If you’re starting PLENVU on the morning of your colonoscopy, Here’s How to Prep

Date of colonoscopy: ______/_____/______  Location of colonoscopy: ________________________________

Time of colonoscopy: ____________ AM/PM  Nothing to drink after: _________________ AM/PM

**PLENVU Dose 1:**
Date: ______/_____/______  Day of week: M T W Th F S Su  Time: ________________ AM

**PLENVU Dose 2:**
Date: ______/_____/______  Day of week: M T W Th F S Su  Time: ________________ AM/PM

**Morning of colonoscopy**

**Take Dose 1:**
1. Use the mixing container to mix the contents of the Dose 1 pouch with at least 16 ounces of water by shaking or using a spoon until it’s completely dissolved. This may take up to 2 to 3 minutes. Take your time—slowly finish the dose within 30 minutes.

2. Refill the container with at least 16 ounces of clear liquid. Again, take your time and slowly finish all of it within 30 minutes. Continue to drink additional clear liquids between the 2 doses.

**Wait at least 2 hours from the start of Dose 1, then...**

**Take Dose 2:**
1. Use the mixing container to mix the contents of Dose 2 (Pouch A and Pouch B) with at least 16 ounces of water by shaking or using a spoon until it’s completely dissolved. This may take up to 2 to 3 minutes. Take your time—slowly finish the dose within 30 minutes.

2. Refill the container with at least 16 ounces of clear liquid. Again, take your time and slowly finish all of it within 30 minutes. Continue to drink additional clear liquids, but be sure to stop drinking liquids at least 2 hours before your colonoscopy or as recommended by your healthcare provider.

For full instructions, refer to the Medication Guide and Instructions for Use in the Prescribing Information.

*The “One-Day Morning Dosing Regimen” (as it is labeled in the Prescribing Information) is referred to as “Same-Day Morning-of-Colonoscopy Dosing.”

**HELPFUL TIP:** PLENVU can be refrigerated. Use within 6 hours after it’s mixed with water

**INDICATION**
PLENVU® (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride, and potassium chloride for oral solution) is a prescription medication used by adults to clean the colon before a colonoscopy.

**IMPORTANT SAFETY INFORMATION**
- Do not take PLENVU if you have a blockage in your intestine (bowel obstruction), an opening in the wall of your stomach or intestine (bowel perforation), problems with food or fluid emptying from your stomach (gastric retention), a problem with food moving too slowly through your intestines (ileus), a very dilated large intestine, or an allergy to any of the ingredients in PLENVU.

Please see additional Important Safety Information on back and accompanying full Prescribing Information, including Medication Guide and Instructions for Use.
It’s important to stay hydrated before, during, and after taking PLENVU.

You don’t need to drink only water—you can have your choice of clear liquids. Examples of clear liquids include:

- Clear soda (ginger ale, seltzer)
- Sports drinks
- Clear broth soups
- Strained clear fruit juice (without pulp)
- Strained lemonade or limeade
- Coffee/tea (without milk or creamer)
- Gelatin (without fruit or toppings)
- Popsicles (without pieces of fruit or pulp)

Do not drink alcohol, milk, red or purple colored liquids, or anything containing pulp.

Stop drinking liquids at least 2 hours before your colonoscopy or as recommended by your healthcare provider.

For more information about PLENVU, visit myPLENVU.com or call the toll-free 24-hour hotline at 1-855-MY-PLENVU.

Text PLENVU to 84883* for text message reminders and other helpful tips.

*At no cost with an unlimited texting plan; otherwise, message and data rates may apply. Message frequency determined by user.

Text HELP to 84883 for help. Text STOP to 84883 to cancel. For terms, visit cs1.me/plenvu.

IMPORTANT SAFETY INFORMATION (continued)

- It is important to drink sufficient clear liquids before, during, and after the use of PLENVU. Be sure to consume additional clear liquids after the first dose and second dose of PLENVU. Stop drinking liquids 2 hours prior to colonoscopy.

- Before you take PLENVU, talk to your doctor if you:
  - Have problems with serious loss of body fluid (dehydration) and changes in blood salts (electrolytes).
  - Have heart problems or take medication that affects your heart. Your doctor may consider obtaining an electrocardiogram (ECG) test if you are at an increased risk for heart rhythm abnormalities.
  - Have a history of seizures or take antiseizure medication.
  - Have kidney problems or take medication that affects kidney function. Your doctor may want to perform blood testing before and after your colonoscopy.
  - Have a history of stomach or bowel problems, such as ulcerative colitis, a bowel blockage, or a suspected opening in the wall of your stomach or intestine.
  - Have problems swallowing, heartburn (gastric reflux), or if you inhale food or fluid into your lungs when eating or drinking (aspirate).
  - Have a condition that destroys red blood cells, called glucose-6-phosphate dehydrogenase (G6PD) deficiency.
  - Are withdrawing from drinking alcohol.
  - Have phenylketonuria (PKU). PLENVU contains aspartame equivalent to 491 mg of phenylalanine per treatment.

