

2-Day Split-Dosing

If you're starting PLENVU the **evening before** your colonoscopy,
Here's How to Prep

Date of colonoscopy: ____/____/____

Location of colonoscopy: _____

Time of colonoscopy: _____ AM/PM

Nothing to drink after: _____ AM/PM

Evening

PLENVU Dose 1:

Date: ____/____/____

Day of week: M T W Th F S Su

Time: _____ PM

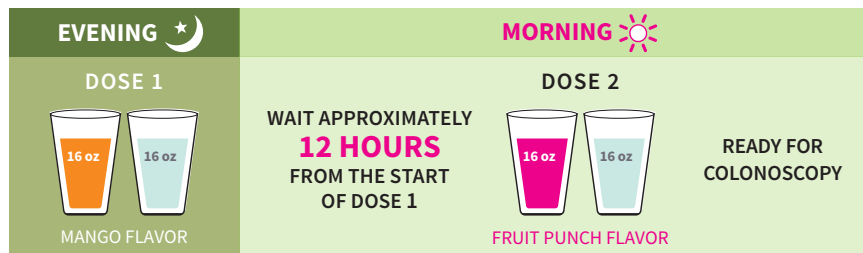
Morning

PLENVU Dose 2:

Date: ____/____/____

Day of week: M T W Th F S Su

Time: _____ AM



Note: actual solution is clear.

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



Stay hydrated!

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

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 throughout the evening.

Wait approximately 12 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.

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

INDICATION

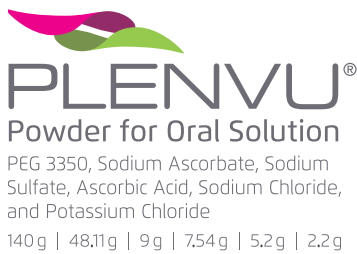
PLENVU® (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride, and potassium chloride for oral solution) is a prescription medication used by adults to clean the colon before a colonoscopy.

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.



Stay Hydrated for Prep Success

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)
- Clear broth soups
- Strained lemonade or limeade
- Gelatin (without fruit or toppings)
- Sports drinks
- Strained clear fruit juice (without pulp)
- Coffee/tea (without milk or creamer)
- 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.**



