PRESCRIBING INFORMATION

Colyte®

Polyethylene Glycol 3350 and Electrolytes for Oral Solution, USP

Gastrointestinal lavage and laxative

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Date of Revision:
March 25, 2021

Submission Control No : 245060

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PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
oral	Powder for oral solution: Polyethylene glycol (PEG) 3350 : 240 g Sodium chloride : 5.84 g Potassium chloride : 2.98 g Sodium bicarbonate : 6.72 g Sodium sulfate (anhydrous) : 22.72 g	(alphabetical) Magnasweet 185, Pineapple Favour and Sodium Saccharin. *For a complete listing see Dosage Forms, Composition and Packaging section.*

INDICATIONS AND CLINICAL USE

Adults

Colyte® (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

Colyte® 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

- Use of Colyte® is not recommended when abdominal pain, nausea, or vomiting are present
- Unconscious or semiconscious patient should be observed during the administration of Colyte® 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 Colyte® for more than 1 week, unless recommended by a physician.
- The safety of long term use of PEG plus electrolytes, like Colyte®, is unknown.

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

Colyte® 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 Colyte®.

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 Colyte® 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

Colyte® 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 Colyte®, 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 Colyte®.

When a large volume of Colyte® 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 abate.

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

There is a potential risk of Ischemic colitis with co-exposure to osmotic laxatives (PEG 3550/Macrogol) such as Colyte®, 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 have 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), Colyte® 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,) and 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 Colyte®, and it is also not known whether Colyte® can affect reproductive capacity or harm the fetus when administered to a pregnant patient. Colyte® 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 Colyte® is administered to a nursing woman.

Pediatrics: Safety and effectiveness of Colyte® 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 of extra risk.

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 Colyte® solution, are nausea, abdominal fullness and bloating. Abdominal cramps, vomiting and anal irritation occur less frequently. These adverse effects are transient.

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 Colyte®:

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 Liter) PEG-based colon preparation has resulted in reports of generalized tonic-clonic seizures (see Warnings and Precautions).

DRUG INTERACTIONS

Drug-Drug Interactions

Colyte®, 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 Colyte®, 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 Colyte® 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 Colyte®.

DOSAGE AND ADMINISTRATION

General considerations

No additional ingredients, e.g. flavouring, should be added to the solution.

Keep refrigerated during treatment, for optimal storage and to improve the taste.

Recommended Dose and Dosage Adjustment

Prior to gastrointestinal examination or procedure

Patients should fast at least 3 hours prior to administration. No foods except clear liquids should be permitted prior to examination after Colyte® administration. Colyte® can be administered orally or by nasogastric tube.

Oral: The recommended adult oral dose is 240 mL of Colyte® solution every 10 minutes. Rapid drinking of each portion is preferred rather than drinking small amounts continuously.

Nasogastric Tube: Colyte® 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 the start of Colyte® administration. Administration of Colyte® should be continued until the fecal discharge is clear. Lavage is usually complete after the ingestion of 3 to 4L of Colyte® solution. 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

Reconstitution of the solution

Colyte® powder 278 g bottle: To prepare Colyte® solution, add lukewarm tap water until half full, replace 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.

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 decrease stool consistency, soften the stools, increase fecal bulk and facilitate bowel movements.

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

The osmotic activity of PEG 3350, in combination with the electrolyte concentration, result 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 Colyte® 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 track, and not metabolized by the colonic bacteria.

Pharmacokinetics of PEG 3350 was 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

Store Colyte® powder at room temperature, between 15 °C and 30 °C.
Once reconstituted, the solution should be used within 48 hours after mixing if stored at room temperature. If kept refrigerated (between 2 °C and 8 °C), use within 30 days. Discard unused portion.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Colyte® Powder for oral solution

Each 278 g bottle of Colyte® powder, to be dissolved in 4 L of water, contains the following medicinal ingredients:
Polyethylene glycol 3350 : 240 g

Sodium chloride : 5.84 g
Potassium chloride : 2.98 g
Sodium bicarbonate : 6.72 g
Sodium sulfate (anhydrous) : 22.72 g

Non-medicinal ingredients: (alphabetical) magnasweet 185, pineapple flavour and sodium saccharin.

