

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use MOVIPREP safely and effectively. See full prescribing information for MOVIPREP.

MOVIPREP® (PEG-3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid for oral solution)
Initial U.S. Approval: 2006

RECENT MAJOR CHANGES

Dosage and Administration (2)	9/2013
Adverse Reactions (.2)	8/2013
Warnings and Precautions (5.9)	7/2012

INDICATIONS AND USAGE

MoviPrep is an osmotic laxative indicated for cleansing of the colon as a preparation for colonoscopy in adults 18 years or older. (1)

DOSAGE AND ADMINISTRATION

- MoviPrep, supplied as powder for oral solution, must be mixed with water before use (2.1).
- Do not consume any food from the start of MoviPrep treatment until after the colonoscopy and do not consume any clear liquids at least 2 hours before your colonoscopy. (2.1)
- There are two possible dosing regimens; each regimen requires different dosing times (2.1)
 - Split-dose (2-Day) regimen is the preferred method (2.2):
 - Dose 1: The evening before the colonoscopy (10 to 12 hours before Dose 2)
 - Dose 2: The next morning, on the day of the colonoscopy (start at least 3 ½ hours prior to the colonoscopy).
 - Evening only (1-Day) regimen is an alternative method (2.3):
 - Dose 1: Begin at least 3 ½ hours prior to bedtime the evening before the colonoscopy
 - Dose 2: Take Dose 2 approximately 1½ hours after starting Dose 1 the evening before the colonoscopy
- Consume additional clear liquids after every dose in either dosing regimen (2.2, 2.3).

DOSAGE FORMS AND STRENGTHS

- Powder for Oral Solution: 2 pouches labeled Pouch A and 2 pouches labeled Pouch B.
- Each pouch A contains 100 grams of polyethylene glycol (PEG) 3350, NF, 7.5 grams of sodium sulfate, USP, 2.691 grams of sodium chloride, USP, and 1.015 grams of potassium chloride, USP, plus the following excipients: aspartame, NF (sweetener), acesulfame potassium, NF (sweetener), and lemon flavoring (3)

- Each pouch B contains 4.7 grams of ascorbic acid, USP and 5.9 grams of sodium ascorbate, USP. (3)

CONTRAINDICATIONS

- Gastrointestinal (GI) obstruction (4)
- Bowel perforation (4)
- Gastric retention (4)
- Ileus (4)
- Toxic colitis or toxic megacolon (4)
- Hypersensitivity to any components of MoviPrep (4)

WARNINGS AND PRECAUTIONS

- Risk of fluid and electrolyte abnormalities, arrhythmias, seizures and renal impairment – encourage adequate hydration, assess concurrent medications, and consider laboratory assessments prior to and after use (5.1, 5.2, 5.3)
- Patients with impaired renal function or patients taking concomitant medications that affect renal function – use caution, ensure adequate hydration and consider testing (5.4)
- Suspected GI obstruction or perforation – rule out the diagnosis before administration (5.6)
- Patients at risk for aspiration—observe during administration (5.7)
- Glucose-6-phosphate dehydrogenase deficiency (G-6-PD) – use with caution (5.8)
- Contains phenylalanine - (5.9)

ADVERSE REACTIONS

Most common adverse reactions for split dosing (incidence ≥ 5%) are malaise, nausea, abdominal pain, vomiting, and upper abdominal pain (6). The most common adverse reactions for evening only dosing (incidence ≥ 5%) are abdominal distension, anal discomfort, thirst, nausea, abdominal pain, sleep disorder, rigors, hunger, malaise, vomiting, and dizziness (6).

To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals, Inc. at 1-800-508-0024 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Oral medications may not be absorbed when administered while taking MoviPrep. (7)

USE IN SPECIFIC POPULATIONS

- Pregnancy: No human or animal data. Use only if clearly needed. (8.1)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: September 2013

FULL PRESCRIBING INFORMATION: CONTENTS*

- INDICATIONS AND USAGE
- DOSAGE AND ADMINISTRATION
 - Dosing Overview
 - Split-dose (2-Day) Regimen (Preferred Method)
 - Evening only (1-Day) Regimen (Alternative Method)
- DOSAGE FORMS AND STRENGTHS
- CONTRAINDICATIONS
- WARNINGS AND PRECAUTIONS
 - Serious Fluid and Electrolyte Abnormalities
 - Cardiac Arrhythmias
 - Seizures
 - Renal Impairment
 - (Colonic) Mucosal Ulceration, Ischemic Colitis and Ulcerative Colitis
 - Use in Patients with Significant Gastrointestinal Disease
 - Aspiration
 - Glucose-6-phosphate dehydrogenase (G-6-PD) Deficiency
 - Contains Phenylalanine
- ADVERSE REACTIONS
 - Clinical Studies Experience
 - Postmarketing Experience