MEDICATION GUIDE PLENVU® (plen-vu) (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution)
<p>Read this Medication Guide and Instructions for Use before your colonoscopy and again before you start taking PLENVU.</p> <p>What is the most important information I should know about PLENVU? PLENVU and other bowel preparations can cause serious side effects, including:</p> <ul style="list-style-type: none"> • Serious loss of body fluid (dehydration) and changes in blood salts (electrolytes) in your blood. These changes can cause: <ul style="list-style-type: none"> ○ abnormal heartbeats that can cause death. ○ seizures. This can happen even if you have never had a seizure. ○ kidney problems. <p>Your chance of having fluid loss and changes in body salts with PLENVU is higher if you:</p> <ul style="list-style-type: none"> • have heart problems. • have kidney problems. • take water pills (diuretics), high blood pressure medicine or non-steroidal anti-inflammatory drugs (NSAIDs). <p>Tell your healthcare provider right away if you have any of these symptoms of serious loss of body fluid (dehydration) while taking PLENVU:</p> <ul style="list-style-type: none"> • vomiting • dizziness • urinating less often than normal • headache <p>See “What are the possible side effects of PLENVU?” for more information about side effects.</p>
<p>What is PLENVU? 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). Cleaning your colon helps your healthcare provider see the inside of your colon more clearly during your colonoscopy. It is not known if PLENVU is safe and effective in children.</p> <p>Do not take PLENVU if your healthcare provider has told you that you have:</p> <ul style="list-style-type: none"> • 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 problem with food moving too slowly through your intestines (ileus). • a very dilated intestine (toxic megacolon). • an allergy to any of the ingredients in PLENVU. See the end of this leaflet for a complete list of ingredients in PLENVU. <p>Before taking PLENVU, tell your healthcare provider about all of your medical conditions, including if you:</p> <ul style="list-style-type: none"> • have problems with serious loss of body fluid (dehydration) and changes in blood salts (electrolytes). • have heart problems. • have seizures or take medicines for seizures. • have kidney problems or take medicines for kidney problems. • have stomach or bowel problems, including ulcerative colitis. • have problems with swallowing, gastric reflux or if you inhale food or fluid into your lungs when eating or drinking (aspirate). • have a condition called glucose-6-phosphate dehydrogenase (G6PD) deficiency that destroys red blood cells. • are withdrawing from drinking alcohol. • have phenylketonuria (PKU). PLENVU contains phenylalanine. • are allergic to any of the ingredients in PLENVU. • are pregnant or plan to become pregnant. It is not known if PLENVU will harm your unborn baby. Talk to your healthcare provider if you are pregnant. • are breastfeeding or plan to breastfeed. It is not known if PLENVU passes into your breast milk. You and your healthcare provider should decide if you will take PLENVU while breastfeeding. <p>Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. PLENVU may affect how other medicines work. Do not take medicines by mouth 1 hour before or after the start of PLENVU. Especially tell your healthcare provider if you take:</p> <ul style="list-style-type: none"> • medicines to treat a blood salt (electrolyte) imbalance. • medicines for blood pressure or heart problems. • medicines for seizures (antiepileptics). • medicines for kidney problems. • water pills (diuretics). • non-steroidal anti-inflammatory drugs (NSAIDs). • laxatives. Do not take other laxatives while taking PLENVU. • medicines for depression or other mental health problems. <p>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.</p>
<p>How should I take PLENVU? See the “Instructions for Use” for dosing instructions. You must read, understand, and follow these instructions to take PLENVU the right way.</p> <ul style="list-style-type: none"> • Take PLENVU exactly as your healthcare provider tells you to take it. Your healthcare provider will tell you to take the Two-Day Split-Dosing option or the One-Day Morning Dosing option. • Drink only clear liquids before, during, and after you take PLENVU, until 2 hours before your colonoscopy to help prevent fluid loss (dehydration). • Do not eat solid food while taking PLENVU until after your colonoscopy. • It is important for you to drink the additional amount of clear liquids listed in the <i>Instructions for Use</i>. • You may have stomach-area (abdomen) bloating after your first dose of PLENVU. <ul style="list-style-type: none"> ○ If you have severe stomach-area (abdomen) discomfort or bloating, stop drinking PLENVU for a short time or wait a longer time between each dose of PLENVU until your stomach-area symptoms improve. If your stomach-area discomfort or bloating continues, tell your healthcare provider. • Your first bowel movement may happen about 1 to 2 hours after you start taking PLENVU. • If you take too much PLENVU, call your healthcare provider.
<p>What are the possible side effects of PLENVU? PLENVU can cause serious side effects including:</p> <ul style="list-style-type: none"> • Changes in certain blood tests. Your healthcare provider may do blood tests after you take PLENVU to check your blood for changes. Tell your healthcare provider if you have any symptoms of too much fluid loss, including: <ul style="list-style-type: none"> ○ vomiting ○ dizziness ○ feel faint, weak or lightheaded especially when you stand up (orthostatic hypotension) ○ heart problems ○ kidney problems ○ seizures ○ dry mouth • 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. • Serious allergic reactions. Symptoms of a serious allergic reaction may include: <ul style="list-style-type: none"> ○ skin rash ○ itching ○ nausea ○ stomach pain or discomfort ○ raised red patches on your skin (hives) ○ swelling of the face, lips, tongue and throat ○ vomiting ○ dehydration ○ kidney problems <p>The most common side effects of PLENVU include:</p> <ul style="list-style-type: none"> ○ nausea ○ stomach pain or discomfort ○ vomiting ○ dehydration <p>These are not all the possible side effects of PLENVU. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.</p>
<p>How should I store PLENVU?</p> <ul style="list-style-type: none"> • Store PLENVU (before opening and after mixed) at room temperature, between 68°F to 77°F (20°C to 25°C). PLENVU may also be stored in a refrigerator. • Use PLENVU within 6 hours after mixing with water. <p>Keep PLENVU and all medicines out of the reach of children.</p>
<p>General information about the safe and effective use of PLENVU. Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use PLENVU for a condition for which it was not prescribed. Do not give PLENVU to other people, even if they are going to have the same procedure you are. It may harm them. You can ask your pharmacist or healthcare provider for information that is written for healthcare professionals.</p>
<p>What are the ingredients in PLENVU? Active ingredient: Dose 1: PEG 3350, sodium sulfate, sodium chloride, potassium chloride Dose 2 Pouch A: PEG 3350, sodium chloride, potassium chloride Dose 2 Pouch B: sodium ascorbate, ascorbic acid Inactive ingredients: Dose 1: sucralose, encapsulated citric acid, mango flavoring Dose 2 Pouch A: aspartame, fruit punch flavoring</p>
<p>Manufactured for: Salix Pharmaceuticals, a division of Valeant Pharmaceuticals North America LLC Bridgewater, NJ 08807 USA</p> <p>Manufactured by: Norgine Limited 7 Tir-y-berth Industrial Estate New Road, Tir-y-berth Hengoed, CF82 8SJ United Kingdom (GBR)</p> <p>U.S. Patent Numbers: 8,999,313; 9,326,969; 9,592,252; and 9,707,297 Please see www.salix.com for patent information. PLENVU is a registered trademark of the Norgine group of companies used under license. © Valeant Pharmaceuticals North America LLC For more information, go to www.PLENVU.com or call 1-800-321-4576.</p>

