



### PLENVU<sup>®</sup> has 2 dosing flavors for a positive bowel prep experience\*

It's important to take PLENVU<sup>®</sup> exactly as prescribed. Your healthcare provider will tell you to take the 2-Day Split-Dosing option or the 1-Day Morning Dosing option.<sup>†</sup>



DOSE 1: MANGO



DOSE 2: FRUIT PUNCH

When taking PLENVU<sup>®</sup>, refer to your instructions for use, but keep these steps in mind:

**Dose 1 (Pouch labeled Dose 1):**       Date       at       Time      

1 /



Use container provided to mix PLENVU<sup>®</sup> powder with at least 16 ounces of water until completely dissolved. This may take 2 or 3 minutes.

- Slowly drink and finish the dose within 30 minutes
- Try drinking it through a straw and have some hard candies or mints (no red, blue, or purple)

2 /



Refill same container with at least 16 ounces of a clear liquid, like water or lemonade

- Again, finish drinking within 30 minutes

3 /



Drink additional clear liquids between your 2 doses of PLENVU<sup>®</sup>

- Some examples include water, ginger ale, seltzer, clear broth soups, sports drinks, clear fruit juice, and popsicles (without pieces of fruit or pulp)

**Dose 2 (Pouches A & B):**       Date       at       Time      

4 /



Once it is time for you to take dose 2, **repeat steps 1-3 with Pouch A and Pouch B (to be taken together).**



**Remember to wait until the time that your healthcare provider instructed before starting your second dose of PLENVU<sup>®</sup>.**

**NOTE:** Stop drinking liquids at least 2 hours before your colonoscopy or as recommended by your doctor. You'll need to finish both doses of PLENVU<sup>®</sup> to complete your prep. It is important to take PLENVU<sup>®</sup> exactly as directed by your healthcare provider. PLENVU<sup>®</sup> may affect how other medicines work. If you need to take any other medicines by mouth, take those medicines at least 1 hour before starting each dose of PLENVU<sup>®</sup>.

\*Based on diary ratings given by patients who took PLENVU<sup>®</sup> or Suprep<sup>®</sup> during a clinical trial. There were no differences between the ratings given for easy-to-follow instructions, easy to drink, effectiveness of bowel cleansing, and interference with normal daily activities

<sup>†</sup>If instructed to take the 1-Day Morning Dosing option, both doses will be taken on the same day as your scheduled colonoscopy

### ADDITIONAL HELPFUL TIPS

#### PLENVU<sup>®</sup> CAN BE REFRIGERATED

Drink within 24 hours after it's mixed with water



#### STAY NEAR A BATHROOM

Your first bowel movement will likely happen 1 to 2 hours after you first start taking PLENVU<sup>®</sup>



#### AVOID CERTAIN BEVERAGES

Includes alcohol, milk, red or purple colored liquids, or drinks containing pulp



#### STAY HYDRATED

It is important that you drink clear liquids before, during, and after your prep



#### WATCH HOW TO TAKE PLENVU<sup>®</sup>

Scan to visit [myPLENVU.com/how-to-take](https://myPLENVU.com/how-to-take) for full dosing instructions and to watch videos about the convenient dosing options for PLENVU<sup>®</sup>

### INDICATION

PLENVU<sup>®</sup> (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<sup>®</sup> 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<sup>®</sup>.

**Please see additional Important Safety Information on reverse side and accompanying full Prescribing Information.**

## **IMPORTANT SAFETY INFORMATION** *(continued)*

- PLENVU® and other bowel preparations can cause serious side effects including loss of body fluid (dehydration) and changes in blood salts (electrolytes) in your blood. These changes can cause abnormal heartbeats that may result in death, seizures (even if you have never had a seizure), or kidney problems. Your chance of having fluid loss and changes in body salts with PLENVU® is higher if you have heart problems, kidney problems, or take water pills, high blood pressure medicine, or non-steroidal anti-inflammatory drugs (NSAIDs).
- Your healthcare provider may do blood tests after you take PLENVU® to check your blood for changes. Tell your healthcare provider right away if you have any symptoms of too much fluid loss (dehydration) including vomiting, dizziness, heart problems, kidney problems, seizures, dry mouth, urinating less often than normal; headache, or feel faint, weak, or light-headed, especially when you stand up.
- PLENVU® can cause 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.
- PLENVU® can cause serious allergic reactions that may include skin rash, itching, raised red patches on your skin (hives); swelling of the face, lips, tongue, and throat; and kidney problems.
- The most common side effects in patients taking PLENVU® were nausea, vomiting, dehydration, and stomach pain or discomfort.
- Tell your healthcare provider about all of your medical conditions and medicines you take, including prescription, non-prescription medicines, vitamins, and herbal supplements before you take PLENVU®.