- DRUG INTERACTIONS
 - Drugs That May Increase Risks Due to Fluid and Electrolyte Abnormalities
 - Potential for Altered Drug Absorption
- USE IN SPECIFIC POPULATIONS
 - Pregnancy
 - Nursing Mothers
 - Pediatric Use
 - Geriatric Use
- OVERDOSAGE
- DESCRIPTION
- CLINICAL PHARMACOLOGY
 - Mechanism of Action
 - Pharmacokinetics
- NONCLINICAL TOXICOLOGY
 - Carcinogenesis, Mutagenesis, Impairment of Fertility
- CLINICAL STUDIES
- HOW SUPPLIED/STORAGE AND HANDLING
- PATIENT COUNSELING INFORMATION

* Sections or subsections omitted from the full prescribing information are not listed

FULL PRESCRIBING INFORMATION

1. INDICATIONS AND USAGE

MoviPrep is an osmotic laxative indicated for cleansing of the colon as a preparation for colonoscopy in adults 18 years of age or older.

2. DOSAGE AND ADMINISTRATION

2.1. Dosing Overview

There are two possible dosing regimens. Each regimen requires different dosing times:

- Split-dose (2-Day) [see *Dosage and Administration (2.2)*]
- Evening only (1-Day) [see *Dosage and Administration (2.3)*]

Both MoviPrep dosing regimens require administration of MoviPrep using the mixing container provided to dilute powder for oral solution (contents of Pouch A and B) with water to the Fill line. Preparation of MoviPrep solution (the contents of one Pouch A and one Pouch B) occurs twice in each dosing regimen. Additional fluids must be consumed in both dosing regimens [see *Dosage and Administration (2.2, 2.3)*]. Instruct patients to consume only clear liquids (no solid food) from the start of MoviPrep treatment until after the colonoscopy [see *Warnings and Precautions (5.1)*]. Additionally, instruct patients to not consume any clear liquids at least 2 hours before the colonoscopy.

2.2 Split-dose (2-Day) Regimen (Preferred Method)

The Split-Dose regimen is the preferred dosing method. Instruct patients to take two separate doses in conjunction with fluids, as follows:

Dose 1 – Take this dose the evening before the colonoscopy (10 to 12 hours before Dose 2)

1. Empty the contents of 1 pouch A and 1 pouch B into the container that comes with MoviPrep.
2. Add lukewarm water to the Fill line on the container.
3. Mix to completely dissolve the contents of pouch A and B into the lukewarm water.
4. Drink one 8 oz. (ounce) glass (240 mL) every 15 minutes. Be sure to drink all of the solution. This should take about 1 hour.
5. Fill the container with 16 oz. (two 8 oz. glasses) of clear liquid and drink all of this liquid before going to bed.

Dose 2 – Take this dose the next morning, on the day of the colonoscopy (start at least 3 ½ hours prior to colonoscopy)

1. Repeat steps 1 through 4 from Dose 1 of the Split-dose (2-Day) instructions.
2. Fill the container with 16 oz. (two 8 oz. glasses) of clear liquid and drink all of this liquid at least 2 hours before the colonoscopy.
3. Drink only clear liquids up to 2 hours before the colonoscopy or as prescribed by your healthcare provider. Then stop drinking liquids until after the colonoscopy.

2.3 Evening only (1-Day) Regimen (Alternative Method)

The Day-Before regimen is the alternative dosing method for patients for whom the Split-Dosing regimen is inappropriate. Instruct patients to take two separate doses in conjunction with fluids as follows:

Dose 1 – Take this dose at least 3 ½ hours before bedtime the evening before the colonoscopy:

1. Empty the contents of 1 pouch A and 1 pouch B into the container that comes with MoviPrep.
2. Add lukewarm water to the Fill Line on the container.
3. Mix to completely dissolve the contents of pouch A and B into the lukewarm water.
4. Drink one 8 oz. (ounce) glass (240 mL) every 15 minutes. Be sure to drink all of the solution. This should take about 1 hour.

Dose 2 – Take Dose 2 about 1 ½ hours after starting Dose 1 on the evening before the colonoscopy:

1. Repeat Steps 1 through 4 from Dose 1 of the Evening only (1-Day) instructions.
2. After you complete step 1 through 4, fill the container again to the Fill Line with clear liquid and drink all of this liquid before going to bed.
3. Drink only clear liquids up to 2 hours before the colonoscopy or as prescribed by your healthcare provider. Then stop drinking liquids until after the colonoscopy.

Additional Information:

MoviPrep solution may be refrigerated before drinking. Keep the mixed solution in an upright position and store in the refrigerator. MoviPrep should be taken within 24 hours after it is mixed in water. Do not add other ingredients to the MoviPrep solution.

3. DOSAGE FORMS AND STRENGTHS

Powder for Oral Solution: MoviPrep is available in a carton that contains 2 pouches labeled Pouch A and 2 pouches labeled Pouch B. Each pouch A contains 100 grams of polyethylene glycol (PEG) 3350, NF, 7.5 grams of sodium sulfate, USP, 2.691 grams of sodium chloride, USP, and 1.015 grams of potassium chloride, USP, plus the following excipients: aspartame, NF (sweetener), acesulfame potassium, NF (sweetener), and lemon flavoring. Each pouch B contains 4.7 grams of ascorbic acid, USP and 5.9 grams of sodium ascorbate, USP.

