PRESCRIBING INFORMATION

BI-PEGLYTE®

Bowel Prep Kit

Polyethylene Glycol 3350 and Electrolytes for Oral Solution USP and
Bisacodyl Delayed Release Tablets USP

Polyethylene Glycol 3350 and Electrolytes for Oral Solution USP

Per sachet:

Polyethylene glycol	59.55 g
Sodium sulphate	5.74 g
Sodium bicarbonate	1.69 g
Sodium chloride	1.46 g
Potassium chloride	0.76 g

Bisacodyl delayed release tablets 5 mg

Gastrointestinal Lavage

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Bi-PEGLYTE®
Bowel Prep Kit

Polyethylene Glycol 3350 and Electrolytes for Oral Solution USP and
Bisacodyl Delayed Release Tablets USP

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Oral	Polyethylene Glycol 3350 and Electrolytes for Oral Solution Per sachet: Polyethylene glycol 3350 …59.55 g Sodium sulphate ……5.74 g Sodium bicarbonate ……...1.69 g Sodium chloride ……1.46 g Potassium chloride ……0.76 g Bisacodyl Delayed Release Tablet USP 5 mg	Polyethylene Glycol 3350 and Electrolytes for Oral Solution (sachet): Fruit flavours, Sodium saccharin Bisacodyl Delayed Release Tablets: Lactose *For a complete listing see Dosage Forms, Composition and Packaging section.*

INDICATIONS AND CLINICAL USE

Bi-PEGLYTE® Bowel Prep Kit (Polyethylene Glycol 3350 and Electrolytes for Oral Solution USP and Bisacodyl Delayed Release Tablets USP) is indicated for cleansing of the colon as a preparation for colonoscopy in adults.

Pediatrics:
Safety and effectiveness of Bi-PEGLYTE® in pediatric patients have not been established.

CONTRAINDICATIONS

Bi-PEGLYTE® is contraindicated in patients with

- ileus
- gastric retention

- gastrointestinal (GI) obstruction
- bowel perforation
- toxic colitis
- toxic megacolon
- acute surgical abdomen
- appendicitis
- rectal bleeding
- gastroenteritis
- diverticulitis
- hypersensitivity to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the *Dosage Forms, Composition and Packaging* section of the Prescribing Information.

WARNINGS AND PRECAUTIONS

General

Use of Bi-PEGLYTE® is not recommended when abdominal pain, nausea, or vomiting are present. No additional flavourings or ingredients should be added to the PEG 3350 and Electrolytes solution (PEG-ELS) of Bi-PEGLYTE®.

Bi-PEGLYTE® may result in a potential interactive effect when used with starch-based food thickeners. The PEG ingredient counteracts the thickening effect of starch, effectively liquefying preparations that need to remain thick for people with swallowing problems. This warning applies to all polyethylene glycol (PEG) containing-products.

Advise all patients to hydrate adequately before, during, and after the use of Bi-PEGLYTE®.

Cardiac Arrhythmias

There have been rare reports of serious cardiac arrhythmias associated with the use of ionic osmotic laxative products for bowel preparation. Use caution when prescribing BI-PEGLYTE® 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.

Gastrointestinal

Bi-PEGLYTE® should be used with caution in patients with severe ulcerative colitis. Patients with impaired gag reflex and patients prone to regurgitation or aspiration during administration of PEG/Electrolyte solution of Bi-PEGLYTE® should be closely observed. If GI obstruction or perforation is suspected, appropriate studies should be performed to rule out these conditions before administration. If a patient experiences severe bloating, distension or abdominal pain, administration of the solution should be slowed or temporarily discontinued until the symptoms

subside. Patients suffering from acute exacerbation of inflammatory bowel disease have not been studied.

Ischemic colitis has been reported with use of a bowel preparation kit which contains the same major active components (PEG 3350 and bisacodyl) and follows the same or similar dosing schedule as Bi-PEGLYTE® (see ADVERSE REACTIONS). If patients develop severe abdominal pain and/or rectal bleeding, immediate evaluation and close medical attention should be provided.

Immunological

Cases of urticaria, rhinorrhea, dermatitis and anaphylactic reactions have been reported with PEG-based colon preparation products, which may represent allergic reactions.

