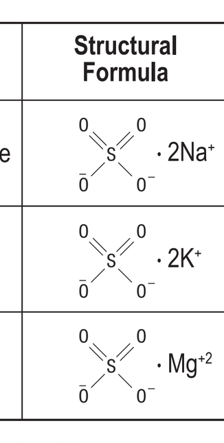
- Some drugs increase risks due to fluid and electrolyte changes. (7.1)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised 12/2016

11 DESCRIPTION

ColPrep Kit (sodium sulfate, potassium sulfate and magnesium sulfate) for oral solution is an osmotic laxative that includes two 200 mL bottles and one 20-ounce mixing container. Each bottle contains 22.7 g of white to off-white granular powder including sodium sulfate 17.5 g, potassium sulfate 3.13 g, and magnesium sulfate 1.6 g and the following inactive ingredients: citric acid anhydrous, sucralose, and lemon flavor.



Component	Structural Formula	Molecular Formula	Molecular Weight
Sodium Sulfate	· 2Na+	Na_2SO_4	142.04
Potassium Sulfate	· 2K+	K_2SO_4	174.26
Magnesium Sulfate	· Mg^{+2}	$MgSO_4$	120.37

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

The osmotic effect of the unabsorbed ions, when ingested with a large volume of water, produces a copious watery diarrhea.

12.3 Pharmacokinetics

Absorption

After administration of another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) in six healthy subjects, the time at which serum sulfate reached its highest point (T_{max}) was approximately 17 hours after the first half dose or approximately 5 hours after the second dose.

Elimination

Serum sulfate concentrations declined with a half-life of 8.5 hours. The mean sulfate levels returned to baseline level by Day 6 after dose initiation. Fecal excretion was the primary route of sulfate elimination in healthy subjects.

Specific Populations

Hepatic and renal impairment

The disposition of sulfate after administration of another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) was studied in patients (N=6) with mild-moderate hepatic impairment (Child-Pugh grades A and B) and in patients (N=6) with moderate renal impairment (creatinine clearance of 30 to 49 mL/min). The renal impairment group had the highest serum sulfate AUC and C_{max}, followed by the hepatic impairment group, and then by healthy subjects. The mean sulfate levels of all three groups returned to their respective baseline levels by Day 6 after dose initiation.

The systemic exposure of serum sulfate (AUC and C_{max}) was similar between healthy subjects and patients with mild to moderate hepatic impairment. Urinary excretion of sulfate over 30 hours, starting after the first half dose, was similar between hepatically impaired patients and healthy subjects.

In patients with moderate renal impairment, mean AUC and C_{max} were 54% and 44% higher than those in healthy subjects, respectively. Urinary excretion of sulfate over 30 hours, starting after the first half dose, was approximately 16% lower in moderate renal impairment patients than in healthy subjects.

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

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of ColPrep Kit. Studies to evaluate the possible impairment of fertility or mutagenic potential of ColPrep Kit have not been performed.

13.2 Animal Toxicology and/or Pharmacology

The sulfate salts of sodium, potassium, and magnesium contained in ColPrep Kit were administered orally (gavage) to rats and dogs up to 28 days up to a maximum daily dose of 5 g/kg/day (approximately 0.9 and 3 times for rats and dogs, respectively, the recommended human dose of 44 g/day or 0.89 g/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

The safety and efficacy of ColPrep Kit has been established based on an adequate, controlled study of another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g). Below is a display of the results of this adequate and well-controlled study.

The colon cleansing efficacy of another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) was evaluated in a randomized, single-blind, active-controlled, multicenter study. In this study, 363 adult patients were 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: another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) or a marketed polyethylene glycol (PEG) bowel prep. In the Study, another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) was administered according to a split-dose preparation regimen *[see Dosage and Administration (2.1)]*. The PEG bowel prep was also given as a split-dose preparation according to its labeled instructions. Patients receiving another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) 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. In the study, no clinically or statistically significant differences were seen between the group treated with another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) and the group treated with the PEG bowel prep. See Table 3 below.