4. CONTRAINDICATIONS

MoviPrep is contraindicated in the following conditions:

- Gastrointestinal (GI) obstruction
- Bowel perforation
- Gastric retention
- Ileus
- Toxic colitis or toxic megacolon
- Hypersensitivity to any components of MoviPrep [see DESCRIPTION (11)]

5. WARNINGS AND PRECAUTIONS

5.1 Serious Fluid and Electrolyte Abnormalities

Advise patients to hydrate adequately before, during, and after the use of MoviPrep. If a patient develops significant vomiting or signs of dehydration after taking MoviPrep consider performing post-colonoscopy lab tests (electrolytes, creatinine, and BUN). Fluid and electrolyte disturbances can lead to serious adverse events including cardiac arrhythmias, seizures and renal impairment.

Patients with electrolyte abnormalities should have them corrected before treatment with MoviPrep. MoviPrep should be used with caution in patients using concomitant medications that increase the risk of electrolyte abnormalities [such as diuretics, angiotensin converting enzyme (ACE)-inhibitors or angiotensin receptor blockers (ARBs)] or in patients with known or suspected hyponatremia. Consider performing pre-dose and post-colonoscopy laboratory tests (sodium, potassium, calcium, creatinine, and BUN) in these patients. [See DRUG INTERACTIONS (7.1)]

5.2 Cardiac Arrhythmias

There have been rare reports of serious arrhythmias associated with the use of ionic osmotic laxative products for bowel preparation. Use caution when prescribing MoviPrep 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.

5.3 Seizures

There have been rare reports of generalized tonic-clonic seizures and/or loss of consciousness associated with use of bowel preparation products in patients with no prior history of seizures. The seizure cases were associated with electrolyte abnormalities (e.g., hyponatremia, hypokalemia, hypocalcemia, and hypomagnesemia) and low serum osmolality. The neurologic abnormalities resolved with correction of fluid and electrolyte abnormalities.

Use caution when prescribing MoviPrep for patients with a history of seizures and in patients at increased risk of seizure, such as patients taking medications that lower the seizure threshold (e.g., tricyclic antidepressants), patients withdrawing from alcohol or benzodiazepines, or patients with known or suspected hyponatremia.

5.4 Renal Impairment

Use with caution in patients with impaired renal function or patients taking concomitant medications that affect renal function (such as diuretics, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, or non-steroidal anti-inflammatory drugs). Advise these patients of the importance of adequate hydration, and consider performing pre-dose and post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN) in these patients.

5.5 (Colonic) Mucosal Ulceration, Ischemic Colitis and Ulcerative Colitis

Osmotic laxatives may produce colonic mucosal aphthous ulcerations and there have been reports of more serious cases of ischemic colitis requiring hospitalization. Concurrent use of stimulant laxatives and MoviPrep may increase the risk and is not recommended. The potential for mucosal ulcerations resulting from the bowel preparation should be considered when interpreting colonoscopy findings in patients with known or suspected inflammatory bowel disease.

5.6 Use in Patients with Significant Gastrointestinal Disease

If gastrointestinal obstruction or perforation is suspected, perform appropriate diagnostic studies to rule out these conditions before administering MoviPrep. If a patient experiences severe bloating, abdominal distension, or abdominal pain, administration should be slowed or temporarily discontinued until symptoms abate.

Use with caution in patients with severe ulcerative colitis.

5.7 Aspiration

Patients with impaired gag reflex and patients prone to regurgitation or aspiration should be observed during the administration of MoviPrep. Use with caution in these patients.

5.8 Glucose-6-phosphate Dehydrogenase (G-6-PD) Deficiency

Since MoviPrep contains sodium ascorbate and ascorbic acid, MoviPrep should be used with caution in patients with glucose-6-phosphate dehydrogenase (G-6-PD) deficiency, especially G-6-PD deficiency patients with an active infection, with a history of hemolysis, or taking concomitant medications known to precipitate hemolytic reactions.

5.9 Contains Phenylalanine

Phenylketonurics: Contains aspartame 233 mg per treatment which corresponds to 131 mg of phenylalanine per treatment (after hydrolysis of the aspartame molecule in-vivo to aspartic acid and phenylalanine).

6. ADVERSE REACTIONS

6.1 Clinical Studies Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

In the MoviPrep trials, abdominal distension, anal discomfort, thirst, nausea, and abdominal pain were some of the most common adverse reactions to MoviPrep administration. Since diarrhea was considered as a part of the efficacy of MoviPrep, diarrhea was not defined as an adverse reaction in the clinical studies. Tables 1 and 2 display the most common drug-related adverse reactions of MoviPrep and its comparator in the controlled MoviPrep trials.

