PREPOPIK® Fact Sheet

What is Prepopik?
- Prepopik (sodium picosulfate, magnesium oxide, and anhydrous citric acid) is a combination stimulant laxative and osmotic laxative that is indicated for cleansing of the colon as a preparation for colonoscopy in adults.¹

How is Prepopik designed to work?
- **Stimulant laxative activity:** Sodium picosulfate, an ingredient of Prepopik, is hydrolyzed (able to be broken down by chemical reaction with water) by bacteria in the colon to form the active metabolite, BHPM, which acts directly on the lining of the colon to stimulate muscle contractions.¹
- **Osmotic laxative activity:** Magnesium oxide and citric acid, other ingredients in Prepopik, react to create magnesium citrate in solution, which causes water to be retained within the gastrointestinal tract.¹
- When combined together, the stimulant laxative and the osmotic laxative produce a purgative effect which, when ingested with additional fluids, produce watery diarrhea, which clears the colon of fecal matter.¹

Why is proper bowel preparation important in colonoscopies?
Good visualization of the colon is essential for a quality colonoscopy, meaning the colon must be completely purged of fecal material before the procedure in order to provide an unobstructed view of the bowel wall.² Research shows patient compliance with colonoscopy preparation instructions improves effectiveness and efficiency of colonoscopy, and minimizes risk of procedural complications.³

Dosing
- Prepopik is a powder that must be reconstituted (mixed) with cold water immediately before its use, and no sooner than that.¹
- The product has two different dosing regimens depending on patient need:
  - The preferred regimen is “Split Dose” and requires administering the product in two separate doses – the first dose is taken the evening before the colonoscopy, (e.g. 5:00 PM – 9:00 PM), followed by five 8-ounce drinks of clear liquids before bed (within 5 hours). The second dose is taken the next day, or the morning of the colonoscopy, approximately five hours before the exam, followed by at least three 8-ounce drinks of clear liquids, which may be consumed up until two hours before the time of the exam.¹
  - The alternative regimen is “Day Before” dosing which requires taking the entire dose in the evening before the colonoscopy in two separate doses. Patients take the first dose during the afternoon or early evening (e.g., 4:00 PM to 6:00 PM) before the colonoscopy, followed by five 8-ounce drinks of clear liquids. Patients should then take the second dose six hours later (e.g., 10:00 PM to 12:00 AM), followed by three 8-ounce drinks of clear liquids within 5 hours.¹

What clinical data support the use of PREPOPIK in preparation for colonoscopy?
- The colon cleansing efficacy of Prepopik was evaluated for non-inferiority against a comparator in two randomized, investigator-blinded, active-controlled, multicenter U.S. trials in patients scheduled to have an elective colonoscopy.²
- Patients randomized to Prepopik in the two studies were treated with one of two dosing regimens:¹
  - In Study 1, Prepopik was given by “Split Dose” (evening before and day of dosing)
  - In Study 2, Prepopik was given by “Day Before” (afternoon/evening before only dosing)
- In both studies, Prepopik was non-inferior to the comparator. In addition, Prepopik provided by “Split Dose” met the pre-specified criteria for superiority to the comparator for colon cleansing in Study 1. 1 (84% vs 74%, respectively, achieving "excellent or good” visualization).

Adverse events
- Most common adverse reactions (>1%) are nausea, headache and vomiting.¹
- Since abdominal bloating, distension, pain/cramping, and watery diarrhea are known to occur in response to colon cleansing preparations, these effects were documented as adverse events in the clinical trials only if they required medical intervention.¹

Indication and Important Safety Information
Prepopik is a prescription medicine used by adults to clean the colon before a colonoscopy. Prepopik 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.

- Do not take Prepopik if your healthcare provider has told you that you have serious kidney problems, a blockage in your intestine (bowel obstruction), an opening in the wall of your stomach or intestines (bowel perforation), a very dilated intestine (toxic megacolon), problems with the emptying of food and fluid from your stomach (gastric retention), or an allergy to any of the ingredients in Prepopik

Please see additional Important Safety Information on reverse side
Tell your healthcare provider right away if you have any of these symptoms of a loss of too much body fluid (dehydration) while taking Prepopik: vomiting that prevents you from keeping down the additional prescribed amounts of clear liquids that you must drink after taking Prepopik, dizziness, urinating less often than normal, or headache.

Prepopik and other bowel preparations 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), or kidney problems. Your chance of having fluid loss and changes in blood salts with Prepopik is higher if you have heart problems, have kidney problems, or take water pills or non-steroidal anti-inflammatory drugs (NSAIDS). The most common side effects of Prepopik include nausea, headache, and vomiting.

Please refer to the full Product Information, available at [www.PREPOPIK.com](http://www.PREPOPIK.com).

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**References**