(b) (4)

Table 3: Colon Cleansing Response Rates

Treatment Group	Regimen	N	Responders[1] % (95% C. I.)	sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) – PEG Difference (95% CI)
sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) (with light breakfast)	Split-Dose	180	**97%** (94%, 99%)	**2%**[2] (-2%, 5%)
PEG bowel prep (with normal breakfast & light lunch)	Split-Dose	183	**96%** (92%, 98%)	

1 Responders were patients whose colon preparations were graded excellent (no more than small bits of adherent feces/fluid) or good (small amounts of feces or fluid not interfering with the exam) by the colonoscopist.
2 Does not equal difference in tabled responder rates due to rounding effects.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied:

Each ColPrep Kit contains:

- Two 200 mL round white high density polyethylene bottles with 38 mm white plastic caps. Each bottle contains sodium sulfate 17.5 g, potassium sulfate 3.13 g, and magnesium sulfate 1.6 g and the following inactive ingredients: citric acid anhydrous, sucralose, and lemon flavor.
- One 20-ounce polypropylene mixing container with a 16 ounce fill line.

ColPrep Kit NDC 10702-283-23

Storage:

Store at 20º to 25°C (68º to 77°F). Excursions permitted between 15ºC and 30°C (59ºF and 86°F). [See USP controlled room temperature]
Keep out of reach of children.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide and Instructions for Use)

Instruct patients:

- Two doses of ColPrep Kit are required for a complete preparation for colonoscopy as a split-dose (two-day regimen).
  - Dose 1: administered in the evening before colonoscopy, 10 to 12 hours before the second dose
  - Dose 2: administered the morning of colonoscopy, at least 3 ½ hours before colonoscopy
- To reconstitute each bottle of ColPrep Kit and to dilute the reconstituted solution in water before ingestion.
- To drink additional water, as described in the Instructions for Use.
- Direct ingestion of the undiluted reconstituted solution may increase the risk of nausea, vomiting, and dehydration *[see Warnings and Precautions (5.8)]*.
- Not to take other laxatives while they are taking ColPrep Kit.
- On the day before colonoscopy: A light breakfast may be consumed. Only clear liquids may be consumed after a light breakfast. Examples of clear liquids are found in the Instructions for Use.
- To avoid red and purple liquids, milk, and alcoholic beverages.
- Not to take oral medications within one hour of starting each dose of ColPrep Kit.
- The first bowel movement may occur approximately 1 hour after the start of ColPrep Kit administration. Abdominal bloating and distention may occur before the first bowel movement. If severe abdominal discomfort or distention occurs, stop drinking ColPrep Kit temporarily or drink each portion at longer intervals until these symptoms diminish. If severe symptoms persist, notify their healthcare provider.
- To notify their healthcare provider, if they develop significant vomiting or signs of dehydration after taking ColPrep Kit or if they experience seizures or loss of consciousness *[see Warnings and Precautions (5.1, 5.3)]*.

Manufactured for: **GATOR PHARMACEUTICALS, INC. ST. AUGUSTINE, FL 32080**
Item ID # 6190/07
Rev.: 12/2016

Reference ID: 4034201

Medication Guide
ColPrep (ko-l Prep) Kit
(sodium sulfate, potassium sulfate, and magnesium sulfate)
for oral solution

What is the most important information I should know about ColPrep Kit?
ColPrep Kit 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 risk of having fluid loss and changes in body salts with ColPrep Kit is higher if you:

- have heart problems
- have kidney problems
- take water pills, high blood pressure medicine, 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 ColPrep Kit:

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

Tell your healthcare provider right away if you have a seizure or faint (lose consciousness).
See "What are the possible side effects of ColPrep Kit?" for more information about side effects.

What is ColPrep Kit?
ColPrep Kit is a prescription medicine used by adults to clean the colon before a colonoscopy. ColPrep Kit cleans your colon by causing you to have diarrhea. Cleaning your colon helps your healthcare provider see the inside of your colon more clearly during your colonoscopy.

It is not known if ColPrep Kit is safe and effective in children.

Do not take ColPrep Kit if your healthcare provider has told you that you have:

- a blockage in your bowel (obstruction).
- an opening in the wall of your stomach or intestine (bowel perforation).
- a problem with food and fluid emptying from your stomach (gastric retention).
- a problem with food moving too slowly through your intestines (ileus).
- a very dilated intestine (toxic megacolon).
- an allergy to any of the ingredients in ColPrep Kit. See the end of this leaflet for a complete list of ingredients in ColPrep Kit.

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

- have heart problems.
- have stomach or bowel problems, including ulcerative colitis.
- have problems with swallowing, gastric reflux, or if you inhale food or fluid into your lungs when eating or drinking (aspirate).
- have gout.
- have a history of seizures.
- are withdrawing from drinking alcohol.
- have a low blood salt (sodium) level.
- have kidney problems.
- are pregnant. It is not known if ColPrep Kit can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ColPrep Kit passes into your breast milk. You and your healthcare provider should decide if you will take ColPrep Kit while breastfeeding.