Table 1: The Most Common Drug-Related Adverse Reactions¹ (≥ 2%) in the Study of MoviPrep vs. 4 Liter Polyethylene Glycol plus Electrolytes Solution

	MoviPrep [®] (split dose) N=180	4L PEG + E ² N=179
	n (% = n/N)	n (% = n/N)
Malaise	35 (19.4)	32 (17.9)
Nausea	26 (14.4)	36 (20.1)
Abdominal pain	24 (13.3)	27 (15.1)
Vomiting	14 (7.8)	23 (12.8)
Upper abdominal pain	10 (5.6)	11 (6.1)

Dyspepsia	5 (2.8)	2 (1.1)
------------------	---------	---------

¹ Drug-related adverse reactions were adverse events that were possibly, probably, or definitely related to the study drug.

² 4L PEG + E is 4 liter Polyethylene Glycol plus Electrolytes Solution

Table 2: The Most Common Drug-Related Adverse Reactions¹ (≥ 5%) in the Study of Moviprep vs. 90 mL Oral Sodium Phosphate Solution

	Moviprep[®] (evening-only) (full dose) N=169	90 mL OSPS² N=171
	n (% = n/N)	n (% = n/N)
Abdominal distension	101 (59.8)	70 (40.9)
Anal discomfort	87 (51.5)	89 (52.0)
Thirst	80 (47.3)	112 (65.5)
Nausea	80 (47.3)	80 (46.8)
Abdominal pain	66 (39.1)	55 (32.2)
Sleep disorder	59 (34.9)	49 (28.7)
Rigors	57 (33.7)	51 (29.8)
Hunger	51 (30.2)	121 (70.8)
Malaise	45 (26.6)	90 (52.6)
Vomiting	12 (7.1)	14 (8.2)
Dizziness	11 (6.5)	31 (18.1)
Headache	3 (1.8)	9 (5.3)
Hypokalemia	0 (0)	10 (5.8)
Hyperphosphatemia	0 (0)	10 (5.8)

¹ Drug-related adverse reactions were adverse events that were possibly, probably, or definitely related to the study drug. In addition to the recording of spontaneous adverse events, patients were also specifically asked about the occurrence of the following symptoms: shivering, anal irritations, abdominal bloating or fullness, sleep loss, nausea, vomiting, weakness, hunger sensation, abdominal cramps or pain, thirst sensation, and dizziness.

² OSPS is Oral Sodium Phosphate Solution

Isolated cases of urticaria, rhinorrhea, dermatitis, and anaphylactic reaction have been reported with PEG-based products and may represent allergic reactions.

Published literature contains isolated reports of serious adverse events following the administration of PEG-based products in patients over 60 years of age. These adverse events included upper gastrointestinal bleeding from a Mallory-Weiss tear, esophageal perforation, asystole, and acute pulmonary edema after aspirating PEG-based preparation.

6.2 Postmarketing Experience

In addition to adverse reactions reported from clinical trials, the following adverse events have been identified during post-approval use of Moviprep. Because they are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These events have been chosen for inclusion due to either their seriousness, frequency of reporting or causal connection to Moviprep, or a combination of these factors.

Cardiovascular: Tachycardia, palpitations, hypertension, arrhythmia, atrial fibrillation, peripheral edema.

General: Hypersensitivity reactions including anaphylaxis (some of which were severe, including shock), rash, urticaria, pruritus, lip, tongue and facial swelling, dyspnea, chest tightness and throat tightness. Fever, chills, and dehydration.

Nervous system: Syncope, tremor, seizure.

Renal: Renal impairment and/or failure.

7. DRUG INTERACTIONS

7.1 Drugs That May Increase Risks Due to Fluid and Electrolyte Abnormalities

Use caution when prescribing Moviprep for patients with conditions, or who are using medications that increase the risk for fluid and electrolyte disturbances or may increase the risk of adverse events of seizure, arrhythmias, and prolonged QT in the setting of fluid and electrolyte abnormalities. Consider additional patient evaluations as appropriate. [See WARNINGS (5)]

7.2 Potential for Altered Drug Absorption

Oral medication administered within 1 hour of the start of administration of Moviprep may be flushed from the gastrointestinal tract and the medication may not be absorbed.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C. Animal reproduction studies have not been performed with Moviprep. It is also not known if Moviprep can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Moviprep should be given to a pregnant woman only if clearly needed.

8.3 Nursing Mothers

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 Moviprep is administered to a nursing woman.

8.4 Pediatric Use

The safety and effectiveness of Moviprep in pediatric patients has not been established.

8.5 Geriatric Use

Of the 413 patients in clinical studies receiving Moviprep, 91 (22%) patients were aged 65 or older, while 25 (6%) patients were over 75 years of age. No overall differences in safety or effectiveness were observed between geriatric patients and younger patients, and other reported clinical experience has not identified differences in responses between geriatric patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

10 OVERDOSAGE

There have been no reported cases of overdose with Moviprep. Purposeful or gross accidental ingestion of more than the recommended dose of Moviprep might be expected to lead to severe electrolyte disturbances, including hyponatremia and/or hypokalemia, as well as dehydration and hypovolemia, with signs and symptoms of these disturbances. The patient who has taken an overdose should be monitored carefully, and treated symptomatically for complications.

