

Plenvu[®] powder for oral solution

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Plenvu?

Plenvu contains the active ingredients Macrogol 3350, Sodium sulphate, Sodium chloride, Potassium chloride, Sodium ascorbate and Ascorbic acid. Plenvu is a type of medicine called a bowel preparation. It makes your bowels clean so that they are ready for examination or surgery. Plenvu works by emptying the contents of your bowels, so you should expect to have lots of watery bowel movements.

For more information, see Section [1. This leaflet provides important information about using Plenvu powder for oral solution \(Plenvu\). You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Plenvu.](#)

2. What should I know before I use Plenvu?

Do not use if you have ever had an allergic reaction to Plenvu or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Plenvu?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Plenvu and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Plenvu?

Plenvu is a dual flavoured laxative with two doses contained in three sachets. There is one sachet for Dose 1 ('Dose 1 Sachet') and two sachets for Dose 2 ('Dose 2 Sachet A' and 'Dose 2 Sachet B').

You need to take all three sachets for one treatment. Dose 1 is mango flavour, Dose 2 is fruit punch flavour.

More instructions can be found in Section [4. How do I use Plenvu?](#) in the full CMI.

5. What should I know while using Plenvu?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Plenvu.Speak to your doctor or pharmacist if you have any side effects that worry you when taking Plenvu.
Driving or using machines	<ul style="list-style-type: none">Plenvu may cause dizziness in some people. In the event this occurs, do not drive or operate machinery.Be careful before you drive or use any machines or tools until you know how Plenvu affects you.
Drinking alcohol	<ul style="list-style-type: none">Do not drink alcohol while taking Plenvu.
Looking after your medicine	<ul style="list-style-type: none">Before use, store Plenvu sachets below 25°C.After you have dissolved Plenvu in the water, the solution may be stored (keeping covered) at or below 25°C. It may also be stored in the refrigerator (2°C to 8°C). Do not keep it for more than 24 hours.

For more information, see Section [5. What should I know while using Plenvu?](#) in the full CMI.

6. Are there any side effects?

It is normal to get diarrhoea when you take Plenvu. If you do not have a bowel movement within 6 hours of taking Plenvu, stop the intake and contact your doctor immediately.

Common, but generally less serious side effects include dehydration, nausea (feeling sick) and vomiting.

As with other medicines there is a small risk of serious allergic reactions. Stop your intake and tell your doctor immediately or go to the Accident & Emergency department of your nearest hospital if you notice any of the following side effects, as these may be symptoms of a severe allergic reaction:

- Extreme fatigue
- Palpitations
- Sudden or severe itching, skin rash, hives.
- Shortness of breath, asthma, wheezing.
- Swelling of your face, lips or tongue (which may make swallowing or breathing difficult), ankles or other part of your body.

For more information, including about other less common side effects and what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

PLENVU[®] powder for oral solution

Macrogol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride.

Consumer Medicine Information (CMI)

This leaflet provides important information about using Plenvu powder for oral solution (Plenvu). **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Plenvu.**

Where to find information in this leaflet:

- [1. Why am I using Plenvu?](#)
- [2. What should I know before I use Plenvu?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Plenvu?](#)
- [5. What should I know while using Plenvu?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Plenvu?

Plenvu contains the active ingredients:

- Macrogol 3350.
- Sodium sulfate.
- Sodium chloride.
- Potassium chloride
- Sodium ascorbate
- Ascorbic acid.

Plenvu is a type of medicine called a bowel preparation. It makes your bowels clean so that they are ready for examination or surgery. Plenvu works by emptying the contents of your bowels, so you should expect to have lots of watery bowel movements.

Plenvu is a dual flavoured laxative with two doses contained in three sachets. There is one sachet for Dose 1 ('Dose 1 Sachet') and two sachets for Dose 2 ('Dose 2 Sachet A' and 'Dose 2 Sachet B'). You need to take all three sachets for one treatment. Dose 1 is mango flavour, Dose 2 is fruit punch flavour.

Plenvu is intended for adults (18 years of age and older), including the elderly, before any clinical procedure that needs a clean bowel.

Ask your doctor if you have any questions about why this medicine has been recommended for you.

2. What should I know before I use Plenvu?

Warnings

When you must not take it

If you are in poor health or have a serious medical condition, you should be particularly aware of the possible side effects listed in the 'Side Effects' section. Contact your doctor, pharmacist or nurse if you are concerned.

