

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use HALFLYTELY AND BISACODYL TABLET BOWEL PREP KIT safely and effectively.

See full prescribing information for HALFLYTELY AND BISACODYL TABLET BOWEL PREP KIT.

HALFLYTELY® AND BISACODYL TABLET BOWEL PREP KIT (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and bisacodyl delayed-release tablet)

Initial U.S. Approval: 2004

RECENT MAJOR CHANGES

Dosage and Administration (2)	07/2010
Contraindications (4)	07/2010
Warnings and Precautions, (5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7)	07/2010

INDICATIONS AND USAGE

HalfLyteLy and Bisacodyl Tablet Bowel Prep Kit is a combination of PEG-3350, an osmotic laxative and bisacodyl, a stimulant laxative, indicated for cleansing of the colon as a preparation for colonoscopy in adults (1)

DOSAGE AND ADMINISTRATION

See FULL PRESCRIBING INFORMATION for complete dosing and administration instructions (2)

- No solid food or milk (clear liquids only) should be consumed on the day of the preparation.
- Take one 5 mg bisacodyl tablet with water. Do NOT chew or crush.
- Dissolve the HalfLyteLy powder in 2 liters of water.
- Wait for a bowel movement (or maximum of 6 hours) then drink all the HalfLyteLy solution at a rate of 8 ounces every 10 minutes.
- Consume only clear liquids until the colonoscopy.

DOSAGE FORMS AND STRENGTHS

- One 5 mg bisacodyl delayed-release tablet (3)
- One 2 liter HalfLyteLy bottle with powder for reconstitution (3)

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

- 5.1 Serious Fluid and Chemistry Abnormalities
- 5.2 Seizures
- 5.3 Renal Impairment
- 5.4 Cardiac Arrhythmias
- 5.5 Ischemic Colitis
- 5.6 Patients with Significant Gastrointestinal Disease
- 5.7 Aspiration

6 ADVERSE REACTIONS

- 6.1 Clinical Studies Experience
- 6.2 Postmarketing Experience

7 DRUG INTERACTIONS

- 7.1 Drugs that May Increase Risks of Fluid and Electrolyte Abnormalities
- 7.2 Potential For Altered Drug Absorption

CONTRAINDICATIONS

- Gastrointestinal (GI) obstruction (4)
- Bowel perforation (4)
- Toxic colitis or toxic megacolon (4)
- Gastric retention (4)
- Ileus(4)

WARNINGS AND PRECAUTIONS

- Risk of fluid and electrolyte abnormalities, arrhythmias, seizures and renal impairment – assess concurrent medications and consider testing in some patients (5.1, 5.2, 5.3, 5.4)
- Patients with renal impairment – use caution, ensure adequate hydration and consider testing (5.3)
- Ischemic colitis has been reported (5.5)
- Suspected GI obstruction or perforation – rule out the diagnosis before administration (5.6)
- Patients at risk for aspiration – observe during administration (5.7)

ADVERSE REACTIONS

Most common adverse reactions (> 3%) are overall discomfort, abdominal fullness, abdominal cramping, nausea, and vomiting. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Braintree Laboratories, Inc. at 1-800-874-6756 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Some drugs (e.g., diuretics, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, or non-steroidal anti-inflammatory drugs) increase risk due to fluid and electrolyte changes (7.1)
- Oral medication administered within one hour of the start of drinking HalfLyteLy solution might not be absorbed fully. (7.2)
- Do not take the bisacodyl tablet within one hour of taking antacid. (7.3)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide

Revised: 07/2010

- 7.3 Interaction with Antacids
- 8 USE IN SPECIFIC POPULATIONS
 - 8.1 Pregnancy
 - 8.3 Nursing Mothers
 - 8.4 Pediatric Use
 - 8.5 Geriatric Use
- 10 OVERDOSAGE
- 11 DESCRIPTION
- 12 CLINICAL PHARMACOLOGY
 - 12.1 Mechanism of Action
 - 12.2 Pharmacodynamics
 - 12.3 Pharmacokinetics
- 13 NONCLINICAL TOXICOLOGY
 - 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
- 14 CLINICAL STUDIES
- 16 HOW SUPPLIED/STORAGE AND HANDLING
- 17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION:

1 INDICATIONS AND USAGE

HalfLytyly and Bisacodyl Tablet Bowel Prep Kit is indicated for cleansing of the colon as a preparation for colonoscopy in adults.

