PRESCRIBING INFORMATION

PegLyte® Powder

Polyethylene Glycol 3350 and Electrolytes for Oral Solution

USP

Gastrointestinal Lavage and Laxative

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INDICATIONS AND CLINICAL USE

Adults

PegLyte® Powder (PEG 3350 and Electrolytes) is indicated for:

- bowel cleansing prior to colonoscopy or barium enema x-ray examination or surgical procedures requiring a clean colon.
- the treatment of constipation

CONTRAINDICATIONS

PegLyte® Powder is contraindicated in patients with:

- ileus
- gastric retention
- bowel perforation
- gastrointestinal obstruction
- toxic colitis
- toxic megacolon
- 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 this prescribing information.

WARNINGS AND PRECAUTIONS

General

Advise all patients to hydrate adequately before, during, and after the use of PegLyte® Powder.

Use of PegLyte® Powder is not recommended when abdominal pain, nausea, or vomiting are present. Unconscious or semiconscious patients should be observed during the administration of PegLyte® Powder via nasogastric tube. A laxative should not be taken within 2 hours of another medicine because the desired effect of the other medicine may be reduced.

For use in the treatment of constipation:
Patients presenting with complaints of constipation should have a thorough medical history and physical examination to detect associated metabolic, endocrine, and neurogenic conditions, and medications. A diagnostic evaluation should include a structural examination of the colon.
Do not take PegLyte® Powder for more than 1 week, unless recommended by a physician.
The safety of long term use of PEG plus electrolytes, like PegLyte® Powder, is unknown.

No additional flavorings or ingredients may be added to the solution.

Cardiovascular

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 PegLyte® Powder 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

PegLyte® Powder should be used with caution in patients with ulcerative colitis (UC). Patients suffering from UC or from an acute exacerbation of inflammatory bowel disease have not been studied.

Patients with impaired gag reflex and patients prone to regurgitation or aspiration should be observed during the administration of PegLyte® Powder, especially if it is administered via nasogastric tube. If gastrointestinal obstruction or perforation is suspected, appropriate studies should be performed to rule out those conditions before administration of PegLyte® Powder.

When a large volume of PegLyte® Powder is used for colon preparation, if a patient experiences severe bloating, distension, or abdominal pain, administration of the solution should be slowed or temporarily discontinued until the symptoms subside.

When used for the treatment of constipation, if diarrhea occurs, the use of PegLyte® Powder should be discontinued.

There is a potential risk of Ischemic Colitis with co-exposure to osmotic laxatives (PEG 3550/Macrogol) such as PegLyte® Powder, 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.

Immune

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

Neurologic

Use of a 4 L volume of 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 been associated with these cases. 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), PegLyte® Powder should be used with caution. In these patients, baseline and post-colonoscopy laboratory tests (sodium, potassium, calcium, creatinine, and BUN) should be monitored.

Renal

The close monitoring of patients with impaired renal function should be performed, especially if severe vomiting occurs. Measurement of electrolytes (sodium, potassium, calcium), BUN, and creatinine is desirable. Mild hypokalemia was reported in a patient treated for constipation during 1 month who concurrently received diuretics. Hyperphosphatemia was reported during long term treatment with PEG-products.

Special Populations

Pregnant Women: Animal reproduction studies have not been conducted with PegLyte® Powder, and it is also not known whether PegLyte® Powder can affect reproductive capacity or harm the fetus when administered to a pregnant patient. PegLyte® Powder should be given to a pregnant patient only if clearly needed.

Breastfeeding 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 PegLyte® Powder is administered to a breastfeeding woman.

Pediatrics: Safety and effectiveness of PegLyte® Powder in children have not been established.

Geriatrics (> 60 years of age): There are isolated reports of serious post-marketing events following the administration of large volumes of PEG-based products for colon preparation 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 in whom fluid and electrolyte

shifts are more risky.