Neurologic

Use of large-volume (4 litres) PEG-based colon preparation products has resulted in reports of generalized tonic-clonic seizures in patients with no prior history of seizures. Electrolyte abnormalities, such as hyponatremia and hypokalemia, as well as severe vomiting and excessive beverage consumption have also been associated with tonic-clonic seizures. A correction of fluid and electrolyte abnormalities resolved the neurologic irregularity. Therefore, in patients with known or suspected hyponatremia, or in patients using concomitant medications that increase the risk of electrolyte abnormalities (such as diuretics), Bi-PEGLYTE® should be used with caution. In these patients, baseline and post-colonoscopy laboratory tests (sodium, potassium, calcium, creatinine, and blood urea nitrogen or BUN) should be monitored.

Renal

Patients with impaired water handling who experience severe vomiting should be closely monitored, including measurement of electrolytes (sodium, potassium, calcium, BUN and creatinine).

Special Populations

Pregnant Women: Reproduction studies of oral doses of bisacodyl tablets have been performed in rats administered up to 70 times the human dose, and have revealed no evidence of impaired fertility damage to the fetus. At the dose which equated to 70 times the human dose, there was some evidence of lower litter survival at weaning. There are however, no adequate and well-controlled studies in pregnant women; hence, bisacodyl tablets should be used during pregnancy only at the discretion of the physician.

Animal reproduction studies have not been conducted with the PEG/Electrolytes powder, and it is also not known whether the PEG/Electrolytes powder can affect reproductive capacity or harm the fetus when administered to a pregnant patient. Bi-PEGLYTE® should be given to a pregnant patient only if clearly needed.

Nursing Women: 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 Bi-PEGLYTE® is used in a

nursing woman.

Pediatrics: Safety and effectiveness of Bi-PEGLYTE® in pediatric patients have not been established.

Geriatrics (> 60 years of age): There are isolated reports of serious post-marketing events following the administration of PEG-based products in patients over 60 years of age (acute pulmonary edema after vomiting and aspirating the PEG-based solution, asystole, esophageal perforation, and upper GI bleeding from a Mallory-Weiss tear). Caution is required in patients with renal and cardiac dysfunction.

Carcinogenesis and Mutagenesis
Long-term carcinogenic and reproductive studies with animals have not been performed.

ADVERSE REACTIONS

Gastrointestinal: Nausea, abdominal fullness and bloating are the most frequent adverse reactions occurring in up to 50% of patients taking 4 L PEG/Electrolyte bowel preparation products. Less frequent adverse reactions to these products are abdominal cramps, vomiting and anal irritation. These adverse effects are transient.

A number of clinical studies in the literature have demonstrated that administration of 2 L PEG-Electrolyte Solution (PEG-ELS) products similar to the PEG-ELS found in Bi-PEGLYTE®, in conjunction with bisacodyl tablets (15 or 20 mg), resulted in significantly less nausea and vomiting (approximately 43% and 50%, respectively) than administration of a 4 L PEG-ELS product. In addition, the 2 L PEG-ELS + bisacodyl regimen also resulted in less abdominal pain, bloating, fullness, anal irritation and overall feeling of discomfort, resulting in better patient compliance.

The most frequent adverse reactions occurring in up to 50% of patients taking Bi-PEGLYTE in a split-dose regimen (1L in the evening and 1L in the morning) are abdominal cramps, bloating, nausea, vomiting, insomnia (from frequent bathroom trips) and headache (see CLINICAL TRIALS).

Cramping and abdominal discomfort has occurred in some patients after bisacodyl administration; no systemic effects have been reported.

Rare and mild ischemic colitis (IC) has been reported with use of a bowel preparation kit which contains the same major active ingredients (PEG 3350 and bisacodyl) and follows a similar dosing schedule as the full-dosing regimen of Bi-PEGLYTE®. The IC is shown to be dose-dependent with bisacodyl and found to occur at an oral dose as low as 10 mg bisacodyl. Bi-PEGLYTE® contains 15 mg of bisacodyl.

The following rare adverse events have been reported following administration of 4 L PEG-ELS products which contain the same or similar major active ingredient, PEG 3350, as Bi-PEGLYTE®.

