

POLYETHYLENE GLYCOL AND ELECTROLYTES

Category

Evacuant (bowel) 16, 19.

Indications

Accepted

Bowel evacuation, preoperative, and

Bowel evacuation, pre-radiography Polyethylene glycol (PEG) 3350 and electrolytes oral solution is indicated for bowel cleansing prior to gastrointestinal examination (e.g., colonoscopy, barium enema, intravenous pyelography) and colon surgery. 1, 2, 3, 4, 5, 6, 8, 9, 13, 14, 20, 21, 22

For double contrast barium enema, administration of the PEG-electrolyte solution alone has not been found to be an adequate method of bowel cleansing. PEG-electrolyte solution followed by oral administration of bisacodyl has been reported to achieve better removal of feces and correct degraded mucosal coating. 4, 7

Pharmacology/Pharmacokinetics

Physicochemical characteristics:

Molecular weight 23

Potassium chloride: 74.55

Sodium bicarbonate: 84.01

Sodium chloride: 58.44

Sodium sulfate: 322.20

Osmolality 280 mOsmol per kg of water. 1

Mechanism of action/Effect:

Evacuant (bowel) Cleansing of the bowel is achieved by fluid overload with the osmotically balanced PEG-electrolyte solution, which induces a liquid stool within a short period of time. The concentration of electrolytes in the solution causes no net absorption or secretion of ions; thus no significant changes in water or electrolyte balance occur. 1, 4, 5, 6, 9, 14, 15, 16, 17, 18, 20, 21, 22

Absorption:

Negligible absorption from gastrointestinal tract. 1, 4, 10

Onset of action:

30 to 60 minutes. 1

Elimination:

Negligible renal excretion (<0.1%). 10

Precautions to Consider

Carcinogenicity/Mutagenicity

Studies to evaluate carcinogenic or mutagenic potential have not been performed. 14, 20, 21, 22

Pregnancy/Reproduction

Pregnancy%Studies have not been done in humans.

Studies have not been done in animals.

FDA Pregnancy Category C. 1, 14, 20, 21

Breast-feeding

It is not known whether PEG-electrolyte solution is distributed into breast milk. However, problems in humans have not been documented.

Pediatrics

Studies performed in children ranging in age from 6 months to 18 years have not demonstrated pediatrics-specific problems that would limit the usefulness of PEG-electrolyte solution in children. 4, 12, 17, 18

Geriatrics

Appropriate studies performed to date have not demonstrated geriatrics-specific problems that would limit the usefulness of PEG-electrolyte solution in the elderly. 2, 5, 11

Drug interactions and/or related problems

The following drug interactions and/or related problems have been selected on the basis of their potential clinical significance (possible mechanism in parentheses where appropriate)¼not necessarily inclusive (>> = major clinical significance):

>> Oral medications, other

(other oral medications administered within 1 hour of administration of PEG-electrolyte solution may be flushed from the gastrointestinal tract and not absorbed 1, 14, 20, 21)

Laboratory value alterations

The following have been selected on the basis of their potential clinical significance (possible effect in parentheses where appropriate)¼not necessarily inclusive (>> = major clinical significance):

With diagnostic test results

Barium sulfate, rectal

(administration of PEG-electrolyte solution on the same day as a barium enema [either single or double contrast] may result in retained fluid and thus barium dilution and may prevent barium coating of the intestinal wall 5, 16)

Medical considerations/Contraindications

The medical considerations/contraindications included have been selected on the basis of their potential clinical significance (reasons given in parentheses where appropriate)¼ not necessarily inclusive (>> = major clinical significance).

Except under special circumstances, this medication should not be used when the following medical problems exist

>> Intestinal obstruction or

>> Paralytic ileus or

>> Perforated bowel or

>> Toxic colitis or

>> Toxic megacolon

(condition may be aggravated; colonic perforation may occur in patients with intestinal obstruction or toxic colitis 1, 3, 4, 14, 20, 21, 22)

Risk-benefit should be considered when the following medical problems exist

Aspiration, predisposition to or

Impaired gag reflex or

Regurgitation, predisposition to or

Unconscious or semiconscious state

(administration via nasogastric tube may increase risk of complications 1, 14, 20, 21, 22)

Ulcerative colitis, severe 1, 14, 20, 21

(condition may be aggravated)

Side/Adverse Effects

Note: Hypothermia was reported in one patient after ingestion of 5 liters of chilled PEG-electrolyte solution. 2, 4

One patient experienced cardiac asystole after a large bowel movement following administration of PEG-electrolyte solution. Further studies are needed to establish a causal relationship. 4

The following side/adverse effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate)¾not necessarily inclusive:

Those indicating need for medical attention

Incidence rare

Allergic reaction 1, 20, 21 (skin rash)

Those indicating need for medical attention only if they continue or are bothersome

Incidence more frequent

Bloating 1, 4, 5, 6, 14, 20, 21, 22; nausea 1, 4, 5, 14, 20, 21, 22

Incidence less frequent

Abdominal or stomach cramps 1, 4, 5, 6, 14, 20, 21; anal irritation 1, 4, 14, 20, 21; vomiting 1, 5, 14, 20, 21, 22

Patient Consultation

As an aid to patient consultation, refer to Advice for the Patient, Polyethylene Glycol and Electrolytes (Local).