11 DESCRIPTION

Moviprep (PEG-3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid for oral solution) is an osmotic laxative consisting of 4 pouches (2 of pouch A and 2 of pouch B) containing white to yellow powder for reconstitution. Each pouch A contains 100 grams of polyethylene glycol (PEG) 3350, NF, 7.5 grams of sodium sulfate, USP, 2.691 grams of sodium chloride, USP, and 1.015 grams of potassium chloride, USP, plus the following excipients: aspartame, NF (sweetener), acesulfame potassium, NF (sweetener), and lemon flavoring. Each pouch B contains 4.7 grams of ascorbic acid, USP and 5.9 grams of sodium ascorbate, USP. When 1 pouch A and 1 pouch B are dissolved together in water to a volume of 1 liter, Moviprep (PEG-3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid) is an oral solution having a lemon taste.

The entire, reconstituted, 2-liter Moviprep colon preparation contains 200 grams of PEG-3350, 15 grams of sodium sulfate, 5.38 grams of sodium chloride, 2.03 grams of potassium chloride, 9.4 grams of ascorbic acid, and 11.8 grams of sodium ascorbate plus the following excipients: aspartame (sweetener), acesulfame potassium (sweetener), and lemon flavoring.

A container for reconstitution is enclosed.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The primary mode of action is thought to be through the osmotic effect of polyethylene glycol 3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid, which causes water to be retained in the colon and produces a watery stool.

12.3 Pharmacokinetics

The pharmacokinetics of MoviPrep have not been studied in patients with renal or hepatic insufficiency.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals to evaluate the carcinogenic potential have not been performed with MoviPrep. Studies to evaluate potential for impairment of fertility or mutagenic potential have not been performed with MoviPrep.

14 CLINICAL STUDIES

The colon cleansing efficacy and safety of MoviPrep was evaluated in two randomized, actively-controlled, multi-center, investigator-blinded, phase 3 trials in patients scheduled to have an elective colonoscopy.

In the first study, patients were randomized to one of the following two colon preparation treatments: 1) 2 liters of MoviPrep with 1 additional liter of clear liquid split into two doses (during the evening before and the morning of the colonoscopy) and 2) 4 liters of polyethylene glycol plus electrolytes solution (4L PEG + E) split into two doses (during the evening before and the morning of the colonoscopy). Patients were allowed to have a morning breakfast, a light lunch, clear soup and/or plain yogurt for dinner. Dinner had to be completed at least one hour prior to initiation of the colon preparation administration.

The primary efficacy endpoint was the proportion of patients with effective colon cleansing as judged by blinded gastroenterologists on the basis of videotapes recorded during the colonoscopy.

The blinded gastroenterologists graded the colon cleansing twice (during introduction and withdrawal of the colonoscope) and the poorer of the two assessments was used in the primary efficacy analysis.

The efficacy analysis included 308 adult patients who had an elective colonoscopy. Patients ranged in age from 18 to 88 years old (mean age about 59 years old) with 52% female and 48% male patients. Table 3 displays the results.

Table 3: Effectiveness of Overall Colon Cleansing in the Study of MoviPrep vs 4 Liter Polyethylene Glycol plus Electrolytes Solution

	Responders A ² or B ³ (%)	C ⁴ (%)	D ⁵ (%)
MoviPrep[®] (N=153)	88.9	9.8	1.3
4L PEG + E¹ (N=155)	94.8	4.5	0.6

¹ 4L PEG + E is 4 Liter Polyethylene Glycol plus Electrolytes Solution

² A: colon empty and clean or presence of clear liquid, but easily removed by suction

³ B: brown liquid or semisolid remaining amounts of stool, fully removable by suction or displaceable, thus allowing a complete visualization of the gut mucosa

⁴ C: semisolid amounts of stool, only partially removable with a risk of incomplete visualization of the gut mucosa

⁵ D: semisolid or solid amounts of stool; consequently colonoscopy incomplete or needed to be terminated.

4 L PEG+E's responder rate was not significantly higher than MoviPrep's responder rate.

In the second study, patients were randomized to one of the following two colon preparation treatments: 1) 2 liters of MoviPrep with 1 additional liter of clear liquid in the evening prior to the colonoscopy and 2) 90 mL of oral sodium phosphate solution (90 mL OSPS) with at least 2 liters of additional clear liquid during the day and evening prior to the colonoscopy. Patients randomized to MoviPrep therapy were allowed to have a morning breakfast; a light lunch; and clear soup and/or plain yogurt for dinner. Dinner had to be completed at least one hour prior to initiation of the colon preparation administration.

