WARNINGS AND PRECAUTIONS

DOSAGE AND ADMINISTRATION

First dose: administer during evening before the colonoscopy. If taking tetracycline or fluoroquinolone antibiotics, iron, digoxin, chlorpromazine, or penicillamine, take these medications 1 hour before the start of CLENPIQ.

CLENPIQ is ready to drink. It does not need to be diluted prior to administration. One bottle of CLENPIQ is equivalent to 10 mg sodium picosulfate, 3.5 g magnesium oxide, and 12 g anhydrous citric acid.

INDICATIONS AND USAGE

CLENPIQ is a bowel cleansing laxative indicated for use in the preparation of the colon for colonoscopy and sigmoidoscopy.

CONTRAINDICATIONS

CLENPIQ is contraindicated in the following conditions:

- Hypersensitivity to any of the ingredients in CLENPIQ
- Patients with a history of seizures or take medicines for seizures
- Patients with an opening in the wall of your stomach or intestines (bowel perforation)
- Serious loss of body fluid (dehydration) and changes in blood salts (electrolytes) in your blood

HOW SUPPLIED/STORAGE AND HANDLING

CLENPIQ is available in bottles for oral use. Store at room temperature.

DRUG INTERACTIONS

Fluid and electrolyte disturbances can lead to serious adverse reactions including cardiac arrhythmias or seizures and renal impairment. Use caution when prescribing CLENPIQ for patients with impaired renal function, known or suspected inflammatory bowel disease, or known or suspected ischemic colitis requiring hospitalization. Concurrent use of additional stimulant laxatives with CLENPIQ may increase the risk of mucosal ulcerations. Consider the potential for mucosal ulcerations when interpreting colonoscopy findings in patients with known or suspected inflammatory bowel disease. Use with caution in patients with severe active ulcerative colitis.

SIDE EFFECTS

The most common side effects of CLENPIQ include:

- Bloating
- Abdominal cramps
- Diarrhea
- Headache
- Dizziness

There have been rare reports of seizures in patients who have been taking CLENPIQ. If you experience any of these symptoms, discontinue use and contact your healthcare provider.

PRECAUTIONS

Adequate hydration before, during, and after the use of CLENPIQ is important. Consider performing baseline and post-colonoscopy electrolyte measurements. Do not drink alcohol.

ADVERSE REACTIONS

In clinical trials, the most frequently reported adverse reactions included:

- Rectal bleeding
- Headache
- Dizziness

Cases of rectal bleeding and gastrointestinal bleeding have been reported. These cases have occurred in patients who have been taking CLENPIQ for colonoscopy preparation.

CLINICAL TRIALS EXPERIENCE

In a randomized, controlled, single-dose, double-blind, parallel-group study of 302 subjects, CLENPIQ was found to be effective in preparing the colon for colonoscopy.

The study compared CLENPIQ to bisacodyl tablets and found CLENPIQ to be equally effective in preparing the colon for colonoscopy. The study results are consistent with the results of other studies that have compared CLENPIQ to bisacodyl tablets.

No significant differences were observed between the treatment groups in terms of the primary efficacy endpoint of complete colonoscopy preparation.

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**Electrolyte Abnormalities**

For a list of liquids you can drink for your clear liquid diet.

**Important:**

There are 2 different methods for taking CLENPIQ. It is better (preferred) to use the 7.2 Potential for Reduced Drug Absorption

**Use caution when prescribing CLENPIQ for patients with conditions or who are taking other drugs that increase the risk for**

- **Neurologic:**
  - generalized tonic-clonic seizures with and without hyponatremia in epileptic patients

- **Cardiovascular:**
  - hypotension

- **Hematologic:**
  - neutropenia

- **Renal:**
  - reduced serum creatinine</p>

**Metabolism and Excretion**

**Table 2:**

<table>
<thead>
<tr>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 7</th>
<th>Day 14</th>
</tr>
</thead>
<tbody>
<tr>
<td>0/298 (0.0)</td>
<td>0/298 (0.0)</td>
<td>6/293 (2.1)</td>
<td>24/292 (8.2)</td>
</tr>
</tbody>
</table>

**Chemical formula:**

- Sodium: $\text{Na}^+$

**Structural formula:**

- Sodium: $\text{Na}^+$

**Molecular weight:**

- Sodium: 22.99 amu

**Chemical formula:**

- Citric acid: $\text{C}_6\text{H}_8\text{O}_7$

**Structural formula:**

- Citric acid: $\text{C}_6\text{H}_8\text{O}_7$

**Molecular weight:**

- Citric acid: 192.1 amu

**Chemical formula:**

- MgO

**Structural formula:**

- MgO

**Molecular weight:**

- MgO: 40.31 amu

**Sodium picosulfate is a stimulant laxative.**

The following is a description of the three active ingredients contained in CLENPIQ:

- Sodium picosulfate: a stimulant laxative
- Magnesium oxide: a purgative
- Citric acid: acts as a buffer and stimulates colonic peristalsis

**Sodium picosulfate**

Sodium picosulfate is a stimulant laxative.

**Metabolism and Excretion**

The fraction of the absorbed sodium picosulfate dose excreted unchanged in urine was 0.19%. Plasma levels of the free sodium picosulfate were measurable for at least 24 hours after administration. Sodium picosulfate is not an inducer of CYP1A2, CYP2B6, or CYP3A4/5.

**In vitro study using freshly isolated hepatocyte culture, sodium**

picosulfate did not inhibit the major CYP enzymes (CYP 1A2, 2B6, 3A4/5).

**In vitro study using human liver microsomes, sodium**

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**12.1 Mechanism of Action**

Sodium picosulfate is a stimulant laxative. In clinical studies, the effect of sodium picosulfate has been shown to occur within 1-2 hours of administration.

**12.2 Absorption**

Sodium picosulfate is not absorbed systemically. It is rapidly and completely excreted in the urine as sodium picosulfate and sodium.</p>

**12.3 Distribution**

Sodium picosulfate is not distributed systemically. It is rapidly and completely excreted in the urine as sodium picosulfate and sodium.

**12.4 Elimination**

Sodium picosulfate is not eliminated systemically. It is rapidly and completely excreted in the urine as sodium picosulfate and sodium.

**12.5 Special Populations**

**Pediatric**

The safety and effectiveness of CLENPIQ have not been established in pediatric patients under the age of 18 years.

**Geriatric**

In clinical trials, no differences in the safety or effectiveness of CLENPIQ were observed between patients aged 65 years and older and younger patients.

**Renal**

Patients with less severe renal impairment [see Contraindications (4)]

**Liver**

No dosing adjustment is required for patients with mild hepatic impairment.

**Hypertension**

No dosing adjustment is required for patients with hypertension.

**CLENPIQ**

CLENPIQ is supplied in a carton containing two bottles, each holding 160 mL of cranberry-flavored, colorless to slightly yellow, clear oral solution, and is supplied as two bottles in a carton. CLENPIQ (sodium picosulfate, magnesium oxide, and anhydrous citric acid) oral solution is a stimulant and osmotic laxative

**11 CLINICAL PHARMACOLOGY**

**11.1 Pharmacokinetics**

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**11.2 Pharmacodynamics**

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