PRESCRIBING INFORMATION

JAMPLyte

Polyethylene Glycol 3350 and Electrolytes for Oral Solution, USP

Gastrointestinal lavage

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Table of Contents

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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			Fruit flavours, sodium saccharine *For a complete listing see Dosage Forms, Composition and Packaging sections.*
		70 g sachet	**280 g bottle**	
	PEG 3350	59.55 g	238.20 g	
	sodium sulphate	5.74 g	22.96 g	
	sodium bicarbonate	1.69 g	6.76 g	
	sodium chloride	1.46 g	5.84 g	
	potassium chloride	0.76 g	3.04 g	

INDICATIONS AND CLINICAL USE

Adults

JAMPLyte, a polyethylene glycol (PEG)/electrolytes-based product, is indicated for:

- Bowel cleansing prior to colonoscopy or barium enema x-ray examination or surgical procedures requiring a clean colon.

CONTRAINDICATIONS

JAMPLyte 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 JAMPLyte is not recommended when abdominal pain, nausea, or vomiting are present.
- Unconscious or semiconscious patient should be observed during the administration of JAMPLyte 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.

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

Gastrointestinal

JAMPLyte 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 JAMPLyte, 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 JAMPLyte.

If a patient experiences severe bloating, distension or abdominal pain, administration of the solution should be slowed or temporarily discontinued until the symptoms abate.

Immune

Cases of urticaria, rhinorrhea, dermatitis and anaphylactic reactions have been reported with PEG/electrolytes-based lavage products that have the same medicinal ingredients as JAMPLyte but with different brand names. This may represent allergic reactions.

Neurologic

PEG/electrolytes-based gastrointestinal lavage 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), JAMPLyte 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.

Special Population

Pregnant Women: Animal reproduction studies have not been conducted with JAMPLyte, PEG/electrolytes-based gastrointestinal lavage products, like JAMPLyte, and it is also not known whether JAMPLyte can affect reproductive capacity or harm the fetus when administered to a pregnant patient. JAMPLyte 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 JAMPLyte is administered to a nursing woman.

Paediatrics: Safety and effectiveness of JAMPLyte in children have not been established.

Geriatrics(> 60 years of age): There are isolated reports of serious post-marketing events following the administration of PEG/electrolytes-based colon preparation 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 in whom fluid and electrolyte shifts are of extra risk.

Monitoring and Laboratory Test

Monitoring of serum electrolytes is advised.

ADVERSE REACTIONS

Adverse Drug Reaction Overview

The most frequent adverse reactions, occurring in up to 50% of patients who have undergone PEG/electrolytes-based gastrointestinal lavage products, are nausea, abdominal fullness and bloating. Abdominal cramps, vomiting and anal irritation occur less frequently. These adverse effects are transient.

Post-Market Adverse Drug Reactions

The following rare adverse events have been reported following administration of a PEG/electrolytes-based gastrointestinal lavage:

Cardiovascular: bradycardia, acute pulmonary edema, hypotension

Eye: sensitivity to light, painful irritated eyes

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

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.

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

DRUG INTERACTIONS

Drug-Drug Interactions

JAMPLyte, as any other laxatives, should not be taken within 2 hours of another medicine because the desired effect of the other medicine may be reduced.

Drug-Food Interactions

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

DOSAGE AND ADMINISTRATION

General considerations

No additional ingredients, e.g. flavouring, should be added to the solution.
Refrigerate the solution as chilling improves 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 JAMPLyte administration. JAMPLyte can be administered orally or by nasogastric tube.

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

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

Reconstitution of the solution

JAMPLyte (280 g bottle): Dissolve the entire contents of the bottle in 4L of water and stir rapidly to dissolve.

JAMPLyte (70 g sachet): Dissolve the entire contents of one sachet in 1 L (32 ounces) of water and stir rapidly to dissolve.

