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Medication Guide

MoviPrep® (moo-vee-prĕp)

(polyethylene glycol (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 and each time you get a new prescription. There may be new information. This Medication Guide 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 chance 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 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 bowel (obstruction)
- an opening in the wall of your stomach or intestine (bowel perforation)

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- problems with food and fluid emptying from your stomach (gastric retention)
- a very dilated intestine (bowel)
- 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 (hyponatremia)
- are on a diet low in phenylalanine
- have any other medical conditions
- are pregnant. It is not known if MoviPrep will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breast-feed. 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 medicines (NSAID); pain medicines
- laxatives

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 Patient Instructions on the outer product 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.
- It is important for you to drink the additional prescribed amount of clear liquid (e.g. water, clear soup, fruit juice without pulp, soft drinks, tea and/or coffee without milk) listed in the Patient Instructions to prevent fluid loss (dehydration).
- Do not take MoviPrep that has not been mixed with water (diluted).
- Do not take other laxatives while taking MoviPrep.
- Do not eat solid foods while taking MoviPrep. Only clear liquids are allowed while taking and after taking MoviPrep until your colonoscopy.

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- Stop drinking MoviPrep solution temporarily or allow for longer time between each dose if you have stomach discomfort, pain or bloating until your symptoms improve. If symptoms continue, tell your healthcare provider.
- If you take too much MoviPrep, call your healthcare provider or get medical help 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
- **Heart problems (arrhythmias). MoviPrep may cause irregular heartbeats.**
- **Seizures or fainting (black-outs)**
- **Ulcers of the bowel or bowel problems**

The most common side effects of MoviPrep for split dosing include:

- malaise
- nausea
- stomach (abdominal) pain
- vomiting, bloating

The most common side effects of MoviPrep for evening-only full dosing include:

- stomach swelling (abdominal distention)
- anal discomfort
- thirst
- nausea
- stomach (abdominal) pain
- sleep disorder
- rigors
- hunger
- malaise
- 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 healthcare provider 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 between 59°F to 86°F (15°C to 30°C).
- MoviPrep solution that has been mixed with water may be refrigerated. Mixed solution should be taken within 24 hours.

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

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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 or pharmacist. You can ask your pharmacist or healthcare provider for information that is written for healthcare 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 flavor.

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

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