HALFLYTELY® AND BISACODYL TABLET BOWEL PREP KIT

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HALFLYTELY® and BISACODYL TABLET BOWEL PREP KIT (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution) powder for reconstitution combined with bisacodyl delayed-release tablets is indicated prior to colonoscopy.

WARNINGS AND PRECAUTIONS


2. Neurologic: Ischemic colitis has been reported.

3. Endocrine: Seizure cases were associated with electrolyte imbalance, particularly hypocalcemia.


5. Respiratory: Patients with significant respiratory disease requiring a colonoscopy.

6. Other: Patients should be instructed to drink at least 1.5 liters of water in addition to the HalfLytely solution during bowel prep.

7. Drug Interactions: Drugs that may increase risks of fluid and electrolyte abnormalities.

8. Use in Specific Populations: Use with caution in patients with severe active ulcerative colitis.

9. Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when a breast-feeding woman is given this drug. The effects in nursing infants have not been established.

10. Clinical Toxicology: There have been reports of serious anaphylactic reactions associated with the use of oral laxatives for bowel preparation.

11. Overdosage: Patients with severe active ulcerative colitis, patients with severe respiratory disease requiring a colonoscopy, patients should be instructed to drink at least 1.5 liters of water in addition to the HalfLytely solution during bowel prep.

12. Administration of Bisacodyl Tablet Bowel Prep Kit: Onset of action usually occurs 6 to 8 hours after administration.

13. Clinical Studies: A randomized double-blind, placebo-controlled study was conducted in patients with severe active ulcerative colitis.

14. Dosage and Administration: The dosage and administration of Bisacodyl Tablet Bowel Prep Kit is presented in the following sections:

15. Patient Counseling Information: The patient counseling information for HalfLytely and Bisacodyl Tablet Bowel Prep Kit should be given to patients with severe active ulcerative colitis.

16. How Supplied /Storage and Handling: The HalfLytely and Bisacodyl Tablet Bowel Prep Kit is supplied as a powder for reconstitution and a bisacodyl delayed-release tablet.

17. Patient Counseling Information: If a patient becomes unresponsive, contact the nearest medical facilities immediately.

18. Throughput Expectancy: Use the recommended dosage of HalfLytely in conjunction with bisacodyl solution to increase the frequency of bowel movement.

19. Description: The safety and effectiveness of HalfLytely and Bisacodyl Tablet Bowel Prep Kit in patients with severe active ulcerative colitis has not been established.

20. Clinical Studies: A randomized double-blind, placebo-controlled study was conducted in patients with severe active ulcerative colitis.

21. How Supplied /Storage and Handling: The HalfLytely and Bisacodyl Tablet Bowel Prep Kit is supplied as a powder for reconstitution and a bisacodyl delayed-release tablet.

22. Patient Counseling Information: If a patient becomes unresponsive, contact the nearest medical facilities immediately.


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47. Use in Specific Populations: Use with caution in patients with severe active ulcerative colitis.

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Patients are instructed to drink water and not take solid foods for 8 hours before taking the bowel cleansing. In addition, patients are instructed to consume nothing to eat, except clear liquids, for 12 hours before the cleansing is completed. The primary adverse reaction associated with the procedure is patient discontinuation because of the associated side effects. These patients are instructed to contact their healthcare provider if they develop signs and symptoms of dehydration. No adverse reactions are expected in these patients.

Title: Protection of Patients with Successful Colon Cleansing

<table>
<thead>
<tr>
<th>Patient</th>
<th>HalfLytely and Bisacodyl Tablet Bowel Prep Kit (H5)</th>
<th>Preparations with HalfLytely and Bisacodyl Tablet Bowel Prep Kit (H10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successt</td>
<td>75.2% (75/100)</td>
<td>71.4% (61/85)</td>
</tr>
<tr>
<td>Patient</td>
<td>59.7% (56/94)</td>
<td>61.1% (60/98)</td>
</tr>
<tr>
<td>Successt</td>
<td>73.1% (75/102)</td>
<td>70.0% (63/90)</td>
</tr>
</tbody>
</table>

The probability of patients with successful colon cleansing is similar between treatment groups. No differences in success rates between the groups were observed during these colonoscopies. Obstetric data are not available to report these events.