These are not all the possible side effects of PLENVU®. Ask your healthcare provider for more information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://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](mailto:salixmc@dlss.com)

**Please see additional Important Safety Information on reverse side and accompanying full Prescribing Information.**



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**HIGHLIGHTS OF PRESCRIBING INFORMATION**

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

**PLENVU® (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution)**

**Initial U.S. Approval: 2006**

-----**RECENT MAJOR CHANGES**-----

Dosage and Administration (2.1) 9/2023

-----**INDICATIONS AND USAGE**-----

PLENVU is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adults. (1)

-----**DOUSAGE AND ADMINISTRATION**-----

**Preparation and Administration:**

- Two doses of PLENVU are required for a complete preparation for colonoscopy, using a "Two Day" or "One-Day" dosage regimen. (2.1)
- Reconstitute PLENVU in water prior to ingestion. (2.1)
- Consume additional clear liquids after each dose of PLENVU in both dosing regimens. (2.1, 5.1, 5.4)
- Administer oral medications at least 1 hour before starting each dose of PLENVU. (2.1, 7.2)

**Recommended Dosage Regimens:**

*Two-Day Split Dosage:* Dose 1 the evening before the colonoscopy (approximately 4 pm to 8 pm) and Dose 2 the next morning (approximately 12 hours after the start of Dose 1). (2.1, 2.2)

*One-Day Morning Dosage:* Dose 1 the morning of the colonoscopy (approximately 3 am to 7 am) and Dose 2 a minimum of 2 hours after the start of Dose 1. (2.1, 2.3)

- For complete information on dosing, preparation and administration, see full prescribing information at (2.1, 2.2, 2.3).

-----**DOUSAGE FORMS AND STRENGTHS**-----

For Oral Solution: First dose: one pouch labeled Dose 1; Second dose: two pouches labeled Dose 2 Pouch A and Dose 2 Pouch B

- Dose 1 contains 100 grams of polyethylene glycol (PEG) 3350, 9 grams of sodium sulfate, 2 grams of sodium chloride, and 1 gram of potassium chloride. (3)
- Dose 2 Pouch A contains 40 grams of PEG 3350, 3.2 grams of sodium chloride, and 1.2 grams of potassium chloride. (3)
- Dose 2 Pouch B contains 48.11 grams of sodium ascorbate and 7.54 grams of ascorbic acid. (3)

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6.1 Clinical Trials Experience

6.2 Postmarketing Experience

**FULL PRESCRIBING INFORMATION**

**1 INDICATIONS AND USAGE**

PLENVU® is indicated for cleansing of the colon in preparation for colonoscopy in adults.

**2 DOSAGE AND ADMINISTRATION**

**2.1 Important Preparation and Administration Instructions**

- Correct fluid and electrolyte abnormalities before treatment with PLENVU [see *Warnings and Precautions (5.1)*].
- Two doses of PLENVU are required for a complete preparation for colonoscopy. The time interval between the two doses depends on the regimen prescribed and the planned timing of the colonoscopy procedure. [see *Dosage and Administration (2.2, 2.3)*].
- The recommended "Two-Day Split Dosage" method consists of two separate doses: the first dose is taken the evening before the colonoscopy and the second dose is taken the next day, the morning of the day of the colonoscopy [see *Dosage and Administration (2.2)*].
- The recommended "One-Day Morning Dosage" method consists of two separate doses: both doses are taken in the morning of the day of the colonoscopy, with a minimum of 2 hours between the start of the first dose and the start of the second dose [see *Dosage and Administration (2.3)*].
- Reconstitute each pouch of PLENVU in the mixing container with water prior to ingestion. It may take 2 to 3 minutes for complete dissolution. Do not reconstitute with other liquids and/or add starch-based thickeners to the mixing container [see *Warnings and Precautions (5.7)*].
- Consume additional clear liquids (including water) in both dosing regimens [see *Dosage and Administration (2.2, 2.3)*, *Warnings and Precautions (5.1)*].
- Consume only clear liquids (no solid food) from the start of PLENVU treatment until after the colonoscopy.
- Do not eat or drink alcohol, milk, anything colored red or purple or any other foods containing pulp material.
- Do not take other laxatives while taking PLENVU.
- Administer oral medications at least 1 hour before starting each dose of PLENVU [see *Drug Interactions (7.2)*].
- Ensure completion of Dose 2, including all additional liquids, at least 2 hours before the colonoscopy.

**2.2 Recommended Two-Day Split Dosage Regimen**

The recommended Two-Day Split Dosage regimen commences in the evening of the day before the colonoscopy.

Instruct adult patients that on the day before the clinical procedure, they can consume a light breakfast followed by a light lunch, which must be completed at least 3 hours prior to the start of the first PLENVU dose (Dose 1).

Instruct patients to take two separate doses in conjunction with clear liquids as follows: **Dose 1 – In the evening before the colonoscopy, between approximately 4 pm and 8 pm:**

- Empty the contents of Dose 1 into the mixing container that comes with PLENVU.
- Add water to the fill line on the mixing container (at least 16 fluid ounces). Do not add other ingredients to the PLENVU solution.
- Thoroughly mix with a spoon or shake with lid on securely until completely dissolved (which may take 2 to 3 minutes).
- Drink over the next 30 minutes. Be sure to drink all of the solution.
- Refill the mixing container to the fill line (at least 16 fluid ounces) with clear liquids and drink over the next 30 minutes.
- Consume additional clear liquids during the evening.
- If severe bloating, abdominal distention, or abdominal pain occurs following the first dose, delay the second dose until the symptoms resolve.