Monitoring and Laboratory Tests

Repeated or prolonged use of PEG-based products may result in electrolyte imbalance; monitoring of serum electrolytes including phosphate level is advised.

ADVERSE REACTIONS

Adverse Drug Reaction Overview

The most frequent adverse reactions, occurring in up to 50% of patients taking 4 L of PegLyte® Powder, are nausea, abdominal fullness, and bloating. Abdominal cramps, vomiting, and anal irritation occur less frequently. These adverse effects are transient.

The most frequent adverse reactions occurring in up to 48% of patients taking the split 4 L dose (2L in the evening and 2 L in the morning) of PegLyte® Powder are abdominal cramps, bloating, nausea, vomiting, insomnia (from frequent bathroom trips), and headache.

The adverse reactions occurring with PEG products used in the treatment of constipation include: nausea, abdominal bloating, cramping, diarrhea, and/or gas. High doses may produce diarrhea and excessive stool frequency, particularly in elderly nursing home patients.

Post-Market Adverse Drug Reactions

The following rare adverse events have been reported following administration of 4 L of Peglyte® Powder:

Cardiovascular: bradycardia, acute pulmonary edema, hypotension
Eye: sensitivity to light, painful irritated eyes
Gastrointestinal: rectal bleeding (occult blood in stool), sores in mouth, Ischemic Colitis (when used in conjunction with a stimulant laxative)
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
Psychiatric: confused feeling, disorientation
Respiratory, Thoracic and Mediastinal: aspiration
Skin and Subcutaneous Tissue: oily hair and skin, facial swelling, leg swelling

Isolated cases of urticaria, rhinorrhea, and dermatitis have been reported, which may represent allergic reactions.

The use of large volume (4 L) PEG-based colon preparations has resulted in reports of generalized tonic-clonic seizures (see *Warnings and Precautions*).

DRUG INTERACTIONS

Drug-Drug Interactions

PegLyte® Powder, as any other laxatives, should not be taken within two (2) hours of another medicine because the desired effect of the other medicine may be reduced.

There is a potential risk of Ischemic Colitis with co-exposure to osmotic laxatives (PEG 3550/Macrogol) such as PegLyte® Powder 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

When PegLyte® Powder is used for a bowel preparation, no food, except clear liquids, should be taken at least 3 hours prior to administration.

Patients should adequately hydrate before, during, and after the use of PegLyte® Powder.

DOSAGE AND ADMINISTRATION

Reconstitution of the oral solution

PegLyte® Powder (280 g bottle): To prepare PegLyte® Powder in solution, add lukewarm water until half full, replace the cap tightly, and mix well. Fill the bottle the rest of the way to the fill line (total volume 4 L). Replace cap tightly and mix well until all ingredients have completely dissolved. Do not use cold water.

PegLyte® Powder (70 g sachet): Dissolve the entire contents of one sachet in 1 L (32 ounces) of lukewarm water and stir rapidly to dissolve. Do not use cold water.

Patients should be instructed not to add any other ingredient (such as flavors, juice, etc.) than the recommended quantity of water. Keep refrigerated during treatment, for optimal storage and to improve the taste. Using a straw can help to make the solution more palatable and easier to drink.

Recommended Dose and Dosage Adjustment

Prior to gastrointestinal examination or procedure:
On the day before the procedure, the patient should be instructed to have breakfast no later than 11h00 AM or as specified by the physician. After breakfast, no solid foods or milk, except clear liquids, should be taken. Solid foods and milk can be reintroduced after the examination or procedure. PegLyte® Powder can be administered orally or by nasogastric tube.

Oral: PegLyte® Powder can be administered either in a full-dose or in a split-dose regimen.

Recent data suggest that the split-dose method of administration may be more effective and better tolerated.

