CLENPIQ® oral solution is indicated for cleansing of the colon as a preparation for colonoscopy in adults and pediatric patients ages 9 years and older.

IMPORTANT SAFETY INFORMATION

• CLENPIQ is contraindicated in the following conditions: patients with severe reduced renal impairment (creatinine clearance less than 30mL/minute), gastrointestinal obstruction or ileus, bowel perforation, toxic colitis or toxic megacolon, gastric retention, or in patients with a known hypersensitivity to any of the ingredients in CLENPIQ.

• Patients should be advised to hydrate adequately (before, during and after use of CLENPIQ), and post-colonoscopy lab tests should be considered if a patient develops significant vomiting or signs of dehydration, including orthostatic hypotension, after taking CLENPIQ. Patients with electrolyte abnormalities should have them corrected before treatment. Use caution when prescribing CLENPIQ for patients that have conditions or are using medications that increase the risk for fluid and electrolyte disturbances.

• Use caution in patients who have conditions, or are taking concomitant medications that increase the risk for seizures, such as those taking medications that lower the seizure threshold, patients withdrawing from alcohol or benzodiazepines or patients with known or suspected hyponatremia.

• Use caution in patients with impaired renal function or taking medications that may affect renal function, as well as patients at increased risk of arrhythmias, including those patients with a history of prolonged QT, recent myocardial infarction, unstable angina, congestive heart failure, or cardiomyopathy.

Please see instructions on how to take CLENPIQ split-dose regimen on reverse side.

INDICATION
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Please see additional Important Safety Information on the back.
**Step-By-Step Split-Dose Administration**

**Dose 1 – On the day before the colonoscopy:**  
- Instruct patients to consume only clear liquids (no solid food or dairy) on the day before the colonoscopy up until 2 hours before the time of the colonoscopy.  
- Take the first dose (1 bottle) of CLENPIQ during the evening before the colonoscopy (eg, 5:00 to 9:00 pm).  
- Follow CLENPIQ by drinking five or more 8-ounce cups (cup provided) of clear liquids (40 ounces) within 5 hours and before bed.  
- If severe bloating, distention, or abdominal pain occurs following the first dose, delay the second dose until the symptoms resolve.

**Dose 2 – Next morning on the day of the colonoscopy (start approximately 5 hours prior to colonoscopy):**  
- Continue to consume only clear liquids (no solid food or dairy).  
- Take the second dose (the second bottle) of CLENPIQ.  
- Following the CLENPIQ dose, drink at least four or more 8-ounce cups (cup provided) of clear liquids (32 ounces) at least 2 hours before the colonoscopy.

**IMPORTANT SAFETY INFORMATION (CONTINUED)**

- Osmotic laxatives may produce colonic mucosal aphthous ulcerations and there have been reports of more serious cases of ischemic colitis requiring hospitalization. Concurrent use of additional stimulant laxatives with CLENPIQ may increase this risk.
- Use with caution in patients with severe active ulcerative colitis.
- Patients with impaired gag reflex are at risk for regurgitation or aspiration during administration of CLENPIQ. Observe these patients during administration of CLENPIQ.
- The most common adverse reactions reported in a clinical trial with CLENPIQ for colon cleansing in adults were nausea, headache, hypermagnesemia, abdominal pain, and dehydration or dizziness. The most common adverse reactions reported in a clinical trial of another sodium picosulfate, magnesium oxide and anhydrous citric acid product for colon cleansing in pediatric patients aged 9 to 16 years were nausea, vomiting and abdominal pain.
- CLENPIQ can reduce the absorption of co-administered drugs. Do not take oral medications within one hour of starting CLENPIQ. Administer tetracycline and fluoroquinolone antibiotics, iron, digoxin, chlorpromazine and penicillamine, at least 2 hours before and not less than 6 hours after administration of CLENPIQ to avoid chelation with magnesium.

You are encouraged to report negative side effects of prescription drugs to FDA. Visit www.FDA.gov/medwatch, or call 800.FDA.1088.

Please see accompanying full Prescribing Information.

**References:**
2. SUPREP® Bowel Prep Kit [Prescribing Information]. Braintree, MA: Braintree Laboratories, Inc.
6. SUTAB® Braintree Labs Part of Sebela Pharmaceuticals, Braintree MA.

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