Cardiovascular: bradycardia, acute pulmonary edema, hypotension, arrhythmia, cardiac arrest

Eye: sensitivity to light, painful irritated eyes

Gastrointestinal: rectal bleeding (occult blood in stool), sores in mouth, pancreatitis, colitis

General and Administration Site Conditions: chills, loss of appetite

Hematologic: anemia

Metabolism and Nutrition: fluid imbalance, hypoglycaemia

Musculoskeletal and Connective Tissue: muscle pain

Nervous System: headaches, unconscious, coma, seizures, shakes, generalized tonic-clonic seizures

Psychiatric: confused feeling, disorientation

Respiratory, Thoracic and Mediastinal: aspiration

Skin and Subcutaneous Tissue: oily hair and skin, facial swelling, leg swelling

Possible allergic reactions: urticaria, rhinorrhea, dermatitis

In patients over 60 years of age, there are isolated reports of serious post-marketing events following the administration of a sodium sulphate-free PEG electrolyte solution and bisacodyl 20 mg bowel prep kit. These adverse reactions include acute pulmonary edema after vomiting and aspirating the PEG-based solution, asystole, esophageal perforation, and upper GI bleeding from a Mallory-Weiss tear. In addition, the following serious adverse reactions were seen during administration of 4 L of PEG-3350 colon cleansing preparation: two deaths in end-stage renal failure patients who developed diarrhea, vomiting and dysnatremia.

DRUG INTERACTIONS

Drug-Drug Interactions

Oral medications administered within 2 hours before the start of administration of the PEG/ELS may be flushed out from the gastrointestinal tract and may not be adequately absorbed.

There is a potential risk of Ischemic colitis with co-exposure to osmotic laxatives (PEG

3550/Macrogol) such as Bi-PEGLYTE® and stimulant laxatives (e.g., bisacodyl). If patients develop severe abdominal pain and/or rectal bleeding, immediate evaluation and close medical attention should be provided.

Drug-Food Interactions

No solid foods or milk, except clear liquids, should be taken before the clinical procedure.

Patients should adequately hydrate before, during, and after the use of Bi-PEGLYTE®.

DOSAGE AND ADMINISTRATION

Recommended Dose and Dosage Adjustment

The recommended Bi-PEGLYTE® Bowel Prep Kit oral dosage regimen for adults prior to colonoscopy is the entire contents of one kit, administered either in a full-dose regimen or a split-dose regimen.

Prior to Gastrointestinal Examination or Procedure

On the day before the procedure, no solid foods or milk, except clear liquids, should be taken after 11:00 AM. No antacids should be taken within one hour of taking the bisacodyl tablets.

Reconstitution of the PEG/Electrolytes Solution:

1. Dissolve the entire contents of one sachet in 1 L (32 ounces) of lukewarm water and mix rapidly until a clear solution forms. Do not use cold water. Repeat the step with the second sachet. Patients should be instructed not to add any other ingredient (such as flavors, juice, etc) than the recommended quantity of water.
2. Refrigerate the solution as chilling improves the taste. Using a straw may make the solution more palatable and easier to drink
3. Use the freshly-made solution within 48 hours and discard unused portion.

Administration:

	Steps	Full-dosing Regimen*	Split-dosing Regimen*
Day before procedure	**1**	Take 3 bisacodyl tablets (total of 15 mg) with water at a time as instructed by the physician. Do not chew or crush the tablets.	Take 3 bisacodyl tablets (total of 15 mg) with water in the afternoon (at around 2:00 PM**). Do not chew or crush the tablets.
	2	Wait for a bowel movement (or maximum of 6 hours).	Not applicable
	3	After a bowel movement, or if there is no bowel movement within 6 hours of taking the Bisacodyl tablets, rapidly drink a glassful (250 mL) of the PEG/Electrolytes solution every 10 minutes until the 1 litre solution is finished.	In the evening (at around 8:00 PM** or 6 hours after taking the bisacodyl tablets), rapidly drink a glassful (250 mL) of the PEG/Electrolytes solution every 10 minutes until the 1 litre solution is finished.

	4	Take the second PEG/Electrolytes solution and rapidly drink a glassful (250 mL) of the solution every 10 minutes until the 1 litre solution is finished or as directed by a physician.	Not applicable
Day of procedure	**5**	Not applicable	About 4 hours** before the procedure, take the second PEG/Electrolytes solution and rapidly ,drink 250 mL of the solution every 10 minutes until the 1 litre solution is finished.

*Instructions must be followed as prescribed by the physician. Physicians may choose to prescribe the full-dosing or the split-dosing regimen.
**Time to be confirmed by the physician.