Administration:

	The day before the procedure	The day of the procedure
Full-dosing regimen*	In the evening**, rapidly drink a glassful (250 mL) of PegLyte® Powder every 10 to 15 minutes until 4 L are consumed.	Not applicable
Split-dosing regimen*	In the afternoon**, rapidly drink a glassful (250 mL) of PegLyte® Powder every 10 to 15 minutes until 2 L are consumed.	In the morning**, rapidly drink a glassful (250 mL) of PegLyte® Powder every 10 to 15 minutes until 2 L are consumed (must be finished at least 4 hours before procedure).

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

Nasogastric Tube: PegLyte® Powder is administered at a rate of 20 to 30 mL/minute (1.2 to 1.8 L/hour).

The first bowel movement should occur approximately 1 hour after beginning PegLyte® Powder administration. Administration of PegLyte® Powder should be continued until the fecal discharge is clear. Lavage is usually complete after the ingestion of 3 to 4 L of PegLyte® Powder. The unused portion should be discarded. A 1-hour waiting period after the appearance of clear liquid stools should be allowed prior to examination, to complete bowel evacuation.

Constipation:
240 to 480 mL/day (equivalent to a PEG dose of 14 to 28 g/day, plus electrolytes) orally for a week or less, or as recommended by a physician. Do not take any type of laxatives for more than one week, unless your physician has ordered a special schedule for you.

Treatment for two to four days may be required to produce a bowel movement. If no bowel movement is achieved after 4 days, patients should consult their physicians.

OVERDOSAGE

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.

For management of a suspected drug overdose, contact your regional poison control centre immediately.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

Polyethylene glycol 3350 (PEG 3350) is an osmotic laxative which causes water to be retained with the stool leading to decreased stool consistency, softening the stools, increasing fecal bulk, and facilitating bowel movements.

Large volume (about 4 L) of PegLyte® Powder (PEG 3350 and electrolytes) cleanses the bowel by induction of diarrhea.

The osmotic activity of PEG 3350, in combination with the electrolyte concentration, results in virtually no net absorption or secretion of ions, such as sodium or potassium, and water.

Accordingly, large volumes may be administered over a short period of time without significant changes in fluid and electrolyte balance.

Smaller volumes of PegLyte® Powder are used for constipation relief. It may take about 2 to 4 days to produce a bowel movement.

Pharmacokinetics

PEG 3350 is poorly absorbed through the gastrointestinal tract, and is not metabolized by the colonic bacteria.

Pharmacokinetics of PEG 3350 were evaluated in human volunteers after the oral administration of 17 g doses (as a laxative). Results show minimal absorption (<0.28%), low blood levels, rapid excretion through feces, and lack of substantial accumulation of PEG 3350 on multiple dosing regardless of age and gender.

STORAGE AND STABILITY

PegLyte® Powder for oral solution
Store the sachets and bottle at room temperature, between 15ºC and 30ºC.
Once reconstituted, the solution should be used within 48 hours after mixing if stored at room temperature. If kept refrigerated (2ºC to 8°C), use within 30 days. Discard unused portion.

DOSAGE FORMS, COMPOSITION AND PACKAGING

PegLyte® Powder for oral solution **(Fruit flavored)**

280 g bottle
Each 280 g bottle of PegLyte® Powder, to be dissolved in 4 L of water, contains the following medicinal ingredients:

Polyethylene Glycol 3350	238.18 g
Sodium Sulphate	22.96 g
Sodium Bicarbonate	6.76 g
Sodium Chloride	5.85 g
Potassium Chloride	3.05 g

Non-medicinal ingredients: Sodium Saccharin and Fruit Flavours.

Box of 4 x 70 g sachets
Each 70 g sachet of PegLyte® Powder, to be dissolved in 1 L of water, contains the following medicinal ingredients:

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

Non-medicinal ingredients: Sodium Saccharin and Fruit Flavours.