2 DOSAGE AND ADMINISTRATION

The recommended HalfLytyly and Bisacodyl Tablet Bowel Prep Kit oral dosage regimen for adults on the day prior to colonoscopy is as follows:

- No solid food or milk (clear liquids only) should be consumed on the day of the preparation.
- Take one 5 mg bisacodyl delayed-release tablet with water. Do NOT chew or crush the tablet.
- No antacids should be taken within one hour of taking the bisacodyl delayed-release tablet.
- Prepare the HalfLytyly solution according to the instructions on the kit.
- Add flavor pack of choice (if applicable) to the 2 liter container.
- No additional ingredients (other than flavor packs provided) should be added to the solution.
- Prepare the HalfLytyly solution by filling the container to the 2 liter mark with water. Cap the container. Shake to dissolve the powder.
- Wait for a bowel movement (or maximum of 6 hours) then drink the 2 liter HalfLytyly solution at a rate of 8 ounces every 10 minutes. Drink all of the solution.
- If you have abdominal distention or discomfort, stop drinking the HalfLytyly solution temporarily or drink each portion at longer intervals until your symptoms improve.
- Consume only clear liquids after taking the HalfLytyly solution until your colonoscopy.

3 DOSAGE FORMS AND STRENGTHS

- One pink, round, enteric coated 5 mg bisacodyl delayed-release tablet, stamped "BRA"
- One 2 liter HalfLytyly bottle with powder for reconstitution

4 CONTRAINDICATIONS

The HalfLytyly and Bisacodyl Tablet Bowel Prep Kit is contraindicated in the following conditions:

- Gastrointestinal (GI) obstruction
- Bowel perforation
- Toxic colitis and toxic megacolon
- Gastric retention
- Ileus

5 WARNINGS AND PRECAUTIONS

5.1 Serious Fluid and Serum Chemistry Abnormalities

Advise all patients to hydrate adequately before, during, and after the use of HalfLytyly and Bisacodyl Tablet Bowel Prep Kit. If a patient develops significant vomiting or signs of dehydration after taking HalfLytyly and Bisacodyl Tablet Bowel Prep Kit, consider performing post-colonoscopy lab tests (electrolytes, creatinine, and BUN). Fluid and electrolyte disturbances can lead to serious adverse events including cardiac arrhythmias, seizures and renal impairment.

Patients with electrolyte abnormalities should have them corrected before treatment with HalfLytyly and Bisacodyl Tablet Bowel Prep Kit. In addition, use caution when prescribing HalfLytyly and Bisacodyl Tablet Bowel Prep Kit for patients with conditions, or who are using medications, that increase the risk for fluid and electrolyte disturbances or may increase the risk of adverse events of seizure, arrhythmias, and renal impairment. [*see Drug Interactions (7.1)*]

5.2 Seizures

There have been reports of generalized tonic-clonic seizures with the use of large volume (4 liter) PEG-based colon preparation products in patients with no prior history of seizures. The seizure cases were associated with electrolyte abnormalities (e.g., hyponatremia, hypokalemia, hypocalcemia, and hypomagnesemia) and low serum osmolality. The neurologic abnormalities resolved with correction of fluid and electrolyte abnormalities.

Use caution when prescribing the HalfLytyly and Bisacodyl Tablet Bowel Prep Kit for patients with a history of seizures and in patients at risk of seizure, such as patients taking medications that lower the seizure threshold (e.g., tricyclic antidepressants), patients withdrawing from alcohol or benzodiazepines, patients with known or suspected hyponatremia, or patients using concomitant medications (such as diuretics) that increase the risk of electrolyte abnormalities. Monitor baseline and post-colonoscopy laboratory tests (sodium, potassium, calcium, creatinine, and BUN) in these patients.