Watery bowel movements should begin within 1 hour after beginning PEG/Electrolytes administration and patients will continue to have loose bowel movements for 1 to 2 hours after finishing the solution. Lavage is complete when fecal discharge is clear. Patients should be instructed to drink all of the solution.

OVERDOSAGE

For management of suspected drug overdose, consult the regional Poison Control Centre.

There are no specific antidotes that are required to be administered in the event of overdose; however, supportive care may be required in order to prevent dehydration and/or electrolyte imbalance.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

The PEG-ELS in Bi-PEGLYTE® cleanses the bowel by induction of diarrhea. The osmotic activity of PEG 3350 in the PEG-ELS retains water in the lumen of the intestine, promotes intestinal smooth muscle contraction and peristaltic waves and induces bowel movement for evacuation of the colon. The electrolytes at the concentrations used in the PEG-ELS help to maintain electrolyte and water balance in the body.

Bisacodyl is a stimulant laxative pro-drug. After oral administration, bisacodyl is metabolized on the inner surface of the intestine to produce the active metabolite, 4,4'-dihydroxydiphenyl-(2-pyridyl) methane, which induces intestinal contraction and peristalsis and increases intestinal mucosal secretion.

Bisacodyl is very poorly absorbed in the intestine.

STORAGE AND STABILITY

The Bi-PEGLYTE® Bowel Prep Kit carton should be stored at room temperature (15-30°C). The freshly-reconstituted PEG/ELS should be used within 48 hours if stored at room temperature. Discard unused portion.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Bi-PEGLYTE® Bowel Prep Kit (Polyethylene Glycol 3350 and Electrolytes for Oral Solution USP and Bisacodyl Delayed Release Tablets USP) contains two sachets of PEG/Electrolytes powder (Polyethylene Glycol 3350 and Electrolytes for Oral Solution USP, 70 g each) and one blister-pack containing three (3) Bisacodyl Delayed Release Tablets USP.

Each 70 g sachet of PEG/Electrolytes powder (fruit-flavoured), to be dissolved in 1 L of water, contains:

Polyethylene Glycol 3350…..59.55 g
Sodium Sulphate……..5.74 g
Sodium Bicarbonate……1.69 g
Sodium Chloride……..1.46 g
Potassium Chloride……..0.76 g

Also contains (in alphabetical order): Fruit flavour and sodium saccharin.

The mmol/L equivalents of the PEG/Electrolytes ingredient concentrations are as follows:

Polyethylene glycol	18 mmol/L
Sodium	126 mmol/L
Potassium	10 mmol/L
Chloride	35 mmol/L
Sulphate	40 mmol/L
Bicarbonate	20 mmol /L

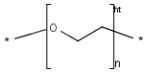
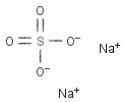
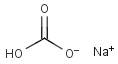
The osmolarity of a prepared solution of PEG/Electrolytes ranges from 235-305 mOsmol.

Each blister-pack of Bisacodyl Delayed Release Tablets USP holds three (3) yellow, enteric coated tablets containing bisacodyl USP 5 mg each. Also contains (in alphabetical order): D&C Yellow No.10 Aluminum Lake, FD&C Yellow No.6 Aluminum Lake, Glyceryl Stearate, Hypromellose, Lactose Monohydrate, Magnesium Stearate, Methylated Silica, Methylcellulose, Microcrystalline Cellulose, Polydextrose, Polydimethylsiloxane, Polyethylene Glycol, Polysorbate 65, Polyvinyl Acetate Phthalate, Silica, Sodium Alginate, Sodium Bicarbonate, Sodium Carboxymethylcellulose, Sorbic Acid, Stearic Acid, Sulphuric Acid, Talc, Titanium Dioxide, Triacetin, Triethyl Citrate.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

PEG/Electrolytes Sachet

Drug Substance	Polyethylene Glycol 3350	Sodium Sulphate	Sodium Bicarbonate	Sodium Chloride	Potassium Chloride
Proper name:	Polyethylene glycol	Sodium sulfate	Sodium bicarbonate	Sodium chloride	Potassium chloride
Chemical name:	Ethanol, 2,2'-(oxybis(2,1-ethanediyloxy)bis-	Bisodium sulfate; Dibasic sodium sulfate	Bicarbonate of soda; Carbonic acid, monosodium salt	Sodium chloride	Potassium chloride
Molecular formula:	$(C_2H_4O)_nH_2O$	$H_2O_4S.2Na$	$CH_2O_3.Na$	NaCl	KCl
Structural formula:					