Once reconstituted with the appropriate volume of water, the solution contains:

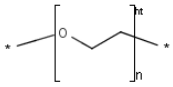
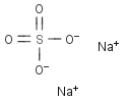
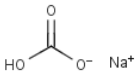
Polyethylene Glycol 3350	17.8 mmol /L
Sodium	126.0 mmol /L
Potassium	10.2 mmol /L
Chloride	35.3 mmol /L
Sulphate	40.4 mmol /L
Bicarbonate	20.1 mmol /L

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

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance

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:	$HO(C_2H_4O)_nH$	Na_2SO_4	$NaHCO_3$	NaCl	KCl
Structural formula:					

CLINICAL TRIALS

A randomized, double-blind, controlled clinical study compared the bowel cleansing efficacy and safety of a PEG electrolyte solution (PEG-E), which is similar to Peglyte® Powder, administrated in a full-dose regimen or a split-dose regimen with or without tegaserod (Abdul-Baki H. et al., 2008). Efficacy of colon cleansing was the primary outcome. In the study groups (Group A and Group C) where tegaserod was not used, patients were allowed a liquid diet in the full-dose group (Group A) or a regular diet in the split-dose group (Group C) with the last meal at 6:00 PM on the day before the colonoscopy, and after which only water was allowed until the procedure for both groups. Between 7:00 PM and 9:30 PM on the day before the procedure, patients in the full-dose group and the split-dose group consumed 4L or 2L of the PEG-E solution, respectively. Patients in the split-dose group consumed further 2L of the PEG-E solution 2 hours before the procedure. The quality of bowel preparation was graded as being excellent, good, fair, or poor.

Patients in the split-dose group had significantly better colon cleansing than those in the full-dose group (86% vs 46.1%). The rate of patients who adhered to dose requirement was higher in the split-dose group than that in the full-dose group (91% vs 68.8%, P<0.05) (Table 1). The reported adverse events (AEs) were nausea, vomiting, abdominal cramps, headache, sleep disturbance, and bloating in both study groups. However, the rate of the AEs was lower in the split-dose group than that in the full-dose group except bloating (Table 1).

Table 1 Comparison of bowel cleansing efficacy, patients' compliance and adverse reactions of a 4 L PEG-E solution administrated in a full-dose regimen or a split-dose regimen (Abdul-Baki H. et al., 2008)

4L PEG-E solution		Full-dose group (n=89)	Split-dose group (n=107)	P value
Patients with good or excellent bowel cleansing quality (%)*		46.1	86.0	-
Patients adhered to required volume of the PEG-E solution (%)**		68.8	91.0	<0.05
Adverse reactions (%)	Nausea	49.4	28.0	-
	Vomiting	7.9	4.7	-
	Abdominal cramps	28.1	18.7	-
	Headache	30.7	20.6	-
	Sleep disturbance	23.6	16.0	-
	Bloating	25.0	35.5	-

*The bowel cleansing quality was rated with a scoring system similar to the Boston Bowel Preparation Score system.
** Independent of the use of tegaserod.

Constipation

Polyethylene glycol and electrolytes solutions (PEG-ELS) are described as part of the medications commonly used for the treatment of constipation. The maximal recommended dose is 17-36 g once or twice a day.

Study demographics and trial design

Table 2 Summary of patient demographics for clinical trials of polyethylene glycol and electrolyte solutions (PEG-ELS) in the treatment of chronic constipation

Study	Trial design	Dosage	Duration	Study subjects	Mean age (years)	Gender
Andorsky and Goldner	Double-blind, placebo-controlled, cross-over study	• PEG-ELS 240 mL/day or 480 mL /day • placebo 240 mL/day or 480 mL /day	2 x 5 days	32	62 (range 42-89)	7 M 25 F
Chaussade and Minic	Prospective, multicenter, double-blind, randomized, parallel-group study	• PEG3350-ELS 5.9 g/day • PEG3350-ELS 11.8 g /day • PEG4000 10 g/day • PEG4000 20 g/day	1 month	266	52.2 ± 18.5	39 M 227 F
Attar *et al.*	Randomized, open-label, parallel-group, multicenter study	• PEG-ELS 2x13g/day • Lactulose 2x10g/day After two weeks of treatment, patients could adjust their dose to 1 to 3 doses per day.	1 month	115	55 (24)	21 M 94 F

