

Medication Guide

MoviPrep® (moo-vee-prěp)

(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.
- 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 Section “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 split dosing 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 (abdominal) 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 that is written for health care 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: Dec 2013