

PRESCRIBING INFORMATION

Jamp-ElectroPEG with Flavour Packet

Polyethylene Glycol 3350 and Electrolytes for Oral Solution, USP

Gastrointestinal lavage

JAMP Pharma Corporation
Boucherville, QC
Canada
J4B 5H2

Date of Creation:
May 10, 2013

Submission Control No: 162309

Table of Contents

PART I: HEALTH PROFESSIONAL INFORMATION	3
SUMMARY PRODUCT INFORMATION.....	3
INDICATIONS AND CLINICAL USE.....	3
CONTRAINDICATIONS.....	3
WARNINGS AND PRECAUTIONS.....	4
ADVERSE REACTIONS	5
DRUG INTERACTIONS.....	6
DOSAGE AND ADMINISTRATION.....	6
OVERDOSAGE	7
ACTION AND CLINICAL PHARMACOLOGY	7
STORAGE AND STABILITY	7
DOSAGE FORMS, COMPOSITION AND PACKAGING	8
PART II: SCIENTIFIC INFORMATION	9
PHARMACEUTICAL INFORMATION.....	9
TOXICOLOGY	9
PART III: CONSUMER INFORMATION	12

Jamp-ElectroPEG with Flavour Packet

Polyethylene Glycol 3350 and Electrolytes for Oral Solution, USP

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Non-medicinal Ingredients											
Oral	Powder for oral solution.	In a flavour pack: Maltodextrin, Sodium saccharin, Natural lemon flavour <i>For a complete listing see Dosage Forms, Composition and Packaging sections.</i>											
	<table border="1"><thead><tr><th colspan="2">Per bottle</th></tr></thead><tbody><tr><td>PEG 3350</td><td>236 g</td></tr><tr><td>sodium sulphate</td><td>22.74 g</td></tr><tr><td>sodium bicarbonate</td><td>6.74 g</td></tr><tr><td>sodium chloride</td><td>5.86 g</td></tr><tr><td>potassium chloride</td><td>2.97 g</td></tr></tbody></table>		Per bottle		PEG 3350	236 g	sodium sulphate	22.74 g	sodium bicarbonate	6.74 g	sodium chloride	5.86 g	potassium chloride
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												

INDICATIONS AND CLINICAL USE

Adults

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

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 with Flavour Packet 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 with Flavour Packet 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 with Flavour Packet,

and it is also not known whether Jamp-ElectroPEG with Flavour Packet can affect reproductive capacity or harm the fetus when administered to a pregnant patient. Jamp-ElectroPEG with Flavour Packet 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 with Flavour Packet is administered to a nursing woman.

Paediatrics: Safety and effectiveness of Jamp-ElectroPEG with Flavour Packet 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 with Flavour Packet, 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 with Flavour Packet 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 with Flavour Packet administration. Jamp-ElectroPEG with Flavour Packet can be administered orally or by nasogastric tube.

Oral: Dissolve the entire contents of the 4L bottle by filling up to the bottle fill line and stir rapidly to dissolve. This preparation can be used with or without the separate flavour packet enclosed in the package. Refrigerate the solution as chilling improves the taste. The recommended adult oral dose is 240 mL of Jamp-ElectroPEG with Flavour Packet solution every 10 minutes. Rapid drinking of each portion is preferred rather than drinking small amounts continuously. For further directions and warnings, see the Consumer Information in the folded pages.

Nasogastric Tube: Jamp-ElectroPEG with Flavour Packet 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 with Flavour Packet administration. Administration of Jamp-ElectroPEG with Flavour Packet

should be continued until the fecal discharge is clear. Lavage is usually complete after the ingestion of 3 to 4L of Jamp-ElectroPEG with Flavour Packet 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 with Flavour Packet 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 with Flavour Packet 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 with Flavour Packet 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 with Flavour Packet 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 in a separate flavour pack: Maltodextrin, Sodium saccharin, Natural lemon flavour.

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

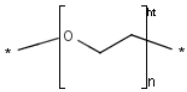
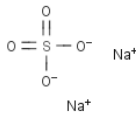
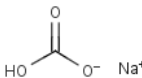
Polyethylene Glycol 3350	17.6 mOsmol /L
Sodium	125 mOsmol /L
Potassium	10 mOsmol /L
Chloride	35 mOsmol /L
Sulphate	40 mOsmol /L
Bicarbonate	20 mOsmol /L

The osmolality of a prepared Jamp-ElectroPEG with Flavour Packet 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-ethanediyoxy)bis-	Bisodium sulphate; Dibasic sodium sulphate	Bicarbonate of soda; Carbonic acid, monosodium salt	Sodium chloride	Potassium chloride
Molecular formula:	$\text{HO}(\text{C}_2\text{H}_4\text{O})_n\text{H}$	Na_2SO_4	NaHCO_3	NaCl	KCl
Structural formula:				$\text{Na}^+ \text{Cl}^-$	$\text{K}^+ \text{Cl}^-$

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 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 (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 F₁ postnatal survival, body weight, developmental landmarks, startle response, motor activity, learning and memory and reproductive performance, intrauterine growth and survival of F₂ fetuses and external and developmental parameters of F₂ fetuses.

REFERENCES

1. Barkun A, Chiba N, Enns R, et al. Commonly used preparations for colonoscopy: efficacy, tolerability and safety - A Canadian Association of Gastroenterology position paper. *Can J Gastroenterol*. 2006 Nov;20(11):699-710.
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 with Flavour Packet

Polyethylene Glycol 3350 and Electrolytes for Oral Solution, USP

This leaflet is part III of a three-part "Prescribing information" published when Jamp-ElectroPEG with Flavour Packet 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 with Flavour Packet. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Jamp-ElectroPEG with Flavour Packet is used for bowel cleansing prior to colonoscopy or barium enema X-ray examination.

What it does:

Jamp-ElectroPEG with Flavour Packet produces a watery stool which cleanses the bowel prior to examination.

When it should not be used:

Do not use Jamp-ElectroPEG with Flavour Packet 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 with Flavour Packet 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 with Flavour Packet is available in a 4 L bottle.

WARNINGS AND PRECAUTIONS

BEFORE you use Jamp-ElectroPEG with Flavour Packet, 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 with Flavour Packet:

- 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 with Flavour Packet, 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 with Flavour Packet. Do not take Jamp-ElectroPEG with Flavour Packet 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 with Flavour Packet

- This preparation can be used with or without the addition of the flavour packet to the Jamp-ElectroPEG solution. Open the sachet and add to the Jamp-ElectroPEG solution.
- 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 the prepared solution.
- Rapidly drink a glass (240mL) 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 the product 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 an accidental overdose, stop taking **Jamp-ElectroPEG with Flavour Packet**, 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 with Flavour Packet 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 with Flavour Packet, 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 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 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