



Prepopik® (sodium picosulfate/magnesium oxide/anhydrous citric acid) – Expanded indication

- On August 15, 2018, the FDA approved Ferring Pharmaceuticals' Prepopik (sodium picosulfate/magnesium oxide/anhydrous citric acid), for cleansing of the colon as a preparation for colonoscopy in adults and pediatric patients ages 9 years and older.
 - Previously, Prepopik was approved for adults only for the same indication.
- The expanded indication for Prepopik is supported by an active-controlled study in 78 pediatric patients from 9 – 16 years of age. Patients were randomized to two-doses of Prepopik or an oral polyethylene glycol (PEG)-based solution. The primary endpoint was the proportion of patients with successful colon cleansing as defined by a rating of either “Excellent” or “Good” using the Aronchick scale.
 - Successful colon cleansing in patients aged 9 – 12 years was demonstrated in 88% of patients taking Prepopik vs. 81% taking the PEG comparator solution.
 - Successful colon cleansing in patients aged 13 – 16 years was demonstrated in 81% of patients taking Prepopik vs. 86% taking the PEG comparator solution.
 - In addition, use of Prepopik in this age group is also supported by evidence from adequate and well-controlled trials of Prepopik in adults.
- The most common adverse reactions (> 5%) with Prepopik use in pediatric patients 9 – 16 years of age were nausea, vomiting, and abdominal pain.
- The recommended dosage of Prepopik for adult and pediatric patients 9 years of age and older is two doses (one packet per dose) administered orally as a Split-Dose (preferred) or Day-Before dosing regimen.
 - The preferred method is the Split-Dose method and consists of two separate doses: the first dose during the evening before the colonoscopy and the second dose the next day, the morning of the day of the colonoscopy.
 - The alternative method is the Day Before method and consists of two separate doses: the first dose during the afternoon or early evening before the colonoscopy and the second dose 6 hours later during the evening before the colonoscopy.
 - Each packet of Prepopik must be dissolved in 5 ounces of cold water prior to ingestion and administered according to the dosing regimen. Direct ingestion of the undissolved powder may increase the risk of nausea, vomiting, dehydration and electrolyte disturbances.
 - Consult Prepopik's drug label for further dosing recommendations.



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