Do not use Plenvu if:

- you are allergic (hypersensitive) to the active ingredients or any of the other ingredients of Plenvu (listed in 'Product Description')
- you have a blockage in your bowel (bowel obstruction);
- you have an opening in the wall of your stomach or bowel (bowel perforation);
- you experience problems with food and fluid emptying from your stomach (gastric retention);
- you have paralysis of the gut (ileus);
- you suffer from phenylketonuria. This is a hereditary inability of the body to use a particular amino acid. Plenvu contains a source of phenylalanine;
- your body is unable to produce enough glucose-6-phosphate dehydrogenase;
- you have severe inflammatory bowel disease, like ulcerative colitis, Crohn's disease, or toxic megacolon;
- you have severe dehydration;
- you have a decreased level of consciousness unless you have suitable medical supervision.

Always check the ingredients to make sure you can use this medicine.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, seek medical advice.

Tell your doctor, pharmacist or nurse before taking Plenvu if any of the points below apply to you. If you:

- have allergies to any other medicines, foods, preservatives or dyes;
- have an allergy to any of the ingredients in Plenvu;
- have heart problems and/or heart rhythm problems;
- have kidney problems;
- have problems with swallowing;

- have a high or low blood salt level (e.g. sodium, potassium);
- have diabetes;
- have any other medical conditions; and/or
- take any medicines for any other condition.

If you have not told your doctor about any of the above, tell him/her before you start taking Plenvu.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor or pharmacists if you are pregnant or intend to become pregnant.

Your doctor or pharmacist can discuss with you the risks and benefits involved.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

It is not known if Plenvu passes into your breast milk. You and your doctor should decide if you will take Plenvu while breastfeeding.

Before you start to take it

To maintain good health, you should hydrate adequately before the use of any bowel preparation. If you develop significant vomiting, or signs of fluid loss (dehydration) tell your doctor, see 'Side Effects' section.

3. What if I am taking other medicines?

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines (e.g. oral contraceptives, diuretics, calcium channel blockers, corticosteroids), as well as any you get without a prescription from your pharmacy, supermarket or health food shop.

Plenvu may interfere with how some other medicines work.

Medicines taken by mouth may not be absorbed properly when taken one hour before, during and one hour after taking Plenvu.

Your doctor and pharmacist have more information on which medicines to be careful with or avoid while taking this medicine.

If you need to thicken fluids in order to swallow them safely, Plenvu may counteract the effect of the thickener.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Plenvu.

4. How do I use Plenvu?

Plenvu with food and drink

Continue to drink clear fluids before, during, and after you take Plenvu, to help prevent fluid loss (dehydration). It is important for you to drink the additional recommended amounts of clear fluids. Your Doctor will tell you a 'Nil By Mouth' time when you should stop drinking.

Examples of clear fluids are water, clear soups, tea or coffee without milk, soft drinks/diluted cordials and clear fruit juices (without pulp).

When taking Plenvu you should continue to take plenty of clear fluids. The fluid content of Plenvu does not replace your regular fluid intake.

Important: Do not drink alcohol, milk, anything coloured red or purple (e.g. blackcurrant juice) or any other drinks containing pulp material and do not eat while taking Plenvu and until after your clinical procedure.

Two-day split dosing schedule and day before dosing schedule

On the day before the clinical procedure you can eat a light breakfast followed by a light lunch and must finish eating this meal at least 3 hours before you start taking Plenvu, after which you may only consume clear fluids.

Morning only dosing schedule

On the day before the clinical procedure you can eat a light breakfast followed by a light lunch, and clear soup and/or plain yogurt for dinner (which should be completed by approximately 8 pm). You may only consume clear fluids from after dinner on the evening before the clinical procedure. No breakfast is allowed on the morning of the clinical procedure.

Your Doctor may give you additional dietary advice which you should follow.

How to take

Unless your doctor has given you specific instructions, please follow these dosage and dietary instructions. Check with your doctor, pharmacist or nurse if you are not sure.

You must read, understand and follow the instructions for use.

Your doctor may prescribe the two-day split dosing schedule, the morning only dosing schedule or the day before dosing schedule depending on the scheduling of your clinical procedure.

Before you take Plenvu, please read carefully the following instructions. You need to know:

- When to take Plenvu.
- How to prepare Plenvu.
- How to drink Plenvu.
- What you should expect to happen.