In providing consultation, consider emphasizing the following selected information (>> = major clinical significance):

Before using this medication

>> Conditions affecting use, especially:

Other oral medicines administered within 1 hour of solution

Other medical problems, especially intestinal obstruction, paralytic ileus, perforated bowel, toxic colitis, or toxic megacolon

Proper use of this medication

Special preparatory instructions may be given; patient should inquire in advance

>> Taking solution exactly as directed for best test results

>> Drinking all the solution for best results, unless otherwise directed by physician

>> Fasting for at least 3 hours prior to ingestion of solution; clear liquids are allowed after ingestion of solution

Directions for the preparation of the powder dosage form

>> Proper dosing

>> Proper storage

Side/adverse effects

Signs of potential side effects, especially allergic reaction

General Dosing Information

Diet/Nutrition

Fasting is recommended for at least 3 hours prior to administration of the PEG-electrolyte solution. 1, 14, 20, 21, 22

The PEG-electrolyte solution may be administered on the morning of the examination, as long as enough time is allowed for the patient to drink the solution (3 hours) and for complete bowel evacuation (1 additional hour). If the patient is having a barium enema examination, the PEG-electrolyte solution should be administered early (e.g., 6 pm) the evening before the examination to permit proper mucosal coating by barium. No foods except clear liquids are allowed after administration of the solution. 1, 16

Rapid drinking of each portion of the the PEG-electrolyte solution is recommended rather than drinking small amounts continuously. 1, 14, 20, 21, 22

Oral Dosage Forms

POLYETHYLENE GLYCOL 3350 AND ELECTROLYTES ORAL SOLUTION

Usual adult and adolescent dose

Bowel evacuant^{3/4}

Oral, 240 mL every ten minutes, up to 4 L, or until the fecal discharge is clear and free of solid matter. 1, 14, 17, 20, 21, 22, 25, 26

Note: May also be given via nasogastric tube at a rate of 20 to 30 mL per minute 1, 2, 14, 20, 21 (1.2 to 1.8 L per hour). 14, 20, 21, 25, 26

Usual pediatric dose

Bowel evacuant^{3/4}Oral or by continuous nasogastric drip, 25 to 40 mL per kg of body weight per hour until the fecal discharge is clear and free of solid matter. 16, 17

Usual geriatric dose

See Usual adult and adolescent dose .

Strength(s) usually available

U.S.^{3/4}

Product	Content (mg/100 mL)				
	PEG 3350	NaCl	NaHCO 3	Na 2SO 4	KCl
U.S.- OCL (Rx)	6000	146	168	569	75
Canada- Peglyte (OTC)	5960	150	170	570	80

Packaging and storage:

Store between 15 and 30 °C (59 and 86 °F). Store in a tight container.

Incompatibilities:

The addition of flavoring agents, such as sugar, nutritional supplements, or other sweeteners, is not recommended. Such additives may change the osmolality of the solution; sucrose or glucose may cause fluid and electrolyte absorption. Additives may also predispose to colonic bacterial fermentation and formation of combustible gases. 1, 4, 25, 26

POLYETHYLENE GLYCOL 3350 AND ELECTROLYTES FOR ORAL SOLUTION USP

Usual adult and adolescent dose

See Polyethylene Glycol 3350 and Electrolytes Oral Solution .

Usual pediatric dose

See Polyethylene Glycol 3350 and Electrolytes Oral Solution .

Usual geriatric dose

See Polyethylene Glycol 3350 and Electrolytes Oral Solution .

Size(s) usually available:

U.S.¼

Product	Content (mg/100 mL)				
	PEG 3350	NaCl	NaHCO 3	Na 2SO 4	KCl
U.S.- Co-Lav (Rx) Colovage (Rx) Colyte (Rx) Colyte-flavored (Rx) Colyte with Flavor Packs (Rx) Go-Evac (Rx) GoLYTELY (Rx) PEG-3350 & Electrolytes (Rx)	6000	146	168	568	74.5
NuLYTELY (Rx) NuLYTELY, Cherry	10500	280	143	-	37

Flavor (Rx)					
Canada-	6000	146	168	568	75
Colyte (OTC)					
GoLYTELY (OTC)					
Klean-Prep (OTC)					
Peglyte (OTC)	6000	150	170	570	80

Packaging and storage:

Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F) 20, 21 , unless otherwise specified by manufacturer. Store in a tight container. 24, 25, 26

Note: After reconstitution, solution should be refrigerated to improve palatability. 4

Preparation of dosage form: 1

See manufacturer"s package label for complete instructions on reconstitution.

Tap water must be used for reconstitution.

To assure that all ingredients have dissolved, solution must be shaken vigorously.

Stability:

Reconstituted solution should be used within 48 hours. Unused portion should be discarded. 14, 20, 21, 22, 25, 26

Incompatibilities:

The addition of flavoring agents, such as sugar, nutritional supplements, or other sweeteners, is not recommended. 14, 20, 21, 22, 25, 26 Such additives may change the osmolality of the solution; sucrose or glucose may cause fluid and electrolyte absorption. Additives may also predispose to colonic bacterial fermentation and formation of combustible gases. 1, 4