**Dose 2 – The next morning, on the day of the colonoscopy, approximately 12 hours after the start of Dose 1 (between approximately 4 am and 8 am):**

- Empty the contents of Dose 2 Pouch A and Dose 2 Pouch B into the mixing container that comes with PLENVU.
- Add water to the fill line on the mixing container (at least 16 fluid ounces). Do not add other ingredients to the PLENVU solution.
- Thoroughly mix with a spoon or shake with lid on securely until completely dissolved (which may take 2 to 3 minutes).
- Drink over the next 30 minutes. Be sure to drink all of the solution.
- Refill the mixing container to the fill line (at least 16 fluid ounces) with clear liquids and drink over the next 30 minutes.
- Consume additional water or clear liquids up to 2 hours before the colonoscopy or as prescribed by your doctor. *Then stop drinking liquids until after the colonoscopy.*

Stop drinking PLENVU temporarily or drink each portion at longer intervals if severe bloating, abdominal discomfort or distention occurs, until these symptoms resolve.

**2.3 Recommended One-Day Morning Dosage Regimen**

The recommended One-Day Morning Dosage regimen commences in the morning of the day of the colonoscopy.

Instruct adult patients that on the day before the clinical procedure, they can consume a light breakfast followed by a light lunch, and clear broth soup and/or plain yogurt for dinner, which should be completed by approximately 8 pm

Instruct patients to take two separate doses in conjunction with clear liquids as follows: **Dose 1 – On the day of the colonoscopy, between approximately 3 am and 7 am:**

- Empty the contents of Dose 1 into the mixing container that comes with PLENVU.
- Add water to the fill line on the mixing container (at least 16 fluid ounces). Do not add other ingredients to the PLENVU solution.
- Thoroughly mix with a spoon or shake with lid on securely until completely dissolved (which may take 2 to 3 minutes).
- Drink over the next 30 minutes. Be sure to drink all of the solution.
- Refill the mixing container to the fill line (at least 16 fluid ounces) with clear liquids and drink over the next 30 minutes.
- If severe bloating, abdominal distention, or abdominal pain occurs following the first dose, delay the second dose until the symptoms resolve.

**Dose 2 – On the day of the colonoscopy, a minimum of 2 hours after the start of Dose 1:**

- Empty the contents of Dose 2 Pouch A and Dose 2 Pouch B into the mixing container that comes with PLENVU.
- Add water to the fill line on the mixing container (at least 16 fluid ounces). Do not add other ingredients to the PLENVU solution.
- Thoroughly mix with a spoon or shake with lid on securely until completely dissolved (which may take 2 to 3 minutes).
- Drink over the next 30 minutes. Be sure to drink all of the solution.
- Refill the mixing container to the fill line (at least 16 fluid ounces) with clear liquids and drink over the next 30 minutes.
- Consume additional water or clear liquids up to 2 hours before the colonoscopy or as prescribed by your doctor. *Then stop drinking liquids until after the colonoscopy.*

Stop drinking PLENVU temporarily or drink each portion at longer intervals if severe bloating, abdominal discomfort or distention occurs, until these symptoms resolve.

**2.4 Recommended One-Day Morning Dosage Regimen**

The recommended One-Day Morning Dosage regimen commences in the morning of the day of the colonoscopy.

Instruct adult patients that on the day before the clinical procedure, they can consume a light breakfast followed by a light lunch, and clear broth soup and/or plain yogurt for dinner, which should be completed by approximately 8 pm

Instruct patients to take two separate doses in conjunction with clear liquids as follows: **Dose 1 – On the day of the colonoscopy, between approximately 3 am and 7 am:**

- Empty the contents of Dose 1 into the mixing container that comes with PLENVU.
- Add water to the fill line on the mixing container (at least 16 fluid ounces). Do not add other ingredients to the PLENVU solution.
- Thoroughly mix with a spoon or shake with lid on securely until completely dissolved (which may take 2 to 3 minutes).
- Drink over the next 30 minutes. Be sure to drink all of the solution.
- Refill the mixing container to the fill line (at least 16 fluid ounces) with clear liquids and drink over the next 30 minutes.
- If severe bloating, abdominal distention, or abdominal pain occurs following the first dose, delay the second dose until the symptoms resolve.

**Dose 2 – On the day of the colonoscopy, a minimum of 2 hours after the start of Dose 1:**

- Empty the contents of Dose 2 Pouch A and Dose 2 Pouch B into the mixing container that comes with PLENVU.
- Add water to the fill line on the mixing container (at least 16 fluid ounces). Do not add other ingredients to the PLENVU solution.
- Thoroughly mix with a spoon or shake with lid on securely until completely dissolved (which may take 2 to 3 minutes).
- Drink over the next 30 minutes. Be sure to drink all of the solution.
- Refill the mixing container to the fill line (at least 16 fluid ounces) with clear liquids and drink over the next 30 minutes.
- Consume additional water or clear liquids up to 2 hours before the colonoscopy or as prescribed by your doctor. *Then stop drinking liquids until after the colonoscopy.*

Stop drinking PLENVU temporarily or drink each portion at longer intervals if severe bloating, abdominal discomfort or distention occurs, until these symptoms resolve.

