INDICATIONS AND USAGE

Storage:

- have phenylketonuria (PKU). MoviPrep contains phenylalanine.
- Ensure completion of Dose 2, including all additional liquids, at least 2 hours before the procedure. Do not eat or drink alcohol, milk, anything colored red or brown, or any foods that contain these colorings. Do not eat or drink anything at all.

- If you have diabetes, tell your healthcare provider before taking MoviPrep. MoviPrep can affect blood glucose. You may need to change your diabetes medicine, insulin, or non-steroidal anti-inflammatory drugs (NSAID).

- Correct fluid and electrolyte abnormalities before treatment with MoviPrep. Bowel perforation (4, 4.6)

- have problems with serious loss of body fluid. Do not take MoviPrep if you have severe heart problems. Do not take other laxatives while taking MoviPrep.

- Tell your healthcare provider right away if you develop any of these serious problems associated with use of bowel preparation products in patients with no prior history of seizures.

- MoviPrep may affect the level of sodium in your blood. These changes can cause:

- Take with fluid. Thoroughly mix with a spoon or shake with lid on securely until the contents of Pouch A and B are completely dissolved. (5.10)

HIGHLIGHTS OF PRESCRIBING INFORMATION

1. INDICATIONS AND USAGE

- cleans your colon by causing you to have diarrhea
- to clean the colon before a colonoscopy. MoviPrep may affect how other medicines

- are withdrawing from alcohol or benzodiazepines.
- laxatives. Do not take other laxatives while taking MoviPrep. Do not eat or drink alcohol, milk, anything colored red or brown, or any foods that contain these colorings. Do not eat or drink anything at all.

- The "Evening Only" is the alternative method and consists of two separate doses:

- are eating or drinking (alcohol, milk, anything colored red or brown, or any foods that contain these colorings). Do not eat or drink alcoholic beverages.

- will add polyethylene glycol (PEG) 3350, sodium carbonate, sodium bicarbonate, and ascorbic acid (vitamin C) to the mixing container. Do not take MoviPrep in conjunction with other laxatives, vitamins, or nutritional supplements. MoviPrep may affect the level of sodium in your blood. These changes can cause:

- bowel perforation (32 fluid ounces). Do not add other ingredients to the MoviPrep solution.

- Tell your healthcare provider if you have heart problems, high blood pressure, or non-steroidal anti-inflammatory drugs (NSAID).

- These highlights do not include all the information needed to use MOVIPREP. For complete information on dosing, preparation and administration see full prescribing information for MOVIPREP. These highlights do not include all the information needed to use MOVIPREP. For complete information on dosing, preparation and administration see full prescribing information for MOVIPREP.
**Serious Fluid and Electrolyte Abnormalities**

For the Two-Day Split-Dosing Regimen:

- **7%**
- **47%**
- **D**

After completing Dose 2, it is important that you drink

- **35%**
- **1%**
- **8%**

Do not

That MoviPrep contains 131 mg of phenylalanine per treatment

- **15%**
- **73.0**

Patients with Renal Impairment

To take each dose of MoviPrep, you will need:

- There are two different options for taking MoviPrep.
- You must finish eating at least 1 hour before you start taking MoviPrep.
- Use MoviPrep with caution in patients with renal impairment or patients taking
- Overdosage of more than the recommended dose of MoviPrep may lead to severe

### Dosage and Administration

**Two-Day Split-Dosing Regimen Dosing Directions**

1. Take this dose the evening before your colonoscopy (10 to 12 hours before Dose 2):
   - Step 1: Drink lukewarm water to the Fill Line on the Mixing Container. You will need at least 30 minutes.
   - Step 2: Add lukewarm water to the Fill Line on the Mixing Container. You will need at least 30 minutes.
   - Step 3: Mix to completely dissolve the medicine from Pouch A and one Pouch B into the Mixing Container that comes with MoviPrep.
   - Step 4: Drink lukewarm water to the Fill Line on the Mixing Container. You will need at least 30 minutes.
   - Step 5: Refill the Mixing Container with 16 oz. (at least 1 hour before your colonoscopy.)

2. Take MoviPrep with food if you cannot tolerate the taste. If you start having severe stomach discomfort, you should stop taking your remaining doses and seek medical care.

3. Do not take any medicines by mouth (oral) within the

4. If you feel like you have severe stomach discomfort or pain, you can stop taking MoviPrep for a short period of time and then continue taking it if you can take smaller sips of MoviPrep so that you space your dose further than 1 hour. If this still does not relieve your discomfort, call your healthcare provider.

5. Do not start any liquids up to 1 hour before the start of your colonoscopy.

6. Do not drink clear liquids up to 2 hours before your colonoscopy as prescribed by your healthcare provider. If you drink clear liquids with after starting the colonoscopy preparation, this may lead to severe fluid and electrolyte abnormalities.

**Precautions (5.8)**

- There are no available data on MoviPrep in pregnant women to inform a drug-associated

**Geriatric Use**

- The efficacy analysis included 280 adult patients who had an elective colonoscopy.
- The colon cleansing efficacy and safety of MoviPrep was evaluated in two randomized,

**General Precautions**

- The entire, reconstituted, 2-liter MoviPrep colon preparation contains 200 grams of

**Hypersensitivity Reactions**

- Inform patients of the signs and symptoms of anaphylaxis, and instruct

**Overdose**

- Overdosage of more than the recommended dose of MoviPrep may lead to severe

**Drug Interactions**

- You must finish eating at least 1 hour before you start taking MoviPrep.

**Use in Specific Populations**

- There are no available data on MoviPrep in pregnant women to inform a drug-associated

**3. Patients with Renal Impairment**

To take each dose of MoviPrep, you will need:

- There are two different options for taking MoviPrep.
- You must finish eating at least 1 hour before you start taking MoviPrep.
- Use MoviPrep with caution in patients with renal impairment or patients taking

**Overdosage**

- Overdosage of more than the recommended dose of MoviPrep may lead to severe

**Drug Interactions**

- You must finish eating at least 1 hour before you start taking MoviPrep.

**Use in Specific Populations**

- There are no available data on MoviPrep in pregnant women to inform a drug-associated

**3. Patients with Renal Impairment**

To take each dose of MoviPrep, you will need:

- There are two different options for taking MoviPrep.
- You must finish eating at least 1 hour before you start taking MoviPrep.
- Use MoviPrep with caution in patients with renal impairment or patients taking

**Overdosage**

- Overdosage of more than the recommended dose of MoviPrep may lead to severe

**Drug Interactions**

- You must finish eating at least 1 hour before you start taking MoviPrep.

**Use in Specific Populations**

- There are no available data on MoviPrep in pregnant women to inform a drug-associated

**3. Patients with Renal Impairment**

To take each dose of MoviPrep, you will need:

- There are two different options for taking MoviPrep.
- You must finish eating at least 1 hour before you start taking MoviPrep.
- Use MoviPrep with caution in patients with renal impairment or patients taking

**Overdosage**

- Overdosage of more than the recommended dose of MoviPrep may lead to severe

**Drug Interactions**

- You must finish eating at least 1 hour before you start taking MoviPrep.