The primary efficacy endpoint was the proportion of patients with effective colon cleansing as judged by the colonoscopist and one blinded gastroenterologist (on the basis of videotapes recorded during the colonoscopy). In case of a discrepancy between the colonoscopist and the blinded gastroenterologist, a second blinded gastroenterologist made the final efficacy determination.

The efficacy analysis included 280 adult patients who had an elective colonoscopy. Patients ranged in age from 21 to 76 years old (mean age about 53 years old) with 47% female and 53% male patients. Table 4 displays the results.

Table 4: Effectiveness of Overall Colon Cleansing in the Study of MoviPrep vs 90mL Oral Sodium Phosphate Solution

	Responders A² or B³ (%)	C⁴ (%)	D⁵ (%)
MoviPrep[®] (N=137)	73.0	23.4	3.6
90 mL OSPS¹ (N=143)	64.4	29.4	6.3

¹ OSPS is Oral Sodium Phosphate Solution

² A: empty and clean or clear liquid (transparent, yellow, or green)

³ B: brown liquid or semisolid remaining small amounts of stool, fully removable by suction or displaceable allowing a complete visualization of the underlying mucosa

⁴ C: semi solid only partially removable/displaceable stools; risk of incomplete examination of the underlying mucosa

⁵ D: heavy and hard stool making the segment examination uninterpretable and, consequently, the colonoscopy needed to be terminated

MoviPrep's responder rate was not significantly higher than OSPS's responder rate.

16 HOW SUPPLIED/STORAGE AND HANDLING

MoviPrep is supplied as a white to yellow powder. MoviPrep is administered as an oral solution after reconstitution.

NDC 65649-201-75, MoviPrep, single use carton.

NDC 65649-201-76, MoviPrep, professional sample carton.

Each carton contains a disposable container for reconstitution of MoviPrep and 2 Pouches labeled Pouch A and 2 pouches labeled Pouch B.

STORAGE

Store carton/container at room temperature, between 68°F to 77°F (20°C to 25°C); excursions permitted to 15-30°C (59-86°F). When reconstituted, store upright and keep solution refrigerated. Use within 24 hours.

17 PATIENT COUNSELING INFORMATION

- Advise patients who require a diet low in phenylalanine that MoviPrep contains aspartame – a maximum of 233 mg per treatment. This sweetener, after hydrolysis in the body, provides 131 mg of phenylalanine to the patient.
- Ask patients to inform you if they have trouble swallowing or are prone to regurgitation or aspiration.
- Instruct patients that each pouch needs to be diluted in water before ingestion and that they need to drink additional clear liquids. Examples of clear liquids are:
 - water
 - clear fruit juices without pulp including apple, white grape, or white cranberry
 - strained limeade or lemonade
 - coffee or tea (Do not use any dairy or non-dairy creamer)
 - clear broth
 - clear soda
 - gelatin (without added fruit or topping)
 - popsicles (without pieces of fruit or fruit pulp)
- Inform patients that oral medications may not be absorbed properly if they are taken within one hour of starting each dose of MoviPrep.
- Tell patients not to take other laxatives while they are taking MoviPrep.
- Tell patients that MoviPrep produces a watery stool (diarrhea) which cleanses the colon before colonoscopy. Advise patients receiving MoviPrep to adequately hydrate before, during, and after the use of MoviPrep. Patients may have

clear soup and/or plain yogurt for dinner, finishing the evening meal at least one hour prior to the start of MoviPrep treatment. No solid food should be taken from the start of MoviPrep treatment until after the colonoscopy.

- Tell patients that the first bowel movement may occur approximately 1 hour after the start of MoviPrep administration. Abdominal bloating and distention may occur before the first bowel movement. If severe abdominal discomfort or distention occurs, stop drinking MoviPrep temporarily or drink each portion at longer intervals until these symptoms diminish. If severe symptoms persist, notify your health provider.

Manufactured for:



Salix Pharmaceuticals, Inc.
Raleigh, NC 27615

2013 Salix Pharmaceuticals, Inc.

Rev Sept 2013

Product protected by U.S. Patent Nos. 7,169,381 and 7,658,914.

Please see www.salix.com for patent information

Medication Guide

MoviPrep® (moo-vee-prep)

(PEG-3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid for oral solution)

Read this Medication Guide before you start taking MoviPrep. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about MoviPrep?

MoviPrep can cause serious side effects, including:

Serious loss of body fluid (dehydration) and changes in blood salts (electrolytes) in your blood.

These changes can cause:

- **abnormal heartbeats that can cause death**
- **seizures.** This can happen even if you have never had a seizure.
- **kidney problems**

Your risk of having fluid loss and changes in body salts with MoviPrep is higher if you:

- have heart problems
- have kidney problems
- take water pills (diuretics), high blood pressure medication, or non-steroidal anti-inflammatory drugs (NSAIDs)

Tell your healthcare provider right away if you have any of these symptoms of a loss of too much body fluid (dehydration) while taking MoviPrep:

- vomiting
- dizziness
- urinating less often than normal
- headache

See “What are the possible side effects of MoviPrep?” for more information about side effects.