-----**CONTRAINDICATIONS**-----

- Gastrointestinal (GI) obstruction (4, 5, 6)
- Bowel perforation (4, 5, 6)
- Gastric retention (4)
- Ileus (4)
- Toxic megacolon (4)
- Hypersensitivity to any ingredient in PLENVU (4, 5, 10)

-----**WARNINGS AND PRECAUTIONS**-----

- Risk of fluid and electrolyte abnormalities:** Encourage adequate hydration, assess concurrent medications, and consider laboratory assessments prior to and after use. (5.1, 5.2, 7.1)
- Cardiac arrhythmias:** Consider pre-dose and post-colonoscopy ECGs in patients at increased risk. (5.2)
- Seizures:** Use caution in patients with a history of seizures and patients at increased risk of seizure, including medications that lower the seizure threshold. (5.3, 7.1)
- Patients with renal impairment or taking concomitant medications that affect renal function:** Use caution, ensure adequate hydration and consider testing. (5.4, 7.1, 8.6)
- Colonic mucosal ulceration, ischemic colitis and ulcerative colitis:** Consider patients at increased risk of colonic mucosal ulceration when interpreting colonoscopy findings in patients with known or suspected inflammatory bowel disease. (5.5)
- Suspected GI obstruction or perforation:** Rule out diagnosis before administration. (4, 5, 6)
- Patients at risk for aspiration:** Observe during administration. (5.7)
- Glucose-6-phosphate dehydrogenase deficiency (G6PD):** Use with caution. (5.8)
- Risks in patients with phenylethanolamine:** Contains phenylethanolamine. (5.9)
- Hypersensitivity reactions, including anaphylaxis:** Inform patients to seek immediate medical care if symptoms occur. (5.10)

-----**ADVERSE REACTIONS**-----

Most common adverse reactions (≥ 2%) are nausea, vomiting, dehydration and abdominal pain/discomfort. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

-----**DRUG INTERACTIONS**-----

Drugs that increase risks due to fluid and electrolyte changes. (7.1)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide. Revised: 9/2023

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

**Storage:**

After reconstitution, keep PLENVU solution at room temperature, between 68°F to 77°F (20°C to 25°C) [see USP Controlled Room Temperature]. The solution may also be stored in a refrigerator. Use within 24 hours after it is mixed in water.

**3 DOSAGE FORMS AND STRENGTHS**

PLENVU (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution) is supplied as a white to yellow powder for reconstitution.

First dose: one pouch labeled Dose 1; Second dose: two pouches labeled Dose 2 Pouch A and Dose 2 Pouch B.

- Dose 1 contains 100 grams of polyethylene glycol (PEG) 3350, 9 grams of sodium sulfate, 2 grams of sodium chloride, and 1 gram of potassium chloride.
- Dose 2 Pouch A contains 40 grams of PEG 3350, 3.2 grams of sodium chloride, and 1.2 grams of potassium chloride.
- Dose 2 Pouch B contains 48.11 grams of sodium ascorbate and 7.54 grams of ascorbic acid.

**4 CONTRAINDICATIONS**

PLENVU is contraindicated in the following conditions:

- Gastrointestinal (GI) obstruction [see *Warnings and Precautions (5.6)*]
- Bowel perforation [see *Warnings and Precautions (5.6)*]
- Gastric retention
- Ileus
- Toxic megacolon
- Hypersensitivity to any ingredient in PLENVU [see *Warnings and Precautions (5.10)*]

**5.1 WARNINGS AND PRECAUTIONS**

**5.1 Serious Fluid and Electrolyte Abnormalities**

Advise patients to hydrate adequately before, during, and after the use of PLENVU. If a patient develops significant vomiting or signs of dehydration after taking PLENVU, consider performing post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN).

Bowel preparations can cause fluid and electrolyte disturbances, which can lead to serious adverse reactions including cardiac arrhythmias, seizures, and renal impairment. Correct fluid and electrolyte abnormalities before treatment with PLENVU. PLENVU 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)) [see *Drug Interactions (7.1)*]. Consider performing pre-dose and post-colonoscopy laboratory tests (sodium, potassium, calcium, creatinine, and BUN) in patients receiving these drug medications.

**5.2 Cardiac Arrhythmias**

There have been rare reports of serious arrhythmias (including atrial fibrillation) associated with the use of ionic osmotic laxative products for bowel preparation. These occur predominantly in patients with underlying cardiac risk factors and electrolyte disturbances. Use caution when prescribing PLENVU 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, cardiomyopathy or electrolyte imbalance). Consider pre-dose and post-colonoscopy ECGs 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, hypocalcemia, hypocalcemia, and hypomagnesemia) and low serum osmolality. The neurologic abnormalities resolved with correction of fluid and electrolyte abnormalities.

Use caution when prescribing PLENVU for patients with a history of seizures and in patients at increased risk of seizures, 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 hypocalcemia. [see *Drug Interactions (7.1)*].

**5.4 Use in Patients with Renal Impairment**

Use PLENVU with caution in patients with renal impairment or patients taking concomitant medications that affect renal function (such as diuretics, ACE inhibitors, angiotensin receptor blockers, or nonsteroidal anti-inflammatory drugs) [see *Drug Interactions (7.1)*]. These patients may be at risk for renal injury. Advise these patients of the importance of adequate hydration before, during and after the use of PLENVU, and consider performing pre-dose and post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN) in these patients [see *Use in Specific Populations (8.6)*].

**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 PLENVU may increase the risk and is not recommended. Consider the potential for mucosal ulcerations resulting from the bowel preparation 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 PLENVU [see *Contraindications (4)*]. Use with caution in patients with severe ulcerative colitis.

