



## Clenpiq™ (sodium picosulfate/magnesium oxide/anhydrous citric acid) – Expanded indication

- On August 8, 2019, the [FDA approved](#) Ferring Pharmaceuticals' [Clenpiq \(sodium picosulfate/magnesium oxide/anhydrous citric acid\)](#), for cleansing of the colon as a preparation for colonoscopy in adults and pediatric patients 9 years of age and older.
  - Clenpiq was previously only approved for this indication in adults.
- The approval of Clenpiq in this age group is supported by evidence from a single study in 78 pediatric patients 9 to 16 years of age. The study evaluated another oral product of sodium picosulfate/magnesium oxide/anhydrous citric acid vs. polyethylene glycol (PEG). The primary efficacy endpoint was the proportion of patients with successful colon cleansing as defined as a rating of either “Excellent” (> 90% of mucosa seen, mostly liquid stool, minimal suctioning needed for adequate visualization) or “Good” (> 90% of mucosa seen, mostly liquid stool, significant suctioning needed for adequate visualization).
  - Successful colon cleansing was achieved in 88% (95% CI: 62, 98) and 81% (95% CI: 54, 96) of patients receiving sodium picosulfate/magnesium oxide/anhydrous citric acid and PEG, respectively, in patients age 9 to 12 years.
  - Successful colon cleansing was achieved in 81% (95% CI: 54, 96) and 86% (95% CI: 57, 98) of patients receiving sodium picosulfate/magnesium oxide/anhydrous citric acid and PEG, respectively, in patients age 13 to 16 years.
- The most common adverse reactions (> 5%) with Clenpiq use in pediatric patients were nausea, vomiting, and abdominal pain.
- For both adult and pediatric patients, two doses (two bottles; 160 mL each) of Clenpiq are required for complete preparation for colonoscopy.
  - Refer to the Clenpiq drug label for complete information on preparation before colonoscopy and administration of the dosage regimen.



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