Study results

A double-blind, placebo-controlled, cross-over study by Andorsky and Goldner assessed the effectiveness of a PEG-ELS for the treatment of chronic constipation. 32 patients were instructed to drink 240 mL or 480 mL of PEG-ELS or placebo daily during 5 consecutive days, then received the same volume of the second treatment (PEG-ELS or placebo) after a 2-day washout period. Daily number of bowel movements and stool consistency were recorded. The two-factor analysis of variance results confirmed that PEG-ELS was superior to placebo with regard to the mean stool frequency (7.75 ± 4.55 vs. 4.88 ± 2.62, $p < 0{,}01$) and the mean stool consistency (2.56 ± 1.17 vs. 1.91 ± 0.94, $p < 0.05$). Furthermore, PEG-ELS 480 mL per day was superior to all other groups with regard to the measured variables. Side effects reported with the PEG-ELS solution included cramping, gas, nausea, and loose stools; side effects did not lead to treatment cessation. The finding that PEG-ELS resulted in significant effects on both stool frequency and stool consistency further supports its efficacy in the treatment of constipation.

A multicentre, double-blind, randomized, parallel-group study by Chaussade and Minic compared the efficacy and tolerability of standard and maximum daily doses of PEG-ELS (PEG 3350 and electrolytes) and PEG 4000 in the treatment of chronic constipation. Results showed that both doses of PEG-ELS and PEG 4000 were similarly effective in treating the symptoms of constipation (stool frequency and stool consistency were improved when compared to baseline). Diarrhea was observed in 13% of patients treated with low dose of PEG-ELS and 36% after the higher dose. Side effects reported were abdominal distention, flatulence, and abdominal pain, similarly distributed across all groups. Vital signs were normal in 95% of the patients.

A randomized, open-label, parallel-group, multicenter study by Attar *et al*. compared PEG-ELS to lactulose for treatment of constipation. 115 patients with chronic idiopathic constipation were instructed to take two 13 g sachets of PEG-ELS or two 10 g lactulose sachets, in divided doses. After two weeks of treatment, dosage could be adjusted to 1 to 3 sachets/day. Treatment lasted for 4 weeks. PEG was well tolerated in the young and elderly population and the treatment of constipation was better than lactulose in terms of number of bowel movements, straining, and use of suppositories and minienemas.

TOXICOLOGY

Acute Toxicity:

The oral LD_{50} is >50 g/kg in mice, rats, and rabbits.

Rats
Chronic oral toxicity studies were conducted in rats (up to 6 g/kg/day) up to six months duration. The major target organ of toxicity in the rat appeared to be the kidney (focal or multi focal cytoplasmic vacuolation in cortical tubular epithelial cells in males at 6 g/kg/day).

Dogs
Chronic oral toxicity studies were conducted in dogs (up to 3 g/kg/day) up to nine months duration.

Following oral administration of PEG 3350 for 28-days, the target organs of toxicity appeared to be the lungs (minimal to moderate interstitial fibrosis characterized by thickening of alveolar septa with associated pneumocyte hypertrophy/hyperplasia and the presence of a small number of mononuclear inflammatory cells and alveolar histiocytes; foamy or vacuolated histiocytes in perivascular or peribronchiolar regions characterized as perivascular mononuclear infiltrates), gastrointestinal tract (minimal subacute inflammation or crypt abscesses, hemorrhage and lymphoid hyperplasia in cecum, colon, ileum, and/or rectum; lymphoid hyperplasia of the gut-associated lymphoid tissue in females at 3, 6, and 9.3 g/kg/day), testes (hypospermia in the epididymides and seminiferous tubule degeneration or multiucleated spermatids of the testes), and salivary gland (atrophy).