**5.7 Aspiration**

Patients with impaired gag reflex or other swallowing abnormalities are at risk for regurgitation or aspiration of PLENVU. Observe these patients during the administration of PLENVU. Use with caution in these patients.

Do not combine PLENVU with starch-based thickeners [see *Dosage and Administration (2.1)*]. Polyethylene glycol (PEG), a component of PLENVU, when mixed with starch-based thickeners reduces the viscosity of the starch-thickened liquid. With a PEG-based product used for another indication, water mixed in starch-based thickeners liquid used in patients with dysphagia, thinning of the liquid occurred and cases of choking and aspiration were reported.

**5.8 Glucose-6-Phosphate Dehydrogenase (G6PD) Deficiency**

Since PLENVU contains sodium ascorbate and ascorbic acid, PLENVU should be used with caution in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency, especially G6PD deficient patients with an acute infection, with a history of hemolysis, or taking concomitant medications known to precipitate hemolytic reactions.

**5.9 Risks in Patients with Phenylethanolamine**

Phenylethanolamine can be harmful to patients with phenylethanolamine (PKU). PLENVU contains phenylethanolamine, a component of aspartame. Each PLENVU treatment contains 61 mg of phenylethanolamine. Before prescribing PLENVU to a patient with PKU, consider the combined daily amount of phenylethanol from all sources, including PLENVU.

**5.10 Hypersensitivity Reactions**

PLENVU contains PEG and may cause serious hypersensitivity reactions including anaphylaxis, angioedema, rash, urticaria, and anaphylactic shock [see *Adverse Reactions (6.1, 6.2)*]. Inform patients of the signs and symptoms of anaphylaxis, and instruct them to seek immediate medical care should signs and symptoms occur.

**6 ADVERSE REACTIONS**

The following serious or otherwise important adverse reactions for bowel preparations are described elsewhere in the labeling:

- Serious Fluid and Electrolyte Abnormalities [see *Warnings and Precautions (5.1)*]
- Cardiac Arrhythmias [see *Warnings and Precautions (5.2)*]
- Seizures [see *Warnings and Precautions (5.3)*]
- Patients with Renal Impairment [see *Warnings and Precautions (5.4)*]
- Colonic Mucosal Ulceration, Ischemic Colitis and Ulcerative Colitis [see *Warnings and Precautions (5.5)*]
- Patients with Significant Gastrointestinal Disease [see *Warnings and Precautions (5.6)*]
- Aspiration [see *Warnings and Precautions (5.7)*]
- Glucose-6-Phosphate Dehydrogenase (G6PD) Deficiency [see *Warnings and Precautions (5.8)*]
- Risks in Patients with Phenylethanolamine [see *Warnings and Precautions (5.9)*]
- Hypersensitivity Reactions [see *Warnings and Precautions (5.10)*]

**6.1 Clinical Trials 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 practice.

The safety of PLENVU Two-Day Split Dosage and One-Day Morning Dosage regimens was evaluated in two randomized, parallel group, multicenter, investigator-blinded clinical trials (Two-Day Split Dosage in the NOCT and MORA trials and One-Day Morning Dosage in the MORA trial) in 1351 adult patients undergoing colonoscopy. The mean age of the study population was 56 years (range 18 to 86 years), 92% of patients were Caucasian and 51% were female. In the NOCT trial, 61% of patients had mild renal impairment. In the MORA trial, 67% had mild renal impairment and 5% had moderate renal impairment. Patients with severe renal impairment were not enrolled in the clinical trials of PLENVU [see *Clinical Studies (14)*].

The most common adverse reactions (>2%) in the PLENVU treatment groups in both trials were nausea, vomiting, dehydration and abdominal pain/discomfort.

Table 1 and Table 2 display adverse reactions reported in at least 1% of patients in one or more treatment groups in the NOCT and MORA trials, respectively. Since diarrhea was considered as a part of the efficacy assessment, it was not defined as an adverse reaction in these trials.

**Table 1: Common Adverse Reactions\* in Patients Undergoing Colonoscopy in the NOCT Trial by Treatment Group**

Preferred Term	PLENVU Two-Day Split Dosage Regimen (N = 275) %	Trisulfate Two-Day Split Dosage Regimen (N = 271) %
Nausea	7	2
Vomiting	6	2
Dehydration <sup>†</sup>	4	3
Abdominal Pain/Discomfort <sup>‡</sup>	2	2
Decline in Glomerular Filtration Rate (GFR) <sup>§</sup>	2	2
Electrolyte Abnormalities <sup>¶</sup>	2	1
Fatigue	2	1
Headache	2	1
Headache	2	1
Abdominal Distension	1	1
Gastritis	1	1
Hiatus Hernia	1	0
Nasopharyngitis	1	1

\* Reported in at least 1% of patients in either treatment group

N = Total number of patients in the treatment group

<sup>†</sup>Trisulfate: Two 6-ounce bottles of oral solution each containing sodium sulfate 17.5 grams, potassium sulfate 3.13 grams, magnesium sulfate 1.6 grams

<sup>‡</sup>Includes signs and symptoms of dehydration, including dizziness, dry mouth, orthostatic hypotension, prur-syncope, syncope, and thirst

<sup>§</sup>Includes abdominal discomfort, abdominal pain, lower abdominal pain, upper abdominal pain, and abdominal tenderness

