PRESCRIBING INFORMATION

Jamp-ElectroPEG

Polyethylene Glycol 3350 and Electrolytes for Oral Solution, USP

Gastrointestinal lavage

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Date of Creation:
May 10, 2013

Submission Control No: 162364

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PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Non-medicinal Ingredients
Oral	Powder for oral solution. **Per bottle** PEG 3350 236 g sodium sulphate 22.74 g sodium bicarbonate 6.74 g sodium chloride 5.86 g potassium chloride 2.97 g	Maltodextrin, Sodium saccharin, Natural lemon flavour *For a complete listing see Dosage Forms, Composition and Packaging sections.*

INDICATIONS AND CLINICAL USE

Adults

Jamp-ElectroPEG, 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

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

Jamp-ElectroPEG 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 Jamp-ElectroPEG, 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 Jamp-ElectroPEG.

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 Jamp-ElectroPEG 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), Jamp-ElectroPEG 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 Populations

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

Pediatrics: Safety and effectiveness of Jamp-ElectroPEG 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 Tests

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

Jamp-ElectroPEG, 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 Jamp-ElectroPEG 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 Jamp-ElectroPEG administration. Jamp-ElectroPEG can be administered orally or by nasogastric tube.

Oral: Dissolve the entire contents of 4 L bottle by filling up to the bottle fill line and stir rapidly to dissolve. No additional ingredients, eg. flavouring should be added to the solution. Refrigerate the solution as chilling improves the taste. For further directions and warnings, see the Consumer Information in the folded pages.

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

Jamp-ElectroPEG powder: Fill water to the top of the line on bottle.

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 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.

Jamp-ElectroPEG 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.

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

STORAGE AND STABILITY

Jamp-ElectroPEG Powder for oral solution
Store the bottle 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.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Each bottle of Jamp-ElectroPEG powder, to be dissolved in 4 L of water, contains the following medicinal ingredients:

Polyethylene Glycol 3350 ..... 236 g
Sodium sulphate .....22.74 g
Sodium bicarbonate..... 6.74 g
Sodium chloride..... 5.86 g
Potassium chloride..... 2.97 g

and the non medicinal ingredients: Maltodextrin, Sodium saccharin, Natural lemon flavour.

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

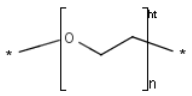
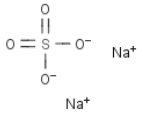
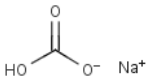
Polyethylene Glycol 3350	17.6 mOsmol /L
Sodium	125 mOsmol /L
Potassium	10 mOsmol /L
Chloride	35 mOsmol /L
Sulphate	40 mOsmol /L
Bicarbonate	20 mOsmol /L

The osmolarity of a prepared Jamp-ElectroPEG solution ranges from 235-304 mOsmol/L.

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 Sulphate	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_2SO_4	$NaHCO_3$	NaCl	KCl
Structural formula:					

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.

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

IMPORTANT: PLEASE READ

Jamp-ElectroPEG

Polyethylene Glycol 3350 and Electrolytes for Oral Solution, USP

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

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

ABOUT THIS MEDICATION

What the medication is used for:
Jamp-ElectroPEG is used for bowel cleansing prior to colonoscopy or barium enema X-ray examination.

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

When it should not be used:
Do not use **Jamp-ElectroPEG** 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 ingredient are:
Polyethylene glycol 3350, sodium sulphate, sodium bicarbonate, sodium chloride, potassium chloride.

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

Jamp-ElectroPEG is available in a 4 L bottle.

WARNINGS AND PRECAUTIONS

BEFORE you use Jamp-ElectroPEG, 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 Jamp-ElectroPEG:
- 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 **Jamp-ElectroPEG**, 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 Jamp-ElectroPEG. Do not take Jamp-ElectroPEG 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 Jamp-ElectroPEG
- Fill water to the top of the line on bottle
- Stir until completely dissolved and then drink the solution.
- For bowel cleansing, do not eat any solid food for 3 hours prior to drinking Jamp-ElectroPEG.
- Rapidly drink a glass (240mL) of Jamp-ElectroPEG every 10 minutes.

- Continue drinking until the water stool is clear and free of solid matter. This usually requires at least 3 L and it is best to drink all of the solution.
- Do not take Jamp-ElectroPEG 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 **Jamp-ElectroPEG**, drink plenty of water and contact a doctor or a poison control centre.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional poison control centre, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Jamp-ElectroPEG 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 OFTEN 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.	√		
Uncommon	Diarrhea	√		
Rare	Allergic 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 Jamp-ElectroPEG 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. Discard unused portion.

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

REPORTING SUSPECTED SIDE EFFECTS

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

1. Report online at www.healthcanada.gc.ca/medeffect

2. Call toll-free at 1-866-234-2345

3. 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 0701C
Ottawa, ON K1A OK9

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 product monograph, prepared for health professionals can be found at: http://www.jamppharma.com or by contacting the sponsor, JAMP Pharma at: 450-449-1236

This leaflet was prepared by JAMP Pharma Corporation.

Last revised: May 10, 2013