Following 9-month oral administration of PEG 3350 in dogs (up to 3 g/kg/day), the target organs of toxicity appeared to be testes (retarded development) and prostate (lymphocyte infiltrate) in the males and mammary gland (glandular hyperplasia), liver (vacuolation) and gallbladder (lymphocyte infiltrate and epithelial hyperplasia) in females.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Carcinogenesis
No tumorigenic effect was seen in mice and rats up to 6 g/kg/day. The carcinogenic potential of PEG 3350 has also been examined in CD-J mice (l04 weeks) and Sprague Dawley rats (l04 weeks).

Mutagenesis
PEG 3350 was negative in the Ames test. No clastogenic potential was shown in the chromosome aberration test with human peripheral blood lymphocytes. It was also negative in *in vivo* oral rat micronucleus test.

Development and reproductive toxicity
Reproduction studies with PEG 3350 have been performed in pregnant rats (oral doses up to 2 g/kg/day) and in pregnant rabbits (oral doses up to 2 g/kg/day) and have revealed no adverse effects on fertility or harm to the fetus.

In pre- and post-natal developmental study in rats up to 2 g/kg/day dose, PEG 3350 did not show any adverse effect on F_1 postnatal survival, body weight, developmental landmarks, startle response, motor activity, learning and memory and reproductive performance, intrauterine growth and survival of F_2 fetuses and external and developmental parameters of F_2 fetuses.

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PART III: CONSUMER INFORMATION

PegLyte® Powder
Polyethylene Glycol 3350 and Electrolytes for Oral Solution, USP

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

ABOUT THIS MEDICATION

What the medication is used for:
- Bowel cleansing prior to examination (e.g., colonoscopy) or surgical procedures requiring a clean colon.
- The treatment of constipation following consultation with your healthcare professional.

What it does:
The polyethylene glycol binds to the water and helps laxation. The electrolytes help maintain the salt balance in this process.

When it should not be used:
Do not take if you have any of the following conditions (ask your healthcare professional if you are unsure):
- ileus (blockage in the bowel)
- gastric retention
- bowel perforation
- gastrointestinal obstruction
- toxic colitis (inflamed large bowel with damage to the intestinal wall)
- toxic megacolon (acute swelling of the large bowel)
- or if you are hypersensitive (allergic) to any ingredient in this formulation (See ***What the important non-medicinal ingredients are***).

What the medicinal ingredients are:

	70 g sachet	280 g bottle
Polyethylene Glycol 3350	59.55 g	238.18 g
Sodium Sulphate	5.74 g	22.96 g
Sodium Bicarbonate	1.69 g	6.76 g
Sodium Chloride	1.46 g	5.85 g
Potassium Chloride	0.76 g	3.05 g

What the important non-medicinal ingredients are:
Sodium Saccharin, Fruit flavours.

What dosage forms it comes in:
Powder for oral solution (fruit flavoured):
- Box of 4 sachets of 70 g powder
- Bottle of 280 g powder

WARNINGS AND PRECAUTIONS

BEFORE you use PegLyte® Powder, talk to your healthcare professional **or pharmacist if:**

- You have taken any other medication within 2 hours of when you plan to start taking PegLyte® Powder (you may be removing this medication from your gastrointestinal tract by taking the PegLyte® Powder).
- You have a history of electrolyte imbalance (e.g., hyponatremia) 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.

Talk to your healthcare professional if you have kidney or heart problemsor 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 trachea (breathing tube to the lungs).

Contact your healthcare professional if the following occurs while taking PegLyte® Powder:
- You develop severe bloating, abdominal pain or distension.
- Do not take this medication if you have abdominal pain, nausea or vomiting.

Other warnings you should know about:

In rare cases, serious heart arrhythmias (an irregular or fast heartbeat) have been associated with the use of medicines such as PegLyte ® Powder. Tell your healthcare professional 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 healthcare professional will decide whether you can take PegLyte® Powder.