5.3 Renal Impairment

Patients with impaired water handling who experience severe vomiting should be closely monitored including measurement of electrolytes (sodium, potassium, calcium, BUN and creatinine). Use caution when prescribing HalfLytyly and Bisacodyl Tablet Bowel Prep Kit for patients with impaired renal function or patients taking concomitant medications that may affect renal function (such as diuretics, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, or non-steroidal anti-inflammatory drugs). Advise these patients of the importance of adequate hydration and consider performing baseline and post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN) in these patients.

5.4 Cardiac Arrhythmias

There have been rare reports of serious arrhythmias associated with the use of ionic osmotic laxative products for bowel preparation. Use caution when prescribing HalfLytyly and Bisacodyl Tablet Bowel Prep Kit for patients at increased risk of arrhythmias (e.g. patients with a history of prolonged QT, uncontrolled arrhythmias, recent myocardial infarction, unstable angina, congestive heart failure, or cardiomyopathy). Pre-dose and post-colonoscopy ECGs should be considered in patients at increased risk of serious cardiac arrhythmias.

5.5 Ischemic Colitis

There have been reports of ischemic colitis in patients with use of HalfLytyly and 20 mg Bisacodyl Tablets Bowel Prep Kit and HalfLytyly and 10 mg Bisacodyl Tablets Bowel Prep Kit. If patients develop severe abdominal pain or rectal bleeding, patients should be evaluated as soon as possible.

5.6 Patients with Significant Gastrointestinal Disease

If gastrointestinal obstruction or perforation is suspected, perform appropriate diagnostic studies to rule out these conditions before administering HalfLytyly and Bisacodyl Tablet Bowel Prep Kit.

Use with caution in patients with severe active ulcerative colitis.

5.7 Aspiration

Use with caution in patients with impaired gag reflex and patients prone to regurgitation or aspiration. Such patients should be observed during administration of the HalfLyte and Bisacodyl Bowel Prep Kit solution.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in clinical studies of another drug and may not reflect the rates observed in practice.

In a clinical study of HalfLyte and (5 mg vs. 10 mg) Bisacodyl Tablets Bowel Prep Kit overall discomfort, abdominal fullness, abdominal cramping, nausea, and vomiting, were the most common adverse reactions (>3%). The data in Table 1 reflects the 154 patients that received HalfLyte and 5 mg bisacodyl tablet vs. the 154 patients that received HalfLyte and 10 mg bisacodyl tablets. The HalfLyte and 5 mg Bisacodyl Tablet Bowel Prep Kit population was 29-87 years of age, 49% male, 51% female, 13% African American, 83% White, 5% Hispanic requiring a colonoscopy. The demographics of the comparator group were similar.

Table 1: Adverse Reactions Observed in at Least 3% of Randomized Patients

	HalfLyte and 5 mg Bisacodyl Tablet Bowel Prep Kit (N=154)	HalfLyte and 10 mg Bisacodyl Tablets Bowel Prep Kit (N=154)
Overall Discomfort	57%	66%
Abdominal fullness	40%	53%
Abdominal cramping	38%	46%
Nausea	34%	42%
Vomiting	10%	7%

6.2 Postmarketing Experience

The following adverse reactions have been identified during post approval use of HalfLyte and Bisacodyl Tablet Bowel Prep Kit. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Allergic Reactions:

Cases of urticaria, rhinorrhea, dermatitis and anaphylactic reactions have been reported with PEG-based products.

Gastrointestinal:

There are isolated reports of serious post-marketing events following the administration of PEG-based products in patients over 60 years of age. These adverse reactions include upper GI bleeding from a Mallory-Weiss tear, esophageal perforation, asystole, and acute pulmonary edema after vomiting and aspirating the PEG-based solution. In addition, during administration of 4 liters of PEG-3350 colon cleansing preparation the following serious adverse reactions were seen: two deaths in end stage renal failure patients who developed diarrhea, vomiting and dysnatremia [see *Warnings and Precautions (5.3)*].