- Are pregnant or plan to become pregnant.
- Are breastfeeding or plan to breastfeed.

- PLENVU may affect how other medications work. Tell your doctor about all other medications (including prescription and nonprescription medicines, vitamins, and herbal supplements) you take before you take PLENVU. Do not take oral medications within 1 hour before or after starting each dose of PLENVU.

- Symptoms of serious allergic reactions may include skin rash, itching, raised red patches on your skin (hives), swelling of the face, lips, tongue, and throat, and kidney problems.

- In clinical studies with PLENVU, the most common side effects in patients taking PLENVU were nausea, vomiting, dehydration, and abdominal pain/discomfort.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For product information, adverse event reports, and product complaint reports, please contact:
Salix Product Information Call Center
Phone: 1-800-321-4576
Fax: 1-510-595-8183
Email: salixmc@dlss.com

Please see additional Important Safety Information on front and accompanying full Prescribing Information, including Medication Guide and Instructions for Use.
PLENVU® is indicated for cleansing of the colon in preparation for colonoscopy in adults.

**FULL PRESCRIBING INFORMATION: CONTENTS**

2. Add water to the fill line on the mixing container (at least 16 fluid ounces). Do not

---

**DOSAGE AND ADMINISTRATION**

---

**INDICATIONS AND USAGE**

Instruct patients to take two separate doses in conjunction with clear liquids as follows:

- **Two-Day Split-Dosing:**
  - First dose: one pouch labeled Dose 1; Second dose: two pouches labeled Dose 2
  - Pouch A contains 6.67 grams of sodium sulfate, 3.34 grams of sodium chloride, and 1.67 grams of potassium chloride.
  - Pouch B contains 0.5 grams of sodium sulfate, 2.8 grams of sodium chloride, and 1.0 gram of potassium chloride.

- **One-Day Morning:**
  - First dose: one pouch labeled Dose 1; Second dose: two pouches labeled Dose 2
  - Pouch A contains 3.34 grams of sodium sulfate, 1.67 grams of sodium chloride, and 0.835 grams of potassium chloride.
  - Pouch B contains 0.267 grams of sodium sulfate, 1.34 grams of sodium chloride, and 0.4 grams of potassium chloride.

---

**INTERACTIONS**

- **Drug Interactions:**
  - PLENVU contains electrolytes, which can alter the absorption of other medications.
  - Use with caution in patients taking medications that may alter electrolyte levels.

---

**ADVERSE REACTIONS**

- **Most common adverse reactions (3% or more):**
  - Sore throat, vomiting, diarrhea, abdominal pain, cramping, and constipation.

---

**USE IN SPECIFIC POPULATIONS**

- **Pregnancy:**
  - Use in pregnant women is not recommended unless the potential benefit justifies the potential risk to the fetus.

---

**CONTRAINDICATIONS**

- **Use in patients with renal impairment or patients taking medications that may alter electrolyte levels.

---

**CLINICAL STUDIES**

- **Non-inferiority was assessed using a one-sided 97.5% confidence interval (CI) for the difference in proportions of those who met the primary endpoint (no stool particles) between PLENVU Two-Day Split-Dosing and One-Day Morning.

---

**PATIENT COUNSELING INFORMATION**

- **If patients experience signs and symptoms of dehydration, including dizziness, dry mouth, or lethargy, immediate medical care should be sought.

---

**PRECAUTIONS**

- **Use PLENVU with caution in patients with renal impairment or patients taking medications that may alter electrolyte levels.

---

**CLINICAL PHARMACOLOGY**

- **Plasma pharmacokinetic parameters for PEG 3350, ascorbate, and sulfate are shown in Table 4.

---

**PATIENTS COUNSELING INFORMATION**

- **Sedation or sedation-like effects from the 16-hour preceding interval are not typical.