Bisacodyl Delayed Released Tablets

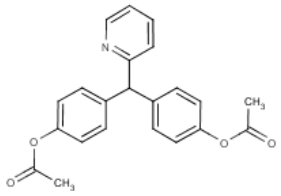
Drug Substance

Proper name: Bisacodyl

Chemical name: Bisacodyl 4,4'-(2-pyridylmethylene) bisphenol diacetate; (4,4'-Diacetoxydiphenyl) (2-pyridyl) methane

Molecular formula: $C_{22}H_{19}NO_4$

Structural formula:



Physicochemical properties: Tasteless crystals, melting point 138 °C. Practically insoluble in water and alkaline solutions. Soluble in acids, alcohol, acetone, propylene glycol, and other organic solvents.

CLINICAL TRIALS

In a published study by Adams et al (1994), a single-blind, randomized, controlled study was conducted to exam the bowel cleansing effect, safety and patient tolerance of a 4L PEG electrolyte solution (4L PEG-E) and a 2L PEG electrolyte solution preceded by 15 mg oral bisacodyl (bisacodyl plus 2L PEG-E). The patients in both groups were allowed a light breakfast on the day before and clear fluids thereafter until 7 AM on the day of the procedure. On the day prior to endoscopic procedure, patients (191) in the 4L PEG-E group orally consumed 4 L PEG-isotonic salt solution over 4 hours from 4 PM, while patients (191) in the bisacodyl plus 2L PEG-E group orally took 3 tablets of 5 mg bisacodyl at 8 AM and then consumed 2 L of PEG-E from 4 PM over 2 hours.

The quality of bowel preparation was rated on a scale of 1 to 5, i.e. 1) all mucosa easily visualized no fecal material present other than a liquid pool in the rectum; 2) multiple liquid pools present through the colon easily aspirated to allow visualization of all mucosa; 3) multiple pools of mixed solid and liquid feces present requiring some effort to see all mucosa; 4) multiple collections of solid feces present and 5) procedure abandoned due to poor preparation.

The rate of patients with bowel preparation rated at 1 or 2 in the bisacodyl plus 2L PEG-E group and the 4L PEG-E group was 69.1% vs 65.4%, respectively (Table 1). Only 66% of the patients in the 4L PEG-E group consumed all 4 liters of the PEG-E solution, whereas 93% in the bisacodyl plus 2L PEG-E group finished the 2 liters of the PEG-E solution.

The common adverse reactions were abdominal pain, nausea and vomiting. In patients who provided symptom information (see Table 1), nausea and vomiting were reported at a higher rate in the 4L PEG-E group than that in the bisacodyl plus 2L PEG-E group, while the reporting rate of abdominal pain was comparable in the two study groups.

Table 1: Comparison of the clinical effects of two bowel preparation regimens

PEG-E regimen		**bisacodyl plus 2L PEG-E**	**4L PEG-E**
		n=191	n=191
Patients with bowel cleansing quality rated at 1 or 2[a]* (%)		69.1	65.4
		n=148**	n=147**
Patients adhered to required PEG-E volume (%)**		93.0	66.0
Adverse reactions (%)**	Nausea	25.0	42.6
	Vomiting	6.8	12.2
	Abdominal pain	30.0	30.4

[a]The bowel cleansing quality was rated in a scoring system similar to the Ottawa Bowel Preparation Score (OBPS) system

* the numbers are based on the data in Table 3 in the article by Adams WJ, et al, 1994

** the numbers are based on or derived from the data in Table 2 in the article by Adams WJ, et al, 1994**.**

A randomized single-blinded clinical study (Brahmania *et al.*, 2014) examined bowel cleansing efficacy and patient tolerability of a 4L PEG electrolytes solution (PEGLYTE) or a 2L PEG electrolytes solution with oral 15 mg bisacodyl (Bi-PEGLYTE) administrated in a split-dose regimen. Patients in both study groups were only allowed a clear-liquid diet starting from 11:00 AM on the day before the procedure until the end of the procedure. Patients in the PEGLYTE group consumed the first 2 liters of the PEG electrolytes solution around 3:00 PM on the day before the procedure and then took the second 2 liters of the PEG electrolytes solution 4 hours before the colonoscopy procedure. Patients in the Bi-PEGLYTE group took three 5mg bisacodyl oral tablets at 2:00 PM and consumed the first liter of the PEG electrolytes solution around 8:00 PM on the day before the procedure and then took the second liter of the PEG electrolytes solution 4 hours before the colonoscopy procedure. The bowel cleansing quality was assessed with both the Ottawa Bowel Preparation Score (OBPS) and the Boston Ottawa Bowel Preparation Score (OBPS).