Ischemic colitis has been reported with use of HalfLyte and 20 mg and 10 mg Bisacodyl Tablets Bowel Prep Kit for colon preparation prior to colonoscopy. However, a causal relationship between these ischemic colitis cases and the use of HalfLyte and Bisacodyl Tablet Bowel Prep Kit has not been established.

Neurologic:

There have been reports of generalized tonic-clonic seizures associated with use of large volume (4 liter) PEG-based colon preparation products in patients with no prior history of seizures. Cases of dizziness and syncope have been reported [see *Warnings and Precautions (5.1)*].

7 DRUG INTERACTIONS

7.1 Drugs That May Increase Risks of Fluid and Electrolyte Abnormalities

Use caution when prescribing HalfLyte and Bisacodyl Tablet Bowel Prep Kit for patients with conditions, or who are using medications, that increase the risk for fluid and electrolyte disturbances or may increase the risk of adverse events of seizure, arrhythmias, and prolonged QT in the setting of fluid and electrolyte abnormalities. Consider additional patient evaluations as appropriate [see *Warnings and Precautions (5.1)*] in patients taking these concomitant medications.

7.2 Potential for Altered Drug Absorption

Oral medication administered within one hour of the start of administration of HalfLyte solution may be flushed from the GI tract and the medication may not be absorbed completely.

7.3 Interaction with Antacids

Do not take the bisacodyl delayed-release tablet within one hour of taking an antacid.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C animal reproduction studies have not been conducted. It is not known whether HalfLyte and Bisacodyl Tablet Bowel Prep Kit can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. HalfLyte and Bisacodyl Tablet Bowel Prep Kit should be given to a pregnant or nursing woman only if clearly needed.

8.3 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 HalfLyte and Bisacodyl Tablet Bowel Prep Kit is administered to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients has not been established.

8.5 Geriatric Use

Of the 148 patients who took HalfLyte and 5 mg Bisacodyl Tablet Bowel Prep Kit in clinical trials, 42 (28%) were 65 years of age or older, while 10 (7%) were 75 years of age or older. The rates of success appear to be lower in patients 65 years and older [see *Clinical Studies (14)*].

10 OVERDOSAGE

Using more than the recommended dosage of bisacodyl in conjunction with HalfLyte solution increases the frequency of common adverse events and may increase the risk of ischemic colitis [see *Warnings and Precautions (5.5)*].

11 DESCRIPTION

HalfLyte and Bisacodyl Tablet Bowel Prep Kit consists of PEG-3350, an osmotic laxative and bisacodyl, a stimulant laxative. Each HalfLyte and Bisacodyl Tablet Bowel Prep Kit [Polyethylene glycol (PEG) 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and bisacodyl delayed-release tablet] consists of one 2 liter bottle of HalfLyte (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution) powder for reconstitution and one 5 mg bisacodyl, delayed-release tablet.

- **Bisacodyl delayed-release tablet:** Each pink, round, enteric coated bisacodyl delayed-release tablet (stamped “BRA”) contains 5 mg of bisacodyl, USP (C₂₂H₁₉NO₄) with a molecular weight of 361.40. Inactive ingredients include lactose (anhydrous) NF, microcrystalline cellulose NF, croscarmellose sodium NF, magnesium stearate NF, Eudragit L 30-55, polyethylene glycol 400, talc USP, gelatin, calcium sulfate (anhydrous) NF, confectioners sugar, kaolin USP, sucrose NF, Opalux pink, beeswax, and carnauba wax. The bisacodyl delayed-release tablet is administered orally prior to drinking the HalfLyte solution [see *Dosage and Administration (2)*].
- **HalfLyte (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution):** A white powder for reconstitution containing 210 grams of PEG-3350, 2.86 grams of sodium bicarbonate, 5.6 grams of sodium chloride, 0.74 grams of potassium chloride and 1 gram of flavoring ingredient (if applicable). Flavor Packs are available in Cherry, Lemon-Lime, Orange and Pineapple. This preparation can be used without the addition of a Flavor Pack. When dissolved in water to a volume of 2 liters, the HalfLyte solution is isosmotic, clear, and colorless. The HalfLyte solution is administered orally after taking the one bisacodyl delayed-release tablet [see *Dosage and Administration (2)*].