<sup>¶</sup>Decreased or abnormal GFR

<sup>‡</sup>Includes increased anion gap, decreased blood bicarbonate, hypomagnesemia, hyperosmolarity, hypokalemia, hyperkalemia, hypercalcemia, hypernatremia, hyperosmolar state, hyperuricemia, hypocalcemia, and hypophosphatemia

**Table 2: Common Adverse Reactions\* in Patients Undergoing Colonoscopy in the MORA Trial by Treatment Group**

Preferred Term	PLENVU One-Day Morning Dosage Regimen (N = 271) %	PLENVU Two-Day Split Dosage Regimen (N = 265) %	2 Liter PEG + Electrolytes Two-Day Split Dosage Regimen <sup>†</sup> (N = 269) %
Vomiting	7	4	1
Nausea	6	6	3
Dehydration <sup>†</sup>	4	3	2
Abdominal Pain/Discomfort <sup>‡</sup>	3	2	3
Hypertension <sup>§</sup>	2	1	0
Headache	2	2	2
Electrolyte Abnormalities <sup>¶</sup>	1	1	0

\* Reported in at least 1% of patients in either treatment group

N = Total number of patients in the treatment group

<sup>†</sup> 2 Liter PEG Plus Electrolytes: Two doses each containing PEG 3350 100 grams, sodium sulfate 5.9 grams, sodium chloride 2.691 grams, potassium chloride 1.015 grams, sodium ascorbate 7.5 grams, and ascorbic acid 4.7 grams

<sup>‡</sup>Includes signs and symptoms of dehydration, including dizziness, dry mouth, orthostatic hypotension, prur-syncope, syncope, and thirst

<sup>§</sup>Includes abdominal discomfort, abdominal pain, lower abdominal pain, upper abdominal pain, and abdominal tenderness

<sup>¶</sup>Includes increased anion gap, decreased blood bicarbonate, hypomagnesemia, increased blood hypercalcemia, hypokalemia, hyperkalemia, hypercalcemia, hypernatremia, hyperosmolar state, hyperuricemia, hypocalcemia, and hypophosphatemia

**Increases in serum sodium, chloride, calcium, magnesium, phosphate, and urate were noted in more patients treated with PLENVU compared to control in one of both trials. The majority of these changes were transient and not clinically significant. Associated decreases in bicarbonate and increases in serum osmolality were also noted.**

**Renal Function**

Decreases in creatinine clearance and increases in blood urea nitrogen (BUN) were also noted in more patients treated with PLENVU compared to control in both trials. Changes of a magnitude indicative of possible acute renal injury, or worsening of baseline chronic renal impairment, were noted infrequently and occurred at a similar incidence in both PLENVU and comparator arms.

Adverse reactions in patients with mild renal impairment were similar to those in patients with normal renal function.

**Less Common Adverse Reactions**

Less common adverse reactions (less than 1%) in the NOCT and MORA trials include: anorectal discomfort, hypersensitivity reaction (including rash), migraine, somnolence, asthma, chills, pains, achas, palpitation, sinus tachycardia, hot flush, and transient increase in liver enzymes.

An additional 235 patients were exposed to the One-Day Morning Dosage Regimen of PLENVU in a third clinical trial, utilizing a comparator not approved in the United States. The adverse reaction profile for patients receiving PLENVU in that trial was similar to what is described above.

**6.2 Postmarketing Experience**

The following adverse reactions have been identified during post-approval use of another oral formulation of polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride or other polyethylene glycol (PEG)-based bowel preparations. Because these reactions 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 use.

*Hypersensitivity:* urticaria/rash, pruritus, dermatitis, rhinorrhea dyspnea, chest and throat tightness, fever, angioedema, anaphylaxis and anaphylactic shock [see *Contraindications (4)*]. *Cardiovascular:* arrhythmia, atrial fibrillation, peripheral edema, astyote, and acute pulmonary edema after aspiration

**7 DRUG INTERACTIONS**

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

Use caution when prescribing PLENVU for patients with conditions and/or who are using medications that increase the risk of fluid and electrolyte disturbances or may increase the risk of renal impairment, seizures, arrhythmias, or QT prolongation in the setting of fluid and electrolyte abnormalities [see *Warnings and Precautions (5.1, 5.2, 5.3, 5.4)*]. Consider additional patient evaluations as appropriate.

**7.2 Potential for Reduced Drug Absorption**

PLENVU can reduce the absorption of other coadministered oral drugs. Administer oral medications at least 1 hour before starting each dose of PLENVU [see *Dosage and Administration (2.1)*].

**7.3 Stimulant Laxatives**

Concurrent use of stimulant laxatives and PLENVU may increase the risk of mucosal ulceration or ischemic colitis. Avoid use of stimulant laxatives (e.g., bisacodyl, sodium picosulfate) while taking PLENVU [see *Warnings and Precautions (5.5)*].

**8 USE IN SPECIFIC POPULATIONS**

**8.1 Pregnancy**

**Risk Summary**

There are no available data with PLENVU in pregnant women to inform a drug-associated risk for adverse developmental outcomes. Animal reproduction studies have not been conducted with PLENVU.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

**8.2 Lactation**

There are no data available to assess the presence of PLENVU in human milk, the effects on the breastfed child or the effects on milk production. The lack of clinical data during lactation precludes a clear determination of the risk of PLENVU to a child during lactation; therefore, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for PLENVU and any potential adverse effects on the breastfed child from PLENVU or from the underlying maternal condition.