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.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action
Polyethylene glycol 3350 (PEG 3350) is an osmotic lavage which causes water to be retained with the stool leading to decrease stool consistency, soften the stools, increase fecal bulk and facilitate bowel movements.

JAMPLyte 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.

Pharmacokinetics

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

STORAGE AND STABILITY

JAMPLyte for oral solution

Store the sachets and bottle at room temperature, between 15-30°C.

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

DOSAGE FORMS, COMPOSITION AND PACKAGING

280 g Bottle

The contents of each bottle of JAMPLyte, to be dissolved with 4 L of water (add water to bottle fill line), contains the following medicinal ingredients:

Polyethylene Glycol 3350	238.20 g
Sodium Sulphate	22.96 g
Sodium Bicarbonate	6.76 g
Sodium Chloride	5.84 g
Potassium Chloride	3.04 g

and the non medicinal ingredients: Sodium saccharin and fruit flavours.

Box of 4 x 70 g sachets

Each 70 g sachet of JAMPLyte 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:

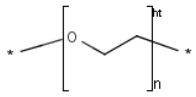
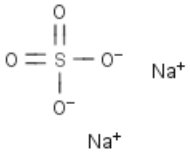
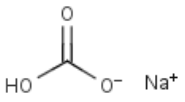
Polyethylene Glycol 335(	17.8 mmol /L
Sodium	126.0 mmol /L
Potassium	10.2 mmol /L
Chloride	35.3 mmol /L
Sulphate	40.4 mmol /L
Bicarbonate	20.1 mmol /L

The osmolarity of a prepared JAMPLyte solution 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 sulphate; Dibasic sodium sulphate	Bicarbonate of soda; Carbonic acid, monosodium salt	Sodium chloride	Potassium chloride
Molecular formula:	$HO(C_2H_4O)_nH$	Na_2S0_4	$NaHCO_3$	NaCl	KCI
Structural formula:				Na^+ Cl^-	K^+ Cl^-

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 (104 weeks) and Sprague Dawley rats (104 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.

REFERENCES

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2. Hammer HF, Santa Ana CA, Schiller LR, Fordtran JS. Studies of osmotic diarrhea induced in normal subjects by ingestion of polyethylene glycol and lactulose. J Clin Invest. 1989 Oct;84(4):1056-62.

3. Pelham RW, Nix LC, Chavira RE, Cleveland MV and Stetson P. Clinical trial: single- and multi-dose pharmacokinetics of polyethylene glycol (PEG-3350) in healthy young and elderly subjects. *Aliment Pharmacol Ther.* 2008;28:256-265.

PART III: CONSUMER INFORMATION

JAMPLyte

Polyethylene Glycol 3350 and Electrolytes for Oral Solution, USP

This leaflet is part III of a three-part "Prescribing information" published when JAMPLyte was approved for sale in Canada and is designed specifically for Consumers.

This leaflet is a summary and will not tell you everything about JAMPLyte. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

JAMPLyte is used for bowel cleansing prior to colonoscopy or barium enema X-ray examination.

What it does:
JAMPLyte produces a watery stool which cleanses the bowel prior to examination.

When it should not be used:
Do not use **JAMPLyte** if:

- You are allergic to polyethylene glycol.
- You have or have had a bowel obstruction (e.g. ileus)
- You have a bowel perforation.
- You have a gastrointestinal obstruction.
- You have toxic colitis (inflamed large bowel with damage to the intestinal wall).
- You have toxic megacolon (acute swelling of the large bowel).

What the medicinal ingredients are:

	70 g sachet	280 g bottle
Polyethylene Glycol 3350	59.55 g	238.20 g
Sodium Sulphate	5.74 g	22.96 g
Sodium Bicarbonate	1.69 g	6.76 g
Sodium Chloride	1.46 g	5.84 g
Potassium Chloride	0.76 g	3.04 g

What the important non-medicinal ingredients are:
Sodium saccharin, fruit flavours.