What is Moviprep?

Moviprep is a prescription medicine used by adults 18 years of age and older to clean the colon before a colonoscopy. Moviprep cleans your colon by causing you to have diarrhea. Cleaning your colon helps your healthcare provider see the inside of your colon more clearly during your colonoscopy.

It is not known if Moviprep is safe and effective in children.

Who should not take Moviprep?

Do not take Moviprep if your healthcare provider has told you that you have:

- a blockage in your intestine (bowel obstruction)
- an opening in the wall of your stomach or intestine (bowel perforation)
- problems with food and fluid emptying from your stomach (gastric retention)
- a very dilated intestine (toxic megacolon)
- an allergy to any of the ingredients in Moviprep. See the end of this leaflet for a complete list of ingredients in Moviprep.

What should I tell my healthcare provider before taking Moviprep?

Before you take Moviprep, tell your healthcare provider if you:

- have heart problems
- have a history of seizures
- have kidney problems
- have stomach or bowel problems, including ulcerative colitis
- have problems with swallowing or gastric reflux
- have a condition that destroys red blood cells called Glucose-6-phosphate dehydrogenase (G6PD) deficiency
- are withdrawing from drinking alcohol
- have a low blood salt (sodium) level
- are on a diet low in phenylalanine
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if Moviprep will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Moviprep passes into your breast milk. You and your healthcare provider should decide if you will take Moviprep while breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Moviprep may affect how other medicines work. Medicines taken by mouth may not be absorbed properly when taken within 1 hour before the start of Moviprep.

Especially tell your healthcare provider if you take:

- medicines for blood pressure or heart problems
- medicines for kidney problems
- medicines for seizures
- water pills (diuretics)
- non-steroidal anti-inflammatory (NSAID) pain medicines
- laxatives
- medicines for depression or mental health problems

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure if you are taking any of the medicines listed above.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take MoviPrep?

See the Instructions for Use on the outer MoviPrep carton for dosing instructions. You must read, understand, and follow these instructions to take MoviPrep the right way.

- Take MoviPrep exactly as your healthcare provider tells you to take it. Your healthcare provider will prescribe the Split-dose (2-Day) option or the Evening only (1-Day) dosing option, depending on the scheduling of your colonoscopy.
- Do not take MoviPrep that has not been mixed with water.
- Do not add other ingredients to the MoviPrep solution.
- Drink clear liquids before, during, and after you take MoviPrep to help prevent fluid loss (dehydration). It is important for you to drink the additional prescribed amount of clear liquids listed in the Instructions for Use.

Examples of clear liquids are:

- water
- clear fruit juices without pulp including apple, white grape, or white cranberry
- strained limeade or lemonade
- coffee or tea (Do not use any dairy or non-dairy creamer)
- clear broth
- clear soda
- gelatin (without added fruit or topping)
- popsicles (without pieces of fruit or fruit pulp)

Do not eat or drink anything colored red or purple.

- Do not take other laxatives while taking MoviPrep.

- You may eat clear broth and plain yogurt for dinner on the evening that you start taking MoviPrep. Finish eating this meal at least 1 hour before you start taking MoviPrep.
- **Do not eat solid foods while taking MoviPrep and until after your colonoscopy.**
- Drink only clear liquids :
 - while taking MoviPrep
 - after taking MoviPrep and until 2 hours before your colonoscopy
- **Do not eat or drink anything 2 hours before your colonoscopy.**
- You may have stomach-area (abdomen) bloating before you have your first bowel movement.
- Stop drinking MoviPrep for a short time or wait a longer time between each dose of MoviPrep if you have severe stomach-area (abdomen) discomfort or bloating until your symptoms improve. If symptoms continue, tell your healthcare provider.
- Your first bowel movement may happen about 1 hour after you start taking MoviPrep.
- If you take too much MoviPrep, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of MoviPrep?

MoviPrep can cause serious side effects, including:

- **See “What is the most important information I should know about MoviPrep?”**
- **changes in certain blood tests.** Your healthcare provider may do blood tests after you take MoviPrep to check your blood for changes. Tell your healthcare provider if you have any symptoms of too much fluid loss, including:
 - vomiting
 - nausea
 - bloating
 - dizziness
 - stomach-area (abdomen) cramping
 - headache
 - urinate less than usual
 - trouble drinking clear liquid
- **ulcers of the bowel or bowel problems (ischemic colitis).** Tell your healthcare provider right away if you have severe stomach-area (abdomen) pain or rectal bleeding.

The most common side effects of MoviPrep for the Split-dose (2-Day) option include:

- discomfort
- nausea
- stomach-area (abdomen) pain
- vomiting
- indigestion

The most common side effects of MoviPrep for the Evening only (1-Day) dosing option include:

- stomach-area (abdomen) bloating
- anal discomfort
- thirst
- nausea
- stomach-area (abdomen) pain
- sleep problems
- chills
- hunger
- discomfort
- vomiting
- dizziness

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of MoviPrep. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store MoviPrep?