---

**Table 2: Clinical Adverse Events in Adults**

<table>
<thead>
<tr>
<th>Event</th>
<th>Two-Day Split-Dosing</th>
<th>One-Day Morning</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal UGIs</td>
<td>(N = 271)</td>
<td>(N = 275)</td>
<td>(N = 275)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>83%</td>
<td>85%</td>
<td>87%</td>
</tr>
<tr>
<td>Nausea</td>
<td>9%</td>
<td>12%</td>
<td>12%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>21%</td>
<td>23%</td>
<td>25%</td>
</tr>
</tbody>
</table>

---

**Table 3: Treatment-Related Changes in the NOCT and MORA Trials**

<table>
<thead>
<tr>
<th>Event</th>
<th>NOCT</th>
<th>MORA</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal UGIs</td>
<td>(N = 271)</td>
<td>(N = 275)</td>
<td>(N = 275)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>83%</td>
<td>85%</td>
<td>87%</td>
</tr>
<tr>
<td>Nausea</td>
<td>9%</td>
<td>12%</td>
<td>12%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>21%</td>
<td>23%</td>
<td>25%</td>
</tr>
</tbody>
</table>

---

**Table 4: Plasma Pharmacokinetic Parameters for PEG 3350, ascorbate, and sulfate**

- **PEG 3350 (g/kg):**
  - PLENVU Two-Day Split-Dosing (N = 271)
  - Average molecular weight: 3350 g/mol
  - Average molecular weight: 3350 g/mol

---

**Table 5: Abnormal UGIs in Adults**

<table>
<thead>
<tr>
<th>Event</th>
<th>Two-Day Split-Dosing</th>
<th>One-Day Morning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal UGIs</td>
<td>(N = 271)</td>
<td>(N = 275)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>83%</td>
<td>85%</td>
</tr>
<tr>
<td>Nausea</td>
<td>9%</td>
<td>12%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>21%</td>
<td>23%</td>
</tr>
</tbody>
</table>

---

**Table 6: Abnormal UGIs in Adults**

<table>
<thead>
<tr>
<th>Event</th>
<th>Two-Day Split-Dosing</th>
<th>One-Day Morning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal UGIs</td>
<td>(N = 271)</td>
<td>(N = 275)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>83%</td>
<td>85%</td>
</tr>
<tr>
<td>Nausea</td>
<td>9%</td>
<td>12%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>21%</td>
<td>23%</td>
</tr>
</tbody>
</table>

---

**Table 7: Treatment-Related Changes in the NOCT and MORA Trials**

<table>
<thead>
<tr>
<th>Event</th>
<th>NOCT</th>
<th>MORA</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal UGIs</td>
<td>(N = 271)</td>
<td>(N = 275)</td>
<td>(N = 275)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>83%</td>
<td>85%</td>
<td>87%</td>
</tr>
<tr>
<td>Nausea</td>
<td>9%</td>
<td>12%</td>
<td>12%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>21%</td>
<td>23%</td>
<td>25%</td>
</tr>
</tbody>
</table>

---

**Table 8: Treatment-Related Changes in the NOCT and MORA Trials**

<table>
<thead>
<tr>
<th>Event</th>
<th>NOCT</th>
<th>MORA</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal UGIs</td>
<td>(N = 271)</td>
<td>(N = 275)</td>
<td>(N = 275)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>83%</td>
<td>85%</td>
<td>87%</td>
</tr>
<tr>
<td>Nausea</td>
<td>9%</td>
<td>12%</td>
<td>12%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>21%</td>
<td>23%</td>
<td>25%</td>
</tr>
</tbody>
</table>
**PLENVU® (polyethylene glycol 3350, saccharin sodium, sodium sulfate, sorbitol, sodium chloride and potassium chloride for oral solution)**

Read this Medication Guide and instructions for use before you take PLENVU and again before you start taking PLENVU.

**What is the most important information that I should know about PLENVU?**

PLENVU and other bowel cleansing medicines 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:
  - Severe dizziness
  - Severe headache
  - Confusion
  - Seizures. This can happen even if you have never had a seizure.

- Ulcers of the bowel or bowel problems (ischemic colitis): Tell your healthcare provider right away if you have severe stomach-area (abdomen) discomfort or bloating after taking PLENVU.

- Changes in certain blood tests.

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

- Have problems, with serious loss of body fluid (dehydration) and changes in blood salts (electrolytes) in your blood.

- Have heart problems.

- Have bowel problems, including chronic diarrhea.

- Have problems with swallowing, gastric reflux or if you inhale food or fluid into your lungs when eating or drinking (aspirate).

- Are allergic to any of the ingredients in PLENVU. See the end of this leaflet for a complete list of ingredients in PLENVU.