What dosage forms it comes in:
JAMPLyte is available as a powder form for oral administration after dissolution in water, juice, soda, coffee, tea, or any other non-alcoholic beverage.

JAMPLyte is available in a bottle of 280 g powder and a box of 4 sachets of 70 g powder.

WARNINGS AND PRECAUTIONS

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

- You have or have had a bowel obstruction, ulcerative colitis or any other inflammatory bowel disease (e.g. Crohn's disease).
- You have a history of electrolyte imbalance (hyponatremia) or are using diuretics.
- You are pregnant, thinking of becoming pregnant or nursing.
- You have difficulty swallowing or have a pronounced gag reflex or prone to vomiting.
- You have kidney problems.
- You are allergic to this medication or any other medications or foods.
- You have any other medical conditions.

Contact your doctor if any of the following occurs while taking JAMPLyte:

- 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.
- Unusual cramps, bloating or diarrhea occur.
- If you are elderly, stop use and contact a doctor immediately if you experience diarrhea.

Do not take a larger dose of **JAMPLyte**, take it more often, or take it for a longer period of time than your doctor tells you to.

INTERACTIONS WITH THIS MEDICATION

No specific drug interactions studies have been done for JAMPLyte. Do not take JAMPLyte within 2 hours of taking another medication as it may be flushed from the gastrointestinal tract and not absorbed.

Tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking.

PROPER USE OF THIS MEDICATION

Direction on how to use JAMPLyte

280 g Bottle:

- Dissolve the entire contents of the bottle with 4L of water (add water to the bottle fill line).
- Stir until completely dissolved and then drink the solution.

70 g Sachet:

- Dissolve the entire contents of one sachet in 1 L (32 ounces) of water and stir rapidly to dissolve.
- Repeat for the other 3 sachets, one at a time, as needed.

For bowel cleansing:

- Do not eat any solid food for 3 hours prior to drinking JAMPLyte.
- Rapidly drink a glass (240 mL) of JAMPLyte every 10 minutes.
- Repeat the procedure with the remaining solution, drinking 240 mL of solution every 10 minutes or as directed by a doctor.
- Do not take JAMPLyte within 2 hours of any other medication.

Overdose:

There have been no reports of accidental overdose. In the event of an overdose, dehydration (with symptoms such as thirst, dry mouth, dry eyes not making tears, no perspiration, etc.) due to diarrhea may result. In the case of accidental overdose, stop taking **JAMPLyte,** drink plenty of water and contact a doctor or a poison control centre.

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

Missed Dose:

If you miss a dose, take the next dose as normal on the next day.

Never take a double dose of JAMPLyte to make up for missed dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

- **JAMPLyte** may cause side effects. Tell a doctor if any of these symptoms are severe or do not go away:
  - Nausea
  - Bloating
  - Cramping
  - Gas
  - Diarrhea
  - Vomiting
  - Anal irritation

Isolated cases of urticaria (hives), rhinorrhea (nasal discharge) and dermatitis (skin inflammation) have been reported. These may be signs of an allergic reaction. If these occur, contact your doctor.

Seizures have occurred in patients using PEG-based colon preparations.

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

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek urgent medical attention
		Only if severe	In all cases	
Common	Nausea, abdominal bloating, cramping, and flatulence.	√		
Uncornmon	Diarrhea	√		
Rare	Allergie reaction (with symptoms such as hives, itching, swelling of the lips, face tongue, throat, trouble breathing, wheezing, shortness of breath, skin rashes)			√

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

HOW TO STORE IT

Store in a dry place at room temperature at 15-30°C.

The reconstituted solution should be used within 48 hours after mixing. If kept refrigerated (2-8°C), use within 30 days. Discard unused portion.

Keep the container tightly closed. Keep out of reach of children.

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/adverse-reaction-reporting.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

If you want more information about JAMPLyte:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html), or by calling 1-866-399-9091.

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