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Polyethylene glycol (PEG), which is an osmotic agent, causes water to be retained within the gastrointestinal tract.

Bisacodyl is hydrolyzed by intestinal brush border enzymes and colonic bacteria to form an active metabolite [bis-(p-hydroxyphenyl) pyridyl-2 methane; (BHPM)] that acts directly on the colonic mucosa to produce colonic peristalsis.

12.2 Pharmacodynamics

The stimulant laxative effect of bisacodyl, together with the osmotic effect of the unabsorbed PEG when ingested with a large volume of water, produces watery diarrhea.

12.3 Pharmacokinetics

When taken orally, PEG 3350 is minimally absorbed.

Bisacodyl, which is a prodrug, is converted to its active metabolite BHPM by intestinal brush border enzymes and colonic bacteria. The pharmacokinetics of bisacodyl following oral administration of the bisacodyl tablet has not been adequately characterized.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of HalfLyte and Bisacodyl Tablet Bowel Prep Kit. Studies to evaluate its potential for impairment of fertility or its mutagenic potential have not been performed.

14 CLINICAL STUDIES

The colon cleansing efficacy of HalfLyte and Bisacodyl Tablet Bowel Prep Kit (with 5 mg of bisacodyl) was evaluated in a randomized, single blind (endoscopist only), active-controlled, multicenter study. In this study, 293 adult patients were included in the efficacy analysis. Patients ranged in age from 19 to 87 years old (mean age 55 years old) with 55% female and 45% male patients. Race was distributed as follows: 83% White, 12% African American, 8% Hispanic or Latino, and 4% other.

Patients were randomized to one of the following two colon preparations: **1)** HalfLyte and Bisacodyl Tablets Bowel Prep Kit [10 mg of bisacodyl tablets were given at noon on the day before colonoscopy followed by 2 liters of HalfLyte (after the first bowel movement or maximum of 6 hours)] at a rate of 8 ounces every 10 minutes and **2)** a modified HalfLyte and Bisacodyl Tablet Bowel Prep Kit [containing a 5 mg bisacodyl tablet given at noon on the day before colonoscopy followed by 2 liters of HalfLyte (after the first bowel movement or maximum of 6 hours)] at a rate of 8 ounces every 10 minutes.

Patients were instructed to refrain from solid food and to have clear liquids on the day before colonoscopy. In addition, patients were instructed to consume nothing by mouth, except clear liquids, from the time the preparation was completed until after the colonoscopy was completed.

The primary efficacy endpoint was the proportion of patients with successful colon cleansing (assessed by the colonoscopists), see Table 2 below. Successful colon cleansing was defined as preparations that were graded excellent (no more than small bits of adherent feces/fluid) or good (small amounts of feces or fluid not interfering with the exam) by the colonoscopist.

Table 2: Proportion of Patients with Successful Colon Cleansing

	HalfLyte and 5 mg Bisacodyl Tablet Bowel Prep Kit (H5)		HalfLyte and 10 mg Bisacodyl Tablets Bowel Prep Kit (H10)		Difference between treatment groups (H5 – H10)	
	% (n/N)	Two-sided 95% CI ¹	% (n/N)	Two-sided 95% CI ¹	Percent Difference %	Two-sided 95% CI for Percent Difference
All Patients	78 (114/147)	(69.9, 84.0)	80 (117/146)	(72.7, 86.3)	-2.0	(-11.9, 6.8)

¹Confidence Interval (CI) for within treatment percent success is from an exact Chi Square test.

The proportion of patients with successful colon cleansing was similar between treatment groups. No differences in response rates by gender or race were noted in the HalfLyte and 5 mg bisacodyl group. In patients ≥ 65 years of age treated with the HalfLyte and 5 mg Bisacodyl Tablet Bowel Prep Kit the proportion with successful colon cleansing was 67% (n=28/42)[95% CI: (50.5, 80.4)].