**8.4 Pediatric Use**

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

**8.5 Geriatric Use**

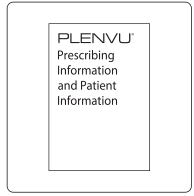
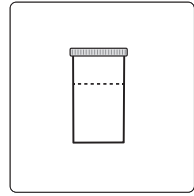
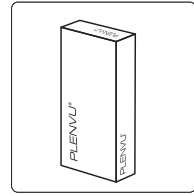
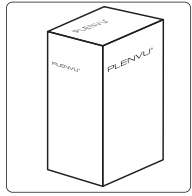
Of the approximately 1,000 patients in clinical trials receiving PLENVU, 217 (21%) patients were 65 years of age or older. No overall differences in safety or effectiveness were observed between younger and older patients, and other reported clinical experience has not identified differences in responses between geriatric patients and younger patients. However, elderly patients are more likely to have decreased hepatic, renal, or cardiac

**Instructions for Use**  
**PLENVU® (plen-vu)**  
**(polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride**  
**and potassium chloride for oral solution)**

There are two different options for taking PLENVU. Your healthcare provider will tell you to take the Two-Day Split Dosage option or the One-Day Morning Dosage option.

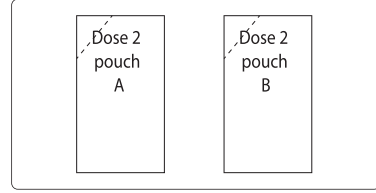
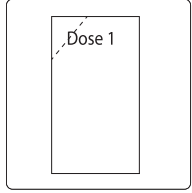
**The following are provided with the pack:**

- An outer carton:
- An inner carton:
- A mixing container with removable lid:
- Prescribing Information and Patient Information



**The inner carton contains:**

- Dose 1
- Dose 2 Pouch A and Dose 2 Pouch B (to be taken together)



**Additional supplies** (not included in the pack):

- Water (to mix with PLENVU).
- Scissors (optional to cut the pouches on the dotted line).
- 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. See step 1c below).

**Important Information on PLENVU:**

- You must drink all of Dose 1 (one pouch) and Dose 2 (two pouches) of PLENVU for either dosing option. Make sure you finish Dose 2 at least 2 hours before your colonoscopy. **Do not** add any other ingredients to PLENVU.
- **Do not** mix PLENVU with starch-based thickeners.
- PLENVU **must** be mixed with water.
- **Drink clear liquids before, during, and after you take PLENVU, up until 2 hours before your colonoscopy, to help prevent fluid loss (dehydration), and changes in blood salt (electrolyte) levels.**

It is important for you to drink the additional amount of clear liquids listed here in the Instructions for Use.

Examples of clear liquids are:

- water
- clear broth soups
- herbal tea, black tea or coffee
- watered down (diluted) (from concentrate) clear fruit juices (without pulp) including apple juice or white grape juice
- clear soda
- gelatin (without added fruit or topping)
- popsicles (without pieces of fruit or fruit pulp)
- strained limeade or lemonade
- **Do not** eat or drink alcohol, milk, anything colored red or purple or any foods that have pulp.
- **Do not** take other laxatives while taking PLENVU.
- If you need to take any other medicines by mouth (oral), take those medicines at least 1 hour before starting each dose of PLENVU.
- **Do not** eat solid food while taking PLENVU until after your colonoscopy.
- For the Two-Day Split Dosage schedule:
  - On the day before the colonoscopy you can eat a light breakfast followed by a light lunch.
  - You must finish eating lunch at least 3 hours before you start taking PLENVU.
  - After you start taking PLENVU you can only drink clear liquids.
- For the One-Day Morning Dosage schedule:
  - On the day before the colonoscopy you can eat a light breakfast followed by a light lunch. For dinner you may have clear broth soup or plain yogurt.
  - You should finish dinner by about 8 pm.
  - After you start taking PLENVU you can only drink clear liquids.
- **Do not** eat the morning of your colonoscopy.

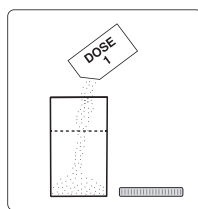
**Two-Day Split Dosage Schedule**

Take Dose 1 in the evening sometime between 4 pm and 8 pm.

Take Dose 2 the next morning, on the day of the colonoscopy. This should be about 12 hours (between about 4 am and 8 am) after you started Dose 1. Make sure you finish Dose 2 at least 2 hours before your colonoscopy.

Follow Step 1 to Step 3 on how to mix with a spoon or shake with lid on securely and take PLENVU:

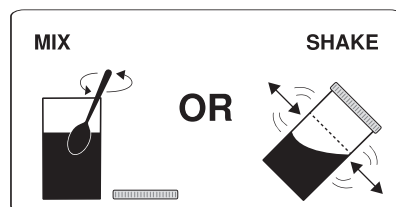
**Step 1a:** Empty Dose 1 into the mixing container that comes with your PLENVU.