The patients with satisfactory bowel cleansing quality (total OBPS $\geq$8) were 64% and 60% in the Bi-PEGLYTE group and the PEGLYTE group, respectively. More than 98% of patients in both study groups consumed more than 80% of the required dosing volume of the PEG-E solution. Also, significantly higher proportions of patients found that Bi-PEGLYTE was easier or acceptable than PEGLYTE (89.9% vs 74.8%, $p < 0.001$) and were willing to repeat the same preparation (98.7% vs 73.6%, $p < 0.001$). Nausea, vomiting, abdominal cramps, headache, sleep disturbance were reported at comparable rates in both study groups (Table 2).

Table 2. Adverse events in patients received PEGLYTE or Bi-PEGLYTE in a split-dose regimen (Brahmania et al., 2014)

Adverse Events	**Bi-PEGLYTE (n=159) %**	**PEGLYTE (n=159) %**
Experienced adverse events	49.7	47.8
Nausea/vomiting	16.4	18.2
Abdominal cramps	15.7	18.9
Headache	13.8	15.1
Sleep disturbance	12.6	10.7
Bloating	17.0	16.4

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PART III: CONSUMER INFORMATION

Bi-PEGLYTE®
Bowel Prep Kit

Polyethylene Glycol 3350 and Electrolytes for Oral Solution USP and Bisacodyl Delayed Release Tablets USP

This leaflet is part III of a three-part "Prescribing Information" published when Bi-PEGLYTE® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Bi-PEGLYTE®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
Bi-PEGLYTE® is used for cleansing of the colon as a preparation for colonoscopy in adults.

What it does:
Bi-PEGLYTE® produces a watery stool which cleanses the bowel before colonoscopy examination. The bisacodyl component of Bi-PEGLYTE® acts as a stimulant laxative directly on the bowel to induce muscle contractions and to promote fluid accumulation in the bowel, and the polyethylene glycol binds to the water to help laxation and together the ingredients speed bowel emptying. The electrolytes help maintain the salt balance in this process.

When it should not be used:
Do not use if you are hypersensitive (allergic) to any ingredient in this formulation (see "What the nonmedicinal ingredients are").

Do not take if you have any of the following stomach/intestine conditions (ask your doctor if you are unsure):

- Ileus (blockage in the bowel)
- Gastric retention (problems with food and fluid emptying from stomach)
- Gastrointestinal (GI) obstruction (a blockage in bowel)
- Bowel perforation (an opening in the wall of your stomach or intestine)
- Toxic colitis (inflamed large bowel with damage to the intestinal wall)
- Toxic megacolon (acute swelling of the large bowel)
- Acute abdominal surgery
- Appendicitis (painful swelling and infection of the appendix, a small pouch attached to the large intestine)
- Rectal bleeding
- Gastroenteritis (inflammation in the gastrointestinal tract)
- Diverticulitis (a digestive disease found in the large intestine)

What the medicinal ingredients are:
Each sachet of PEG/Electrolytes powder gastrointestinal lavage preparation contains:

Polyethylene Glycol 3350…59.55 g
Sodium Sulphate……5.74 g
Sodium Bicarbonate……..1.69 g
Sodium Chloride……1.46 g
Potassium Chloride……0.76 g
Each blister-pack of Bisacodyl delayed release tablets, USP contains: three (3) tablets of bisacodyl 5 mg each.

What the nonmedicinal ingredients are:
PEG/Electrolytes powder sachets (in alphabetical order): Fruit flavour and Sodium Saccharin.