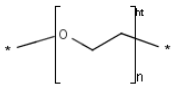
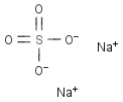
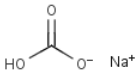
When reconstituted with 4 L of water, the solution contains :
Sodium: 125 mEq/L
Potassium: 10 mEq/L
Bicarbonate: 20 mEq/L
Sulfate: 80 mEq/L
Chloride: 35 mEq/L
Polyethylene glycol 3350: 17.9 mEq/L

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 Sulfate	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

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 4400 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 movement, 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 multinucleated 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

Colyte®
Polyethylene glycol 3350 and Electrolytes for Oral Solution, USP

This leaflet is part III of a three-part "Prescribing Information" published when Colyte® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Colyte®. Contact your doctor 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 doctor.

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 doctor 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 nonmedicinal ingredients are).

What the medicinal ingredient are:
Each bottle contains:
Polyethylene glycol 3350: 240 g
Sodium chloride: 5.84 g
Potassium chloride: 2.98 g
Sodium bicarbonate: 6.72 g
Sodium sulfate (anhydrous): 22.72 g

What the important nonmedicinal ingredients are:
(alphabetical) Magnasweet 185, Pineapple Flavour and Sodium Saccharin.

What dosage forms it comes in:
Powder for oral solution: bottle of 278 g powder

WARNINGS AND PRECAUTIONS

BEFORE you use Colyte®, talk to your doctor or pharmacist if:

- You have taken any other medication within two hours of when you plan to start taking Colyte® (you may be removing this medication from your gastrointestinal tract by taking the Colyte®)
- You have a history of electrolyte imbalance (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
- In rare cases, serious heart arrhythmias (an irregular or fast heartbeat) have been associated with the use of medicines such as Colyte®. 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 Colyte®.

Talk to your doctor if you have kidney or heart problems, kidney impairment or heart failure or any tendency to regurgitate (bring up) food from your stomach into your esophagus or any tendency to accidentally inhale food or regurgitated food into the trachea (breathing tube to the lung).

Colyte® 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.

Contact your doctor if the following occurs while taking Colyte®:

- You develop severe bloating, abdominal pain or distension
- Do not take this medication if you have abdominal pain, nausea or vomiting and contact your doctor

INTERACTIONS WITH THIS MEDICATION

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

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

Drug interaction studies have not been done for Colyte®.

PROPER USE OF THIS MEDICATION

Preparation of the solution:
Add lukewarm tap water until half full, replace 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.

No additional ingredients, e.g. flavouring, should be added to the solution. Keep refrigerated during treatment, for optimal storage and to improve the taste.

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

Usual adult dose:

Colon cleansing before examination

No solid food should be consumed during the period 3 hours before Colyte® consumption.

Drink 240 mL (8 oz) every 10 minutes. Rapid drinking of each portion is preferred rather than drinking small amounts continuously.

The first bowel movement should occur approximately 1 hour after the start of Colyte® administration. Administration of Colyte® should be continued until the watery stool is clear and free of solid matter. This normally requires the consumption of approximately 3 to 4 L, although more or less may be required in some patients. The unused portion should be discarded.

Constipation

Drink 240 to 480 mL/day for a week or less or as recommended by your doctor. Do not take any type of laxatives for more than one week, unless your doctor 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 doctor.

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

Like all medications, Colyte® 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.

The most frequent side effects for a colon preparation (occurring in up to 50% of patients) are:

- nausea
- abdominal fullness
- bloating

Less frequent side effects include:

- abdominal cramps
- vomiting
- anal irritation
- Seizures have also occurred in patients using PEG-based colon preparations.

For patients using Colyte® in the treatment of constipation, the side effects may include:

- nausea
- abdominal bloating
- cramping
- gas
- diarrhea. If diarrhea occurs, stop taking Colyte®.

Isolated cases of urticaria (hives), rhinorrhea (nasal discharge) and dermatitis (skin inflammation) have been reported. These may be signs of an allergic reaction. If you experience these symptoms, seek urgent medical attention.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Ischemic colitis (lack of blood flow to intestines): severe abdominal pain, rectal bleeding			✓

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

HOW TO STORE IT

Store the powder at room temperature (between 15 and 30°C). Keep out of reach of children.

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

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, Ontario
  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 related to 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 obtained by contacting the sponsor at 1-888-550-6060.

This leaflet was prepared by

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Last revised: March 25, 2021