**Medication Guide**

**How should I store HalfLytely and Bisacodyl Tablet Bowel Prep Kit?**

HalfLytely and Bisacodyl Tablet Bowel Prep Kit is a powder for reconstitution containing 210 gram of polyethylene glycol (PEG) 3350, 2.86 gram of sodium bicarbonate, 6.11 gram of potassium chloride for oral solution.

**Dosage and Administration**

- **HalfLytely solution:**
  - To take the place of taking your healthcare provider's medical condition.
  - It is important to follow your healthcare provider's instructions.
  - Inform your healthcare provider if you have any side effect that troubles you or that does not go away.
  - These are some possible side effects of HalfLytely and Bisacodyl Tablet Bowel Prep Kit. For more information, ask your healthcare provider or pharmacist.

**Warnings and Precautions**

See Medication Guide and Boxed Warning.

**Contraindications**

- **HalfLytely solution:**
  - You should not take HalfLytely and Bisacodyl Tablet Bowel Prep Kit if you have:
    - Heart problems
    - Liver problems
    - Kidney problems
    - Blood problems
    - A blockage in your intestine (obstruction)
    - a history of food and fluid emptying from your stomach (gastric retention)

**Side Effects**

- **HalfLytely solution:**
  - The most serious side effects of HalfLytely and Bisacodyl Tablet Bowel Prep Kit may cause:
    - Irregular heartbeats.
    - Decreased blood flow to the intestine (ischemic colitis).
  - These symptoms include:
    - Headache
    - Heart problems
    - Nausea
    - Diarrhea
    - Severe cramping
    - Changes in body salts
    - Headache

**Adverse Reactions**

- **HalfLytely solution:**
  - The most common side effects of HalfLytely and Bisacodyl Tablet Bowel Prep Kit include:
    - Diarrhea
    - Constipation
    - Abdominal bloating
    - Stomach cramping
    - Nausea
    - Headache

**Precautions**

- **HalfLytely solution:**
  - The following are some possible side effects of HalfLytely and Bisacodyl Tablet Bowel Prep Kit. For more information, ask your healthcare provider or pharmacist.

**Interactions**

- **HalfLytely solution:**
  - Take HalfLytely and Bisacodyl Tablet Bowel Prep Kit exactly as your healthcare provider tells you. You must read, understand, and follow these instructions to take HalfLytely and Bisacodyl Tablet Bowel Prep Kit right way.

**Is it safe for me to take HalfLytely and Bisacodyl Tablet Bowel Prep Kit?**

- **HalfLytely solution:**
  - It is not known if HalfLytely and Bisacodyl Tablet Bowel Prep Kit passes into your breast milk. If you are breastfeeding or plan to become pregnant, tell your healthcare provider.

**Is it safe for me to take HalfLytely and Bisacodyl Tablet Bowel Prep Kit?**

- **HalfLytely solution:**
  - Take HalfLytely and Bisacodyl Tablet Bowel Prep Kit exactly as your healthcare provider tells you. You must read, understand, and follow these instructions to take HalfLytely and Bisacodyl Tablet Bowel Prep Kit right way.

**What are the possible side effects of HalfLytely and Bisacodyl Tablet Bowel Prep Kit?**

- **HalfLytely solution:**
  - Headache
  - Nausea
  - Diarrhea
  - Constipation
  - Abdominal bloating
  - Stomach cramping
  - Changes in body salts
  - Headache

**Additional Information**

- **HalfLytely solution:**
  - Take HalfLytely and Bisacodyl Tablet Bowel Prep Kit exactly as your healthcare provider tells you. You must read, understand, and follow these instructions to take HalfLytely and Bisacodyl Tablet Bowel Prep Kit right way.

**Is it safe for me to take HalfLytely and Bisacodyl Tablet Bowel Prep Kit?**

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