Bisacodyl tablets (in alphabetical order): D&C Yellow No.10 Aluminum Lake, FD&C Yellow No.6 Aluminum Lake, Hypromellose, Lactose Monohydrate, Magnesium Stearate, Methylated Silica, Methylcellulose, Microcrystalline Cellulose, Polydextrose, Polydimethylsiloxane, Polyethylene Glycol, Polyvinyl Acetate Phthalate, Silica, Sodium Alginate, Sodium Bicarbonate, Sodium Carboxymethylcellulose, Sorbic Acid, Stearic Acid, Sulphuric Acid, Talc, Titanium Dioxide, Triacetin, Triethyl Citrate.

What dosage forms it comes in:
Bi-PEGLYTE® is a kit containing two sachets of PEG/Electrolytes powder for reconstitution (each sachet is dissolved into 1 L of water – see "Proper use of this Medication") and one blister-pack containing 3 tablets of 5 mg each of bisacodyl. The entire contents of the kit should be used for the product to be effective.

WARNINGS AND PRECAUTIONS

BEFORE you use Bi-PEGLYTE® talk to your doctor or pharmacist if:

- You have taken any other medication within two hours of when you plan to start the PEG/Electrolyte solution (you may be removing this medication from your gastrointestinal tract by taking the PEG/Electrolyte solution)
- You have abdominal pain, nausea, or vomiting
- You have a history of electrolyte imbalance (e.g., change in blood salts (low blood sodium)) or are using diuretics
- You have ulcerative colitis or any other inflammatory bowel disease (e.g., Crohn's disease)
- You are pregnant or nursing
- You have difficulty swallowing or have a pronounced gag reflex or are prone to vomiting
- You have any allergies to this drug or its ingredients
- In rare cases, serious heart arrhythmias (an irregular or fast heartbeat) have been associated with the use of medicines such as BI-PEGLYTE®. Tell your doctor if you have problems with your heart such as:
  - a history of an abnormal electrical signal called "prolongation of the QT interval"
  - an arrhythmia that is not under control
  - a recent heart attack
  - heart failure
  - cardiomyopathy (a disease of the heart muscle that makes it harder for your heart to pump blood to the rest of your body)

Your doctor will decide whether you can take BI-PEGLYTE®.

Talk to your doctor if you have kidney or heart problems or any tendency to regurgitate (bring up) food from your stomach into your esophagus or any tendency to accidentally inhale food or regurgitate food into the airways.

Bi-PEGLYTE contains polyethylene glycol (PEG), which may stop starch based food thickeners from working. This may cause certain mixtures to be watery and difficult to swallow.

Inform your doctor immediately if you experience severe abdominal pain or rectal bleeding.

INTERACTIONS WITH THIS MEDICATION

Oral medications taken within 2 hours of the start of administration of the PEG/Electrolytes powder may be flushed from the gastrointestinal tract and not absorbed.

Tell your doctor and pharmacist about all the medicines you are taking, including prescription and non-prescription medications, vitamins, nutritional supplements, and herbal products.

Bi-PEGLYTE® may interact with stimulant laxatives (e.g. bisacodyl). Stop taking Bi-PEGLYTE® and seek medical help if you experience severe abdominal pain and / or rectal bleeding.

PROPER USE OF THIS MEDICATION

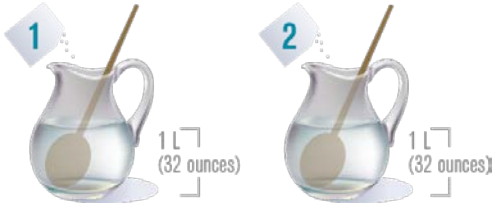
On the day before the procedure no solid foods or milk, except clear liquids, should be taken after 11h00 AM or as specified by your doctor. You can resume eating solid foods and milk only after your procedure or examination. No antacids should be taken within one hour of taking the bisacodyl tablets. Your physician will tell you what time of the day to start your treatment.

Drink plenty of water (or clear liquids) before, during and after using Bi-PEGLYTE®.

You should have been given specific instructions about when to take Bi-PEGLYTE® by your doctor or nurse. Your treatment with Bi-PEGLYTE® must be completed before your clinical procedure.

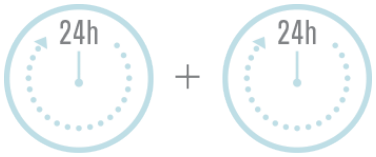
Preparation of the solution:

1. Dissolve the entire contents of one sachet in 1 L (32 ounces) of lukewarm water and mix rapidly until a clear solution forms. Do not use cold water. Repeat the step with the second sachet. Do not add any other ingredients (e.g. flavouring, juice) to the solution.