- Store MoviPrep that has not been mixed with water at room temperature, between 68°F to 77°F (20°C to 25°C).
- Store MoviPrep that has been mixed with water in an upright position in the refrigerator.
- MoviPrep should be taken within 24 hours after it has been mixed with water.

Keep MoviPrep and all medicines out of the reach of children.

General information about the safe and effective use of MoviPrep.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use MoviPrep for a condition for which it was not prescribed. Do not give MoviPrep to other people, even if they are going to have the same procedure you are. It may harm them.

This Medication Guide summarizes the most important information about MoviPrep. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about MoviPrep that is written for health professionals.

For more information, call 1-866-669-7597 or go to www.MoviPrep.com.

What are the ingredients in MoviPrep?

Active ingredients:

Pouch A: polyethylene glycol (PEG) 3350, sodium sulfate, sodium chloride, potassium chloride.

Pouch B: ascorbic acid and sodium ascorbate.

Inactive ingredients:

Pouch A: aspartame, acesulfame potassium, and lemon flavoring.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured for:
Salix Pharmaceuticals, Inc.
Raleigh, NC 27615

Product protected by U.S. Patent Nos. 7,169,381 and 7,658,914.

Please see www.salix.com for patent information

Revised: September 2013

INSTRUCTIONS FOR USE – See inside for Full Prescribing Information

MoviPrep Solution is taken by mouth in one of the following ways:

Split-dose (2-day) MoviPrep Instructions:

Dose 1 – Take this dose the evening before your colonoscopy (10 to 12 hours before Dose 2):

1. Empty the contents of 1 pouch A and 1 pouch B into the container that comes with MoviPrep.
2. Add lukewarm water to the Fill Line on the container.
3. Mix to completely dissolve the contents of pouch A and B into the lukewarm water.
4. Drink one 8 oz. (ounce) glass (240 mL) every 15 minutes. Be sure to drink all of the solution. This should take about 1 hour.
5. Fill the container with 16 oz. (two 8 oz. glasses) of clear liquid and drink all of this liquid before you go to bed.

Dose 2 – Take this dose the next morning on the day of your colonoscopy (start at least 3 ½ hours before your colonoscopy):

1. Repeat steps 1 through 4 from Dose 1 of the Split-dose (2-day) instructions.
2. Fill the container with 16 oz. (two 8 oz. glasses) of clear liquid and drink all of this liquid at least 2 hours before your colonoscopy.
3. Drink only clear liquids up to 2 hours before your colonoscopy or as prescribed by your healthcare provider. Then stop drinking liquids until after your colonoscopy.

OR

Evening only (1-day) Moviprep Instructions:

Dose 1 – Take this dose at least 3 ½ hours before bedtime the evening before your colonoscopy:

1. Empty the contents of 1 pouch A and 1 pouch B into the container that comes with MoviPrep.
2. Add lukewarm water to the Fill Line on the container.

3. Mix to completely dissolve the contents of pouch A and B into the lukewarm water.
4. Drink one 8 oz. (ounce) glass (240 mL) every 15 minutes. Be sure to drink all of the solution. This should take about 1 hour.

Dose 2 – Take Dose 2 about 1 ½ hours after starting Dose 1 the evening before your colonoscopy:

1. Repeat Steps 1 through 4 from Dose 1 of the Evening only (1-day) instructions.
2. After you complete steps 1 through 4, fill the container again to the Fill Line with clear liquid and drink all of this liquid before you go to bed.
3. Drink only clear liquids up to 2 hours before your colonoscopy or as prescribed by your healthcare provider. Then stop drinking liquids until after your colonoscopy.

MoviPrep solution may be refrigerated before drinking. Keep the mixed solution in an upright position and store in the refrigerator. MoviPrep should be taken within 24 hours after it is mixed in water. Do not add other ingredients to the MoviPrep solution.

INSTRUCTIONS FOR USE CONTINUED (from back panel)

MoviPrep[®] (moo-vee-prěp)

(PEG-3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid for oral solution)

Important Information:

- Take MoviPrep as prescribed by your healthcare provider.
- The contents of each pouch of MoviPrep must be mixed with water before taking.
- **Do not eat solid foods while taking MoviPrep and until after your colonoscopy.**
- Drink only clear liquids:
 - while taking MoviPrep
 - after taking MoviPrep and until 2 hours before your colonoscopy or as prescribed by your healthcare provider

You may eat or drink any of the following clear liquids:

- water
- clear fruit juices without pulp including apple, white grape, or white cranberry
- strained limeade or lemonade
- coffee or tea (Do not use any dairy or non-dairy creamer)
- clear broth
- clear soda
- gelatin (without added fruit or topping)
- popsicles (without pieces of fruit or fruit pulp)

Do not eat or drink anything colored red or purple.

Do not eat or drink anything 2 hours before your colonoscopy or as prescribed by your healthcare provider