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

- Allergy to sucralose.

- Allergy to any of the ingredients in PLENVU. See the end of this leaflet for a complete list of ingredients in PLENVU.

**Before taking PLENVU, tell your healthcare provider about all of your medical conditions, including if you:

- Have problems, with serious loss of body fluid (dehydration) and changes in blood salts (electrolytes).

- Have heart problems.

- Have bowel problems, including chronic diarrhea.

- Have problems with swallowing, gastric reflux or if you inhale food or fluid into your lungs when eating or drinking (aspirate).

- Are allergic to any of the ingredients in PLENVU. See the end of this leaflet for a complete list of ingredients in PLENVU.

**What is PLENVU?**

PLENVU® is a prescription medication used by adults to clean the colon before a colonoscopy. PLENVU cleans your colon by causing you to have diarrhea (loose stools). Clearing your colon helps your healthcare provider see the inside of your colon more clearly in an examination.

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

PLENVU is a prescription medicine used by adults to clean the colon before a colonoscopy. PLENVU cleans your colon by causing you to have diarrhea (loose stools). Clearing your colon helps your healthcare provider see the inside of your colon more clearly in an examination.

**How should I store PLENVU?**

- Store PLENVU in a refrigerator.

- Do not freeze PLENVU.

- Keep PLENVU and all medicines out of the reach of children.

**Instructions for Use**

**Dose 1:**

- Dose 1: sucralose, encapsulated citric acid, mango flavoring

**Inactive ingredients:**

- Dose 1 Pouch A: sodium ascorbate, ascorbic acid

**Dose 2 Pouch A:**

- Dose 2 Pouch A: sodium ascorbate, ascorbic acid

**Important Information on PLENVU:**

**Morning Dosing option:**

- Take Dose 1: one pouch and Dose 2 (two pouches) of PLENVU for either dosing option. Make sure you finish Dose 1 at least 2 hours before your colonoscopy. Do not eat or drink anything after taking Dose 1.

- Drink clear liquids before, during, and after you take PLENVU, up to 2 hours before your colonoscopy, to help prevent fluid loss (dehydration).

**Two-Day Split-Dosing Schedule:**

- Take Dose 1 about two hours after you start Dose 1. Make sure you finish Dose 1 at least 2 hours before your colonoscopy.

**Key Points:**

- Do not take medicines by mouth 1 hour before or after the start of PLENVU.

- Do not take PLENVU with any medicine that you are taking for diabetes unless you check with your healthcare provider.

- In general, you should stop all medicines that you are taking for the night before any medicine that causes you to have loose stools.

- Before taking PLENVU, tell your healthcare provider about all of your medical conditions, including if you:

  - Have problems, with serious loss of body fluid (dehydration) and changes in blood salts (electrolytes).

  - Have heart problems.

  - Have bowel problems, including chronic diarrhea.

  - Have problems with swallowing, gastric reflux or if you inhale food or fluid into your lungs when eating or drinking (aspirate).

  - Are allergic to any of the ingredients in PLENVU. See the end of this leaflet for a complete list of ingredients in PLENVU.

**For Dose 2:**

- Take Dose 2 about two hours after you start Dose 1. Make sure you finish Dose 2 at least 2 hours before your colonoscopy.

- Drink clear liquids before, during, and after you take PLENVU, up to 2 hours before your colonoscopy, to help prevent fluid loss (dehydration).

- Do not eat or drink anything after taking Dose 2.

- Do not take medicines by mouth 1 hour before or after starting each dose of PLENVU.

- Do not use clear liquids, milk, anything colored or purple or any foods that have dye.

**For the Day-One Split-Dosing Schedule:**

- On the day before the colonoscopy you can have a light breakfast followed by a light lunch.

- You must finish drinking PLENVU at least 3 hours before your colonoscopy.

- You should drink only clear liquids before your colonoscopy.

- You should drink only clear liquids before your colonoscopy.

- You should drink only clear liquids before your colonoscopy.

- You should drink only clear liquids before your colonoscopy.

**For the Two-Day Split-Dosing Schedule:**

- On the day before the colonoscopy you can have a light breakfast followed by a light lunch.

- For dinner you may have clear broth soup and/or strained limeade or lemonade.

- Drink only clear liquids before your colonoscopy.

- You should drink only clear liquids before your colonoscopy.

**Rocking Instructions:**

- Spoon (optional to mix the water and PLENVU together. You can also mix the water and PLENVU by putting the lid on securely and shaking it. Step 1c).