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

ColPrep Kit may affect how other medicines work. Medicines taken by mouth may not be absorbed properly when taken within 1 hour before the start of each dose of ColPrep Kit.

Especially tell your healthcare provider if you take:

- medicines for blood pressure or heart problems
- medicines for kidney problems
- medicines for seizures
- water pills (diuretics)
- non-steroidal anti-inflammatory drugs (NSAIDs)
- laxatives
- medicines for depression or mental health problems

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 ColPrep Kit?

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

- Take ColPrep Kit exactly as your healthcare provider tells you to take it.
- **Do not take ColPrep Kit powder that has not been mixed with water, it may increase your risk of nausea, vomiting and fluid loss (dehydration).**
- Each bottle of ColPrep Kit powder must be mixed with water and diluted with additional water 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).
- You may eat a light breakfast in the morning on the day before your colonoscopy.
- Do not take other laxatives while taking ColPrep Kit.
- Do not take any medicine by mouth within 1 hour of starting each dose of ColPrep Kit.
- Do not eat solid foods or drink milk or alcohol while taking ColPrep Kit and until after your colonoscopy. Drink only clear liquids:
  - after eating a light breakfast in the morning on the day before your colonoscopy
  - while taking ColPrep Kit
  - after taking ColPrep Kit and until 2 hours before your colonoscopy

Do not eat or drink anything at least 2 hours before your colonoscopy.

- Drink clear liquids before, during, and after you take ColPrep Kit to avoid fluid loss (dehydration). See the Instructions for Use for examples of clear liquids.

Do not eat or drink anything colored red or purple.

- You may have stomach-area (abdomen) bloating before you have your first bowel movement.
- Stop drinking ColPrep Kit for a short time or wait a longer time between each dose of ColPrep Kit if you have severe stomach-area (abdomen) discomfort or bloating until your symptoms improve. If these symptoms continue, tell your healthcare provider.
- Your first bowel movement may happen about 1 hour after you start taking ColPrep Kit.

What are the possible side effects of ColPrep Kit?

ColPrep Kit may cause serious side effects, including:

- **See "What is the most important information I should know about ColPrep Kit?"**
- **Changes in certain blood tests.** Your healthcare provider may do blood tests after you take ColPrep Kit 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
- **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 ColPrep Kit include:

- discomfort
- stomach-area (abdomen) bloating
- stomach-area (abdomen) cramping
- nausea
- vomiting

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

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

How should I store ColPrep Kit?

- Store ColPrep Kit at room temperature between 68°F to 77°F (20°C to 25°C).

Keep ColPrep Kit and all medicines out of the reach of children.

General information about the safe and effective use of ColPrep Kit.

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

What are the ingredients in ColPrep Kit?

Active ingredients: sodium sulfate, potassium sulfate, and magnesium sulfate

Inactive ingredients: citric acid anhydrous, sucralose, and lemon flavor

Manufactured for: **GATOR PHARMACEUTICALS, INC. ST. AUGUSTINE, FL 32080**

For more information, go to www.kvktech.com or call 1-215-579-1842.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Issued: 12/2016

Instructions for Use
ColPrep (ko-l Prep) Kit
(sodium sulfate, potassium sulfate and magnesium sulfate)
for oral solution

On the day before your colonoscopy:

- You may eat a light breakfast.
- **Do not** eat solid foods or drink milk or alcohol while taking ColPrep Kit and until after your colonoscopy.
- **Do not** eat or drink anything colored red or purple.

Drink only clear liquids:

- after eating a light breakfast in the morning on the day before your colonoscopy.
- while taking ColPrep Kit.
- after taking ColPrep Kit and until 2 hours before your colonoscopy.

Do not eat or drink anything at least 2 hours before your colonoscopy.

You may eat or drink any of the following clear liquids:

- water
- clear fruit juices without pulp including apple, white grape, or white cranberry
- strained limeade or lemonade
- coffee or tea (**Do not** use any dairy or non-dairy creamer)
- clear broth
- clear soda
- gelatin (without added fruit or topping)
- popsicles (without pieces of fruit or fruit pulp)

Do not eat or drink anything colored red or purple.

