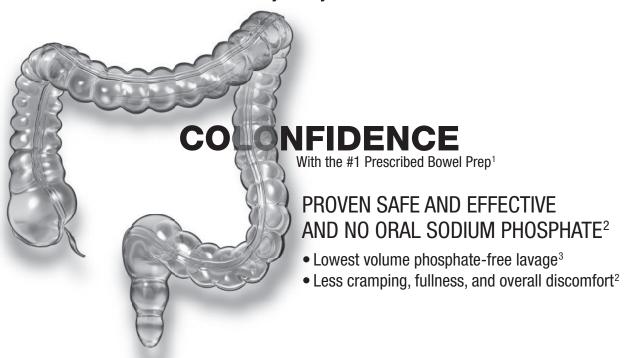


HalfLytely and Bisacodyl Tablets Bowel Prep Kit is a gastrointestinal lavage indicated for cleansing of the colon as a preparation for colonoscopy in adults. Most common adverse reactions (<3%) are abdominal pain/cramping, nausea, vomiting and headache. Use is contraindicated in the following conditions: known allergies to polyethylene glycol or other components of the kit, gastrointestinal (Gl) obstruction, bowel perforation, toxic colitis, toxic megacolon. Use with caution in patients using concomitant medications (such as diuretics) that increase the risk of electrolyte abnormality, patients with known or suspected hyponatremia, patients with severe ulcerative colitis, ileus or gastric retention. There have been reports of ischemic colitis in patients with use of HalfLytely and 20 mg Bisacodyl Tablets Bowel Prep Kit. However, a causal relationship has not been established. If patients develop severe abdominal pain or rectal bleeding, patients should be evaluated as soon as possible. Patients with impaired water handling who experience severe vomiting should be closely monitored including measurement of electrolytes. Hives and skin rashes have been reported with PEG-based products which are suggestive of an allergic reaction.

HalfLytely® & Bisacodyl tablets Bowel Prep Kit

PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and bisacodyl delayed-release tablets



References: 1. IMS Health Inc, NPA Weekly Rx Audit, Jan 2008-Feb 2009. 2. In a clinical study of HalfLytely and Bisacodyl Tablets Bowel Prep Kits (10 mg vs 20 mg bisacodyl tablets) [See package insert; Table 2], Braintree, MA: Braintree Laboratories, Inc. 3. See package inserts: GoLYTELY®(PEG-3350 and Electrolytes for Oral Solution); 2001, NuLYTELY® (PEG-3350, Sodium Chloride, Sodium Bicarbonate and Potassium Chloride for Oral Solution); 2008, HalfLytely® and Bisacodyl Tablets Bowel Prep Kit; 2008. Braintree, MA: Braintree Laboratories Inc., MoviPrep® (PEG-3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate and Ascorbic Acid for Oral Solution); 2006 Morrisville, NC: Salix Pharmaceuticals Inc.

Brief Summary: Before prescribing, please see full prescribing information for HalfLytely and Bisacodyl Tablets Bowel Prep Kit. **INDICATIONS AND USAGE:** A gastrointestinal lavage indicated for cleansing of the colon as a preparation for colonoscopy in adults. **CONTRAINDICATIONS:** Patients with the following conditions: known allergies to polyethylene glycol or other components of the kit, gastrointestinal (GI) obstruction, bowel perforation, toxic colitis, toxic megacolon. WARNINGS AND PRECAUTIONS: Use with caution in patients using concomitant medications (such as diuretics) that increase the risk of electrolyte abnormality, patients with known or suspected hyponatremia, patients with severe ulcerative colitis, ileus or gastric retention. There have been reports of ischemic colitis in patients with use of HalfLytely and 20 mg Bisacodyl Tablets Bowel Prep Kit. However, a causal relationship has not been established. If patients develop severe abdominal pain or rectal bleeding, patients should be evaluated as soon as possible. Patients with impaired water handling who experience severe vomiting should be closely monitored including measurement of electrolytes. Hives and skin rashes have been reported with PEG-based products which are suggestive of an allergic reaction. Pediatric Use: Safety and effectiveness in pediatric patients has not been established. ADVERSE REACTIONS: Most common adverse reactions (<3%) are abdominal pain/cramping, nausea, vomiting and headache. **Oral** Administration: Take two bisacodyl tablets with water (do NOT chew or crush). Wait for a bowel movement (or maximum of 6 hours) then drink the 2 liter solution at a rate of 8 ounces every 10 minutes. Drink all of the solution. **STORAGE:** Store at 20-25°C (59-86°F). When reconstituted you may keep the solution refrigerated. Discard within 48 hours. **Rx only**. Distributed by Braintree Laboratories, Inc. Braintree, MA 02185.

For additional information, please call 1-800-874-6756 or visit us at www.halflytely.com