2. Refrigerate the solution as chilling improves the taste. Using a straw may help the solution taste better and easier to drink.

3. Use the freshly-made solution within 48 hours and discard unused portion.



Dosing regimens your healthcare practitioner may prescribe:

SPLIT-DOSING REGIMEN*

Day before procedure:**

1. Take 3 bisacodyl tablets (total of 15 mg) with water in the afternoon (at around 2:00 PM)**. **Do not chew or crush the tablets.**

2. In the evening (at around 8:00 PM or 6 hours after taking the bisacodyl tablets)**, rapidly drink a glassful (250 mL) of the PEG/Electrolytes solution every 10 minutes until the 1 litre solution is finished.

Day of the procedure (about 4 hours before the procedure):**

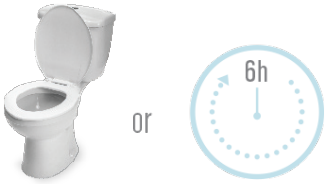
3.Take the second PEG/Electrolytes solution and rapidly drink a glassful (250 mL) of the solution every 10 minutes until the 1 litre solution is finished, or as directed by a physician.

FULL-DOSING REGIMEN*

Day before procedure (start in the afternoon):**

1.Take 3 bisacodyl tablets (total of 15 mg) with water. **Do not chew or crush the tablets.**

2. Wait for a bowel movement (or maximum of 6 hours).



3.After a bowel movement, or if there is no bowel movement within 6 hours of taking the Bisacodyl tablets, rapidly drink a glassful (250 mL) of the PEG/Electrolytes solution every 10 minutes until the 1 litre solution is finished.

4. Take the second PEG/Electrolytes solution and rapidly drink a glassful (250 mL) of the solution every 10 minutes until the 1 litre solution is finished or as directed by a physician.

*Follow instructions as prescribed by your physician. Your physician may choose to prescribe a full-dosing or a split-dosing regimen. **Time to be confirmed by your physician.

You will begin to have watery bowel movements within 1 hour after the start of PEG/Electrolytes administration and you will continue to have loose bowel movements for 1 to 2 hours after finishing the solution. Lavage is complete when the watery stool is clear and free of solid matter.

Make sure to take the entire bowel preparation solution as instructed by your doctor. This will help ensure that the colon will be optimally cleaned and minimize the need to reschedule your procedure.

Abdominal bloating or distention may occur before the first bowel movement. If your abdominal distention or discomfort continues, stop drinking the PEG/Electrolyte solution temporarily or drink each portion at longer intervals until your symptoms disappear. If you experience severe bloating, distention or abdominal pain, administration of the solution should be slowed or temporarily discontinued until the symptoms subside. Report these events to your doctor. **Inform your doctor immediately if you experience severe abdominal pain or rectal bleeding.**

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Nausea, abdominal fullness and bloating are the most frequent side effects occurring in up to half of patients taking PEG/Electrolytes preparations. Abdominal cramps, vomiting and anal irritation occur less frequently. These side effects normally do not last long.

Mild cramping has occurred in some patients after bisacodyl administration.

Bi-PEGLYTE® may cause loss of body fluid (dehydration) and changes in blood salts (electrolytes) in your blood. These changes may cause:

- seizures
- kidney problems
- abnormal heartbeats

Drink sufficient amount of balance salt-containing fluid as directed by your doctor to prevent loss of body fluid and related side-effects.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
Unknown	**Ischemic colitis (lack of blood flow to intestines): severe abdominal pain, rectal bleeding**			√
Isolated Cases	**Allergic reactions with symptoms such as skin rash, hives and runny nose**			√

This is not a complete list of side effects. For any unexpected effects while taking Bi-PEGLYTE®, contact your doctor or pharmacist.

HOW TO STORE IT

Store the contents of the Bi-PEGLYTE® carton at room temperature (15-30°C). The freshly-reconstituted PEG/Electrolyte solution should be used within 48 hours if stored at room temperature. Discard unused portion.

Keep out of reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 0701E
    Ottawa, ON
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information on the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full prescribing information, prepared for health professionals can be found by contacting PENDOPHARM, Division of Pharmascience Inc. at 1-888-550-6060.

This leaflet was prepared by:
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