16 HOW SUPPLIED/STORAGE AND HANDLING

Each HalfLyte and Bisacodyl Tablet Bowel Prep Kit contains:

One 5 mg bisacodyl delayed-release tablet: pink, round, enteric coated, stamped "BRA" in a blister pack.

One 2 liter bottle of HalfLyte (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution) powder for reconstitution containing 210 grams of polyethylene glycol (PEG) 3350, 2.86 grams of sodium bicarbonate, 5.6 grams of sodium chloride, 0.74 grams of potassium chloride, and 1 gram of flavoring ingredient (if applicable). After adding 2 liters of water, the reconstituted HalfLyte solution (clear and colorless) contains 31.3 mmol/L of PEG-3350, 65 mmol/L of sodium, 53 mmol/L of chloride, 17 mmol/L of bicarbonate and 5 mmol/L of potassium.

Lemon-Lime HalfLyte and Bisacodyl Tablet Bowel Prep Kit contains 1 gram lemon-lime flavoring ingredient. HalfLyte and Bisacodyl Tablet Bowel Prep Kit with Flavor Packs contain 4 packs (1gram each Cherry, Lemon-Lime, Orange and Pineapple flavors).

Storage:

Store at 20-25°C (68-77°F). Excursions permitted between 15-30°C (59-86°F). The reconstituted HalfLyte solution, which may be refrigerated, should be used within 48 hours.

Lemon-Lime HalfLyte and Bisacodyl Tablet Bowel Prep Kit
HalfLyte and Bisacodyl Tablet Bowel Prep Kit with Flavor Packs

NDC 52268-523-01
NDC 52268-523-02

17 PATIENT COUNSELING INFORMATION

See Medication Guide

Information for Patients

- Ask patients to let you know if they have trouble swallowing or are prone to regurgitation or aspiration.
- Tell patients not to take other laxatives while they are taking HalfLyte and Bisacodyl Tablet Bowel Prep Kit.
- Tell patients that if they experience severe bloating, distention or abdominal pain, the administration of the solution should be slowed or temporarily discontinued until the symptoms abate. Advise patients to report these events to their health care provider.
- Advise patients that if they have hives, rashes, or any allergic reaction, they should discontinue the medication and contact their health care provider. Medication should be discontinued until they speak to their physician.
- Instruct patients to contact their healthcare provider if they develop signs and symptoms of dehydration. [see *Warnings and Precautions (5.1)*].
- Inform patients that oral medication administered within one hour of the start of administration of HalfLyte solution may be flushed from the GI tract and the medication may not be absorbed completely.

Manufactured by: Braintree Laboratories, Inc. Braintree, MA 02185

Distributed by: Braintree Laboratories, Inc. Braintree, MA 02185

Medication Guide

HalfLyte^{ly} (haf-LITE-lee) and Bisacodyl (BIS-a-CO-dil) Tablet[®] Bowel Prep Kit

(PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and bisacodyl delayed release tablet)

Read this Medication Guide before you start taking HalfLyte^{ly} and Bisacodyl Tablet Bowel Prep Kit. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about HalfLyte^{ly} and Bisacodyl Tablet Bowel Prep Kit?

HalfLyte^{ly} and Bisacodyl Tablet Bowel Prep Kit and other osmotic 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:

- seizures. This can happen even if you have never had a seizure.
- kidney problems
- abnormal heartbeats that can cause death

Your chance of having fluid loss and changes in body salts with HalfLyte^{ly} and Bisacodyl Tablet Bowel Prep Kit is higher if you:

- have heart problems
- have kidney problems
- take water pills or non-steroidal anti-inflammatory drugs (NSAIDS)

Tell your healthcare provider right away if you have any of these symptoms of a loss of too much body fluid (dehydration) while taking HalfLyte^{ly} and Bisacodyl Tablet Bowel Prep Kit:

- dizziness
- urinating less often than normal
- headache

See “What are the possible side effects of HalfLyte^{ly} and Bisacodyl Tablet Bowel Prep Kit?” for more information about side effects.