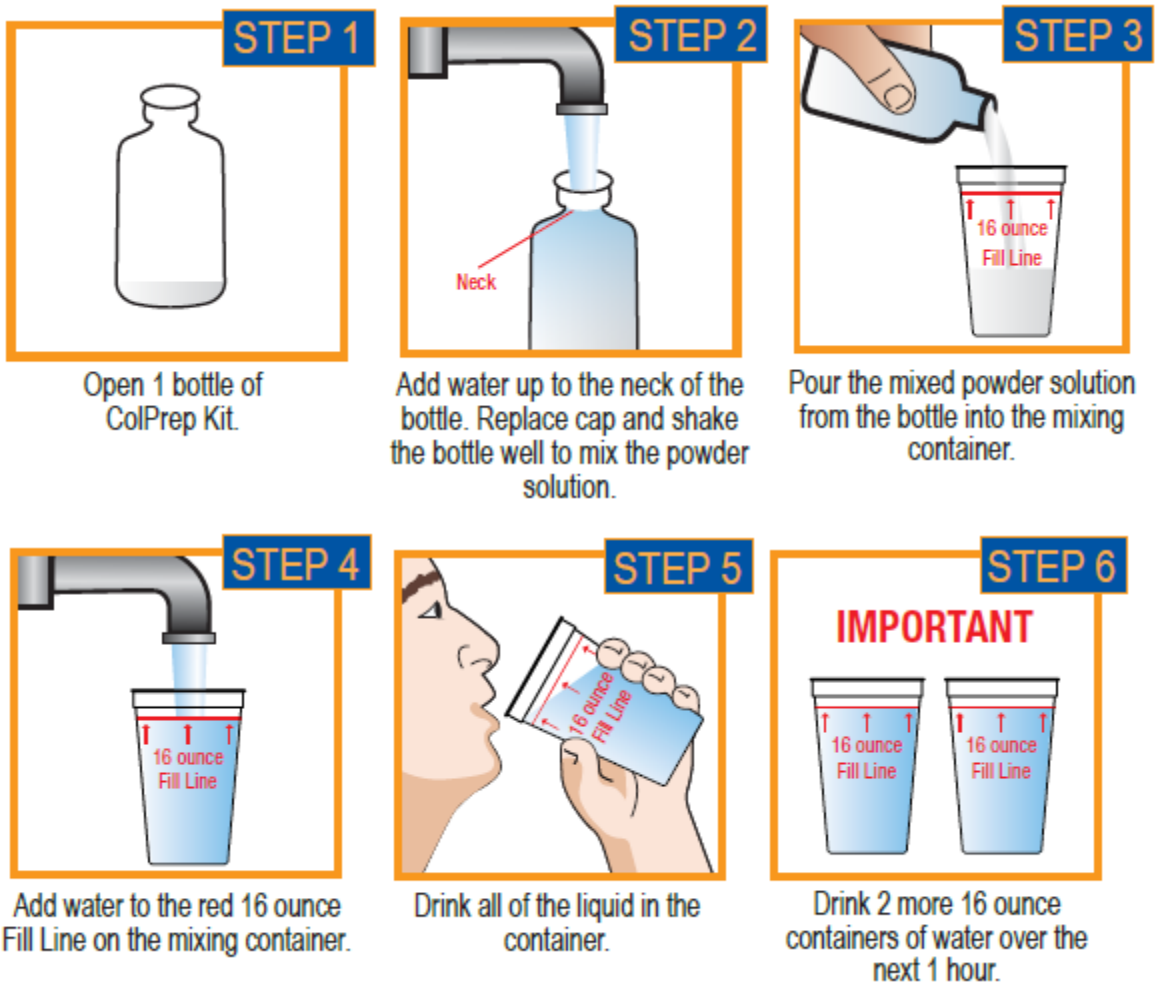
Two doses of ColPrep Kit are required for a complete bowel prep.

Each bottle of ColPrep Kit powder must be mixed with water and diluted with additional water according to instructions.

Split-Dose (2 Day) ColPrep Kit Instructions

Dose 1: Take this dose early in the evening before your colonoscopy, about 10 to 12 hours before you take Dose 2, or when your doctor tells you to take it.
Complete Steps 1 through 6 using 1 bottle of ColPrep Kit before you go to bed.

Dose 2: Take this dose on the morning of your colonoscopy, at least 3 ½ hours before your colonoscopy. Repeat Steps 1 through 6 using the remaining bottle of ColPrep Kit. Finish taking Dose 2 and all of the prescribed water at least 2 hours before your colonoscopy.



This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured for:
GATOR PHARMACEUTICALS, INC.
ST. AUGUSTINE, FL 32080

Issued: 12/2016

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOYCE A KORVICK
12/27/2016