This Medication Guide has been approved by the U.S. Food and Drug Administration.
Issued: May 2018

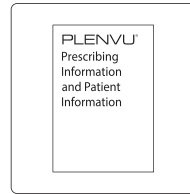
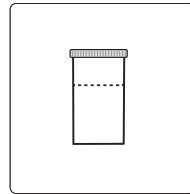
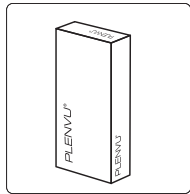
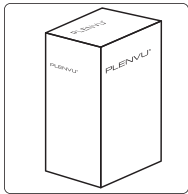
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Instructions for Use PLENVU® (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution)

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

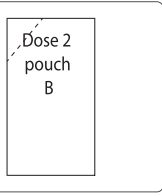
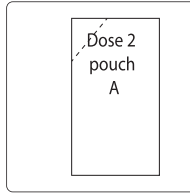
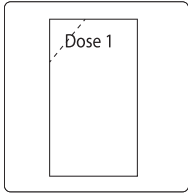
The following are provided with the pack:

- 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:

- 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.
- 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). 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.
- **Do not** take any medicines by mouth (oral) within 1 hour before or after starting each dose of PLENVU.
- **Do not** eat solid food while taking PLENVU until after your colonoscopy.
- For the Two-Day Split-Dosing 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 Dosing 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 and/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.

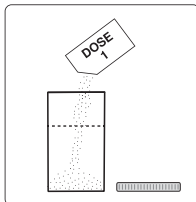
Two-Day Split-Dosing Schedule

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

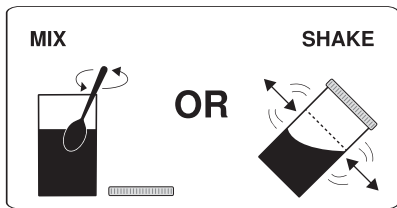
- Step 1a:** Empty Dose 1 into the mixing container that comes with your PLENVU.



- Step 1b:** Add water to the fill line. You will need to add 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.

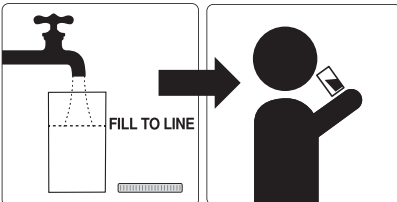


- Step 2:** Drink the entire contents of the mixing container over the next 30 minutes.

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.

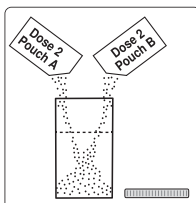


- Step 3:** Rinse the mixing container with water. Refill to the fill line with clear liquids. This will be at least 16 ounces. Drink the entire contents of the mixing container over the next 30 minutes. **Continue to drink additional clear liquids during the evening.** For a list of clear liquids, see 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. **It is important that you drink additional clear liquids, but you must stop drinking all liquids 2 hours before your colonoscopy.**



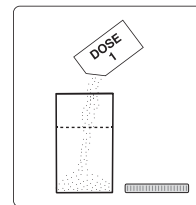
One-Day Morning Dosing Schedule

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 the steps 1 through 3 on how to mix with a spoon or shake with lid on securely and take PLENVU:

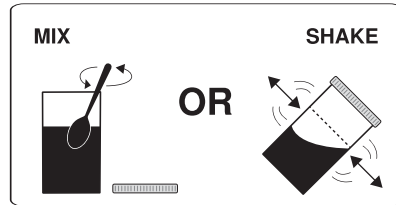
- Step 1a:** Empty Dose 1 into the mixing container that comes with your PLENVU.



- Step 1b:** Add water to the fill line. You will need to add 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.

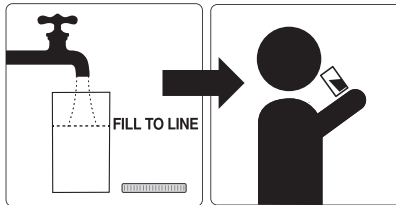


- Step 2:** Drink the entire contents of the mixing container over the next 30 minutes.

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.

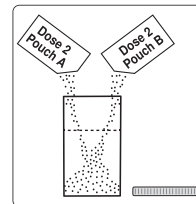


- Step 3:** Rinse the mixing container with water. Refill to fill line with clear liquids. This will be at least 16 ounces. Drink the entire contents of the mixing container over the next 30 minutes. For a list of clear liquids, see examples at the top of the Instructions for Use.



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. **It is important that you drink additional clear liquids, but you must stop drinking all liquids 2 hours before your colonoscopy.**



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U.S. Patent Numbers: 8,999,313; 9,326,969; 9,592,252; and 9,707,297

Please see www.salix.com for patent information.

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This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Issued: May 2018

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REF-PLV-0058