What is HalfLyte^{ly} and Bisacodyl Tablet Bowel Prep Kit?

HalfLytely and Bisacodyl Tablet Bowel Prep Kit is a prescription medicine used by adults to clean the colon before a colonoscopy. HalfLytely and Bisacodyl Tablet Bowel Prep Kit 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.

It is not known if HalfLytely and Bisacodyl Tablet Bowel Prep Kit is safe and effective in children.

Who should not take HalfLytely and Bisacodyl Tablet Bowel Prep Kit?

Do not take HalfLytely and Bisacodyl Tablet Bowel Prep Kit if your healthcare provider has told you that you have:

- a blockage in your bowel (obstruction)
- an opening in the wall of your stomach or intestine (bowel perforation)
- problems with food and fluid emptying from your stomach (gastric retention)
- a very dilated intestine (bowel)
- an allergy to any of the ingredients in HalfLytely and Bisacodyl Tablet Bowel Prep Kit. See the end of this leaflet for a complete list of ingredients in HalfLytely and Bisacodyl Tablet Bowel Prep Kit.

What should I tell my healthcare provider before taking HalfLytely and Bisacodyl Tablet Bowel Prep Kit?

Before you take HalfLytely and Bisacodyl Tablet Bowel Prep Kit, tell your healthcare provider if you:

- have heart problems
- have stomach or bowel problems
- have ulcerative colitis
- have problems with swallowing or gastric reflux
- have a history of seizures
- are withdrawing from drinking alcohol
- have a low blood salt (sodium) level
- have kidney problems
- have any other medical conditions
- are pregnant. It is not known if HalfLytely and Bisacodyl Tablet Bowel Prep Kit will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if HalfLytely and Bisacodyl Tablet Bowel Prep Kit passes into your breast milk. You and your healthcare provider should decide if you will take HalfLytely and Bisacodyl Tablet Bowel Prep Kit while breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

HalfLytely and Bisacodyl Tablet Bowel Prep Kit may affect how other medicines work. Medicines taken by mouth may not be absorbed properly when taken within 1 hour before the start of HalfLytely and Bisacodyl Tablet Bowel Prep Kit.

Especially tell your healthcare provider if you take:

- medicines for blood pressure or heart problems
- medicines for kidney problems
- medicines for depression
- water pills (diuretics)
- non-steroidal anti-inflammatory medicines (NSAID) pain medicines
- laxatives
- antacids

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure if you are taking any of the medicines listed above.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take HalfLytely and Bisacodyl Tablet Bowel Prep Kit?

See the Patient Directions on the outer product carton for dosing instructions. You must read, understand, and follow these instructions to take HalfLytely and Bisacodyl Tablet Bowel Prep Kit the right way.

- Take HalfLytely and Bisacodyl Tablet Bowel Prep Kit exactly as your healthcare provider tells you to take it.
- Do not take other laxatives while taking HalfLytely and Bisacodyl Tablet Bowel Prep Kit.
- Do not take antacids within 1 hour of taking the Bisacodyl tablet.
- Do not chew or crush the Bisacodyl tablet. Take the tablet with water.
- Do not eat solid foods while taking HalfLytely and Bisacodyl Tablet Bowel Prep Kit. Only clear liquids are allowed while taking and after taking HalfLytely and Bisacodyl Tablet Bowel Prep Kit until your colonoscopy.
- Stop drinking HalfLytely solution temporarily or allow for longer time between each dose if you have stomach discomfort, pain or bloating until your symptoms improve.

- Stop taking HalfLyte and Bisacodyl Tablet Bowel Prep Kit and call your healthcare provider right away if you develop hives or a rash. These may be signs of an allergic reaction.