**Step 1b:** Add water to the fill line. You will need to add at least 16 ounces.



**Step 1c:** Mix the water and PLENVU together with a spoon or put lid on mixing container securely and shake the water and PLENVU, until it is completely dissolved. This can take 2 to 3 minutes.

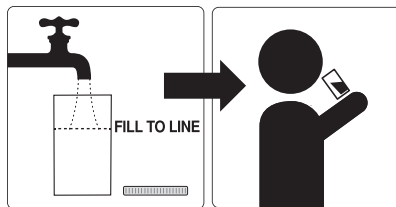


**Step 2:** Drink the entire contents of the mixing container over the next 30 minutes.

If you feel like you have severe stomach pain or discomfort you can stop taking PLENVU for a short time and then continue taking it or you can take smaller sips of PLENVU so that you space out your dose longer than 30 minutes. If you still have severe stomach pain, call your healthcare provider.



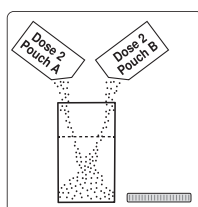
**Step 3:** Rinse the mixing container with water. Refill to the fill line with clear liquids. This will be at least 16 ounces. Drink the entire contents of the mixing container over the next 30 minutes. **Continue to drink additional clear liquids during the evening as this is important to help avoid dehydration.** For a list of clear liquids, see examples at the top of the Instructions for Use.



After taking PLENVU if you have any bloating or feeling like your stomach is upset, wait to take Dose 2 until your stomach feels better.

**For Dose 2:** Rinse the mixing container with water. Repeat Steps 1, 2 and 3 but this time for Dose 2 you will empty two dose pouches (Dose 2 Pouch A and Dose 2 Pouch B) into the mixing container at the same time.

After drinking your 16 ounces of water mixed with PLENVU and the 16 ounces of the clear liquids, **it is important that you drink additional clear liquids to help avoid dehydration.** For a list of clear liquids, see examples at the top of the Instructions for Use. **You must stop drinking all liquids at least 2 hours before your colonoscopy.**



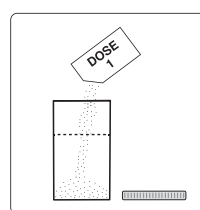
**One-Day Morning Dosage Schedule**

Take Dose 1 the morning of your colonoscopy sometime between 3 am and 7 am.

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

Follow Step 1, Step 2 and Step 3 on how to mix with a spoon or shake with lid on securely and take PLENVU:

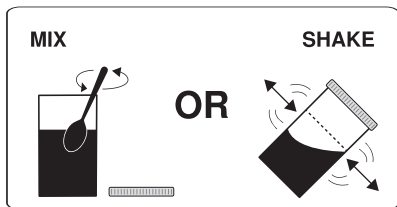
**Step 1a:** Empty Dose 1 into the mixing container that comes with your PLENVU.



**Step 1b:** Add water to the fill line. You will need to add at least 16 ounces.



**Step 1c:** Mix the water and PLENVU together with a spoon or put lid on mixing container securely and shake the water and PLENVU, until it is completely dissolved. This can take 2 to 3 minutes.



**Step 2:** Drink the entire contents of the mixing container over the next 30 minutes.

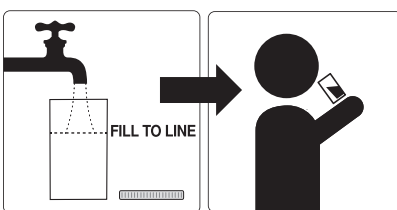
If you feel like you have severe stomach pain or discomfort you can stop taking PLENVU for a short time and then continue taking it or you can take smaller sips of PLENVU so that you space out your dose longer than 30 minutes. If you still have severe stomach pain, call your healthcare provider.



**Step 3:** Rinse the mixing container with water. Refill to fill line with clear liquids. This will be at least 16 ounces. Drink the entire contents of the mixing container over the next 30 minutes.

After drinking your 16 ounces of water mixed with PLENVU and the 16 ounces of the clear liquids, it is **important** that you drink additional clear liquids **in the morning before Dose 2** to help avoid dehydration. For a list of clear liquids, see examples at the top of the Instructions for Use.

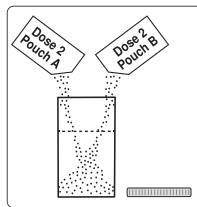
**You must stop drinking all liquids at least 2 hours before your colonoscopy.**



After taking PLENVU if you have any bloating or feeling like your stomach is upset, wait to take Dose 2 until your stomach feels better.

**For Dose 2:** Rinse the mixing container with water. Repeat Step 1, Step 2 and Step 3 but this time for Dose 2 you will empty two dose pouches (Dose 2 Pouch A and Dose 2 Pouch B) into the mixing container at the same time.

After drinking your 16 ounces of water mixed with PLENVU and the 16 ounces of the clear liquids, **it is important that you drink additional clear liquids to help avoid dehydration.** For a list of clear liquids, see examples at the top of the Instructions for Use. **You must stop drinking all liquids at least 2 hours before your colonoscopy.**



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Salix Pharmaceuticals, a division of  
Bausch Health US, LLC  
Bridgewater, NJ 08807 USA

**Manufactured by:**

Norgine Limited  
7 Tir-y-berth Industrial Estate  
New Road, Tir-y-berth  
Hengoed, CF82 8SJ  
United Kingdom (GBR)

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