



### ColPrep™ Kit (sodium sulfate/potassium sulfate/magnesium sulfate) – New Drug Approval

- On December 27, 2016, the [FDA approved](#) Gator Pharmaceuticals' [ColPrep Kit \(sodium sulfate/potassium sulfate/magnesium sulfate\)](#) oral solution for cleansing of the colon as a preparation for colonoscopy in adults.
- ColPrep Kit is an osmotic laxative containing sulfate salts. The osmotic effect of unabsorbed sulfate salts causes water to be retained within the gastrointestinal (GI) tract, ultimately producing a laxative effect.
- The safety and efficacy of ColPrep Kit have been established based on a clinical study of another oral formulation of sodium sulfate/potassium sulfate/magnesium sulfate. A total of 363 patients were randomized to sodium sulfate/potassium sulfate/magnesium sulfate or a polyethylene glycol (PEG) bowel prep. Both bowel preps were administered as a split-dose preparation.
  - No clinically or statistically significant differences were seen in the proportion of patients achieving successful colon cleansing between the group treated with sodium sulfate/potassium sulfate/magnesium sulfate and the group treated with the PEG bowel prep (97% vs. 96%, respectively; difference in response rate: 2%; 95% CI: -2%, 5%).
- ColPrep Kit is contraindicated in those with GI obstruction, bowel perforation, gastric retention, ileus, toxic colitis or toxic megacolon.
- Other warnings and precautions of ColPrep Kit include serious fluid and serum chemistry abnormalities, cardiac arrhythmias, seizures, renal impairment, colonic mucosal ulcerations and ischemic colitis, use in patients with significant GI disease, and aspiration. ColPrep Kit is not for direct ingestion.
- The most common adverse events ( $\geq 3\%$ ) with ColPrep Kit use were overall discomfort, abdominal fullness, nausea, abdominal cramping, and vomiting.
- ColPrep Kit is administered as a two-day regimen. Both doses of ColPrep are required for a complete preparation for colonoscopy. The recommended dosage of ColPrep 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.
  - ColPrep must be reconstituted and diluted in water prior to ingestion. Additional fluids must be consumed after each dose of ColPrep.
- Gator Pharmaceuticals' launch plans for ColPrep Kit are pending. Each ColPrep Kit will contain two bottles. Each bottle contains sodium sulfate 17.5 g, potassium sulfate 3.13 g, and magnesium sulfate 1.6 g.



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