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

HalfLyte and Bisacodyl Tablet Bowel Prep Kit can cause serious side effects, including:

- **See “What is the most important information I should know about HalfLyte and Bisacodyl Tablet Bowel Prep Kit?”**
- **changes in certain blood tests.** Your healthcare provider may do blood tests after you take HalfLyte and Bisacodyl Tablet Bowel Prep Kit to check your blood for changes. Tell your healthcare provider if you have any symptoms of too much fluid loss, including:
 - vomiting
 - nausea
 - bloating
 - dizziness
 - stomach (abdominal) cramping
 - headache
 - urinate less than usual
 - trouble drinking clear liquid
- **heart problems. HalfLyte and Bisacodyl Tablet Bowel Prep Kit may cause irregular heartbeats.**
- **seizures**
- **decreased blood flow to the intestine (ischemic colitis).** There have been reports of ischemic colitis in people who have taken HalfLyte and Bisacodyl Tablet Bowel Prep Kit at higher doses. Tell your healthcare provider right away if you have severe stomach (abdominal) pain or rectal bleeding. These may be symptoms of ischemic colitis.

The most common side effects of HalfLyte and Bisacodyl Tablet Bowel Prep Kit include:

- discomfort
- bloating
- stomach (abdominal) cramping
- nausea
- vomiting

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of HalfLytely and Bisacodyl Tablet Bowel Prep Kit. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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

- Store HalfLytely and Bisacodyl Tablet Bowel Prep Kit at room temperature, between 59°F to 86° (15°C to 30°C).
- HalfLytely solution that has been mixed with water may be refrigerated. Mixed solution should be taken within 48 hours.

Keep HalfLytely and Bisacodyl Tablet Bowel Prep Kit and all medicines out of the reach of children.

General information about the safe and effective use of HalfLytely and Bisacodyl Tablet Bowel Prep Kit.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use HalfLytely and Bisacodyl Tablet Bowel Prep Kit for a condition for which it was not prescribed. Do not give HalfLytely and Bisacodyl Tablet Bowel Prep Kit to other people, even if they are going to have the same procedure you are. It may harm them.

This Medication Guide summarizes the most important information about HalfLytely and Bisacodyl Tablet Bowel Prep Kit. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information that is written for healthcare professionals.

For more information, go to www.braintreeelabs.com or call 1-800-874-6756.

What are the ingredients in HalfLytely and Bisacodyl Tablet Bowel Prep Kit?

Active ingredients bisacodyl tablet: bisacodyl.

Inactive ingredients bisacodyl tablet: lactose, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, Eudragit L 30-55, polyethylene glycol 400, talc, gelatin, calcium sulfate, confectioners sugar, kaolin, sucrose, Opalux pink, beeswax, and carnauba wax.

Active ingredients HalfLyte solution: polyethylene glycol 3350, sodium chloride, sodium bicarbonate, potassium chloride.

Inactive ingredients HalfLyte solution: cherry, lemon-lime, orange and pineapple flavor packs.

Braintree Laboratories, Inc.
Braintree, MA 02185, USA

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Revised Month/Year

**NDA 21-551/S-013 HalfLyte[®] and Bisacodyl Tablet Bowel Prep Kit
(PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution
and bisacodyl delayed-release tablet)**

Gastrointestinal Lavage

Braintree Laboratories, Inc.
60 Columbian Street West
P.O. Box 850929
Braintree, MA 02185

781.843.2202
www.braintreelabs.com

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL

The goal of this REMS for HalfLyte[®] and Bisacodyl Tablet Bowel Prep Kit (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and bisacodyl delayed-release tablet) is to communicate the risks of serious fluid and serum chemistry abnormalities associated with osmotic bowel preparations to patients.

II. REMS ELEMENTS

A. Medication Guide

Braintree Laboratories Inc. will ensure that a currently approved Medication Guide will be dispensed with each HalfLyte[®] and Bisacodyl Tablet Bowel Prep Kit in accordance with 21 CFR 208.24.

B. Timetable for Submission of Assessments

Braintree Laboratories will submit REMS Assessments to FDA 18 months, 3 years and 7 years from the date of approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for the assessment. Braintree will submit each assessment so that it will be received by the FDA on or before the due date.