



## Suprep® Bowel Prep Kit (sodium sulfate/potassium sulfate/magnesium sulfate) – Expanded indication and new strength

- On August 5, 2020, the [FDA approved](#) Braintree's [Suprep Bowel Prep Kit \(sodium sulfate/potassium sulfate/magnesium sulfate\)](#), for cleansing of the colon in preparation for colonoscopy in adult and pediatric patients 12 years of age and older.
  - Previously, Suprep Bowel Prep Kit was approved for this indication in adults only.
- The approval of Suprep Bowel Prep Kit for the expanded indication was based on a single-blind, active-controlled study in 89 pediatric patients 12 years to 16 years of age. Patients were randomized to Suprep Bowel Prep Kit (two 6-ounce doses), Suprep Bowel Prep Kit (two 4.5-ounce doses) or oral PEG solution. The primary efficacy endpoint was the proportion of patients with successful colon cleansing.
  - A total of 85% of patients in the Suprep Bowel Prep Kit (two 4.5-ounce doses) were responders vs. 59% of the oral PEG solution group (Difference: 25%; 95% CI: 3%, 47%).
  - Suprep Bowel Prep Kit (two 6-ounce doses) is not recommended for pediatric patients 12 years and older due to no additional treatment benefits and increased gastrointestinal adverse reactions.
- The most common adverse reactions (> 10%) in pediatric patients with Suprep Bowel Prep Kit use were nausea, abdominal pain, abdominal bloating and vomiting.
- The recommended split-dose (2-day) regimen of Suprep Bowel Prep Kit for the treatment of pediatric patients 12 years and older is two 4.5-ounce doses of Suprep Bowel Prep Kit: the first dose during the evening prior to colonoscopy and the second dose the next day, during the morning of the colonoscopy.
  - Each dose consists of one bottle of Suprep Bowel Prep Kit with additional water.
  - The total volume of liquid required for colon cleansing (using two bottles) is 2.25 quarts.
  - Refer to the Suprep Bowel Prep Kit drug label for dosing for adults.
- Braintree's launch plans for Suprep Bowel Prep Kit pediatric strength are pending. Suprep Bowel Prep Kit pediatric strength will be available as 2 bottles containing 4.5 ounces of oral solution.



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