INTERACTIONS WITH THIS MEDICATION

Oral medications taken within 2 hours of the start of administration of PegLyte® Powder may be flushed from the gastrointestinal tract and not absorbed.

Drug interaction studies have not been done for PegLyte® Powder.

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

PROPER USE OF THIS MEDICATION

Preparation of the solution:
PegLyte® Powder 280 g bottle: Add lukewarm water until half full, replace the cap tightly and mix well. Fill the bottle the rest of the way to the fill line (total volume 4 L). Replace cap tightly and

mix well until all ingredients have completely dissolved. Do not use cold water.

PegLyte® Powder 70 g sachet: Dissolve the entire contents of one sachet in 1 L (32 ounces) of lukewarm water and stir rapidly to dissolve. Repeat for the other 3 sachets, one at a time, as needed. Do not use cold water.

Drink plenty of water (or liquids) before, during and after using PegLyte® Powder.

Do not add any other ingredients (e.g., flavouring, juice) to the solution. Keep refrigerated during treatment, for optimal storage and to improve the taste. Using a straw can help to make the solution taste better and easier to drink.

Usual adult dose:

Colon cleansing before examination

On the day before your procedure or examination, have breakfast no later than 11:00 AM or as specified by your healthcare professional. After breakfast, no solid foods or milk, except clear liquids, should be taken. You can resume eating solid foods and milk only after your procedure or examination.

Dosing regimens your healthcare practitioner might prescribe:

SPLIT-DOSING REGIMEN*

Day before procedure:**

1. In the afternoon, rapidly drink a glassful (250 mL) of PegLyte® Powder every 10-15 minutes until 2 L are consumed.

Day of the procedure (at least 4 hours before the procedure):**

2. Rapidly drink a glassful (250 mL) of PegLyte® Powder every 10-15 minutes until 2 L are consumed.

FULL-DOSING REGIMEN*

Day before procedure**

1. In the evening**, rapidly drink a glassful (250 mL) of PegLyte® Powder every 10-15 minutes until 4 L are consumed.

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

The first bowel movement should occur approximately 1 hour after the start of PegLyte® Powder administration. Administration of PegLyte® Powder should be continued until the watery stool is

clear and free of solid matter. **Make sure to take the entire bowel preparation solution as instructed by your healthcare professional.** This will help ensure that the colon will be optimally cleaned and minimize the need to reschedule your procedure.

Constipation
Drink 240 to 480 mL/day for a week or less or as recommended by your healthcare professional. Do not take any type of laxatives for more than one week, unless your healthcare professional has ordered a special schedule for you. Treatment for 2 to 4 days may be required to produce a bowel movement. If no bowel movement occurs in 4 days, contact your healthcare professional.

Overdose:

If you think you, or a person you are caring for, have taken too much PegLyte® Powder, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medications, PegLyte® Powder can cause some side effects. You may not experience any of them. For most patients, these side effects are likely to be minor and temporary.

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		
	Only if severe	**In all cases**	**Stop taking drug and get immediate medical help**
Ischemic colitis (lack of blood flow to intestines): severe abdominal pain, rectal bleeding			√
Nausea, vomiting		√	
Abdominal fullness, abdominal cramps, bloating, gas		√	
Diarrhea			√
Anal irritation		√	
Seizures			√
RARE			
Allergic reactions: urticaria (hives), rhinorrhea (nasal discharge) and dermatitis (skin inflammation)			√

This is not a complete list of side effects. For any unexpected effects while taking PegLyte® Powder, contact your *healthcare professional* ***or pharmacist.***

HOW TO STORE IT

Store the powder at room temperature (15 ºC - 30ºC). Keep out of reach and sight of children.

Once reconstituted, the solution should be used within 48 hours after mixing if stored at room temperature. If kept refrigerated (2 ºC - 8°C), use within 30 days. Discard unused portion.

REPORTING SUSPECTED SIDE EFFECTS

Reporting Side Effects
You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

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

This leaflet was prepared by:
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