When to take / use Plenvu

Your treatment with Plenvu must be completed before your clinical procedure.

This course of treatment may be taken as divided doses as described below:

Two-day split dosing schedule

Take 500 mL of Dose 1 of Plenvu (including an additional 500 mL of clear fluid) in the evening before the clinical procedure and the second 500 mL Dose 2 (including an additional 500 mL of clear fluid) in the morning of the day of the clinical procedure, approximately 12 hours after the start of the first dose, or

Morning only dosing schedule

Take both doses in the morning of the day of the clinical procedure (including an additional 500 mL of clear fluid); the second dose should be taken a minimum of 2 hours after the start of the first dose, or

Day before dosing schedule

Take both doses in the evening before the clinical procedure (including an additional 500 mL of clear fluid); the second dose should be taken a minimum of 2 hours after the start of the first dose.

The appropriate dosing schedule should be selected according to the timing of the clinical procedure.

Your doctor will tell you which dosing schedule to follow. DO NOT add any other ingredients to the doses.

How to prepare Plenvu Dose 1

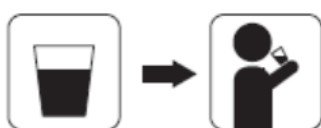
- Open the carton and remove the Dose 1 sachet.
- Pour the contents of Dose 1 into a measuring container that can hold 500 mL of fluid.
- Add water (not chilled) to make up to 500 mL and stir until all the powder has dissolved. This may take up to approximately 8 minutes.



How to drink Plenvu Dose 1

Drink the 500 mL Dose 1 solution, plus an additional 500 mL of clear fluid, over a period of 60 minutes. Alternating between the reconstituted solution and the clear fluid is acceptable. Try to drink a glassful every 10 to 15 minutes.

Clear fluid may include water, clear soup, diluted cordials/clear fruit juice (without pulp) tea or coffee without milk.



How to prepare Plenvu Dose 2

- When you are ready to take Dose 2, pour the contents of Dose 2 Sachet A and Dose 2 Sachet B into a measuring container that can hold 500 mL of fluid.
- Add water (not chilled) to make up to 500 mL and stir until all the powder has dissolved. This may take up to approximately 8 minutes.



How to drink Plenvu Dose 2

When directed based on the recommended dosing schedule, make up and drink the 500 mL Dose 2 plus an additional 500 mL of clear fluid over a period of 60 minutes. Alternating between the reconstituted solution and the clear fluid is acceptable.



In addition to Plenvu and the additional clear fluid to be taken with each dose, you are encouraged to drink extra clear fluid as needed to avoid thirst. Drinking clear fluids will help prevent fluid loss (dehydration). You must stop drinking all fluids at least 2 hours prior to your clinical procedure. Your doctor should tell what time to stop drinking fluid.

What you should expect to happen

When you start drinking the Plenvu solution, it is important that you stay close to a toilet. At some point, you will start to experience watery bowel movements. This is quite normal and indicates that the Plenvu solution is working. You may have stomach area bloating before you have your first bowel movement.

If you follow these instructions, your bowel will be clean, and this will help you to have a successful clinical procedure. You should allow sufficient time after your bowel movements have subsided to travel to the clinic/hospital.

If you forget to use Plenvu

If you forget to take Plenvu as instructed, take it as soon as you realise you have not taken it and contact your doctor, pharmacist or nurse for advice prior to the clinical procedure. It is important that you have allowed sufficient time to complete your course of Plenvu in order to ensure your bowel is fully cleaned at least 2 hours prior to the clinical procedure.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

If you use too much Plenvu

If you think that you have used too much Plenvu, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre
- (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Plenvu?

Things you should do

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Call your doctor straight away if you:

- Do not feel well while you are using Plenvu.
- Speak to your doctor if you have any side effects and they worry you.

Remind any doctor, dentist or pharmacist you visit that you are using Plenvu.

Things you should not do

- Do not use Plenvu for any other conditions unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Plenvu affects you.

Plenvu may cause dizziness in some people.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not use this medicine after the expiry date which is stated on the sachets and carton, after "EXP".

The expiry date refers to the last day of that month.

Please note that the expiry dates may be different for each of the sachets and carton.

Before use, store Plenvu sachets below 25°C.

After you have dissolved Plenvu in the water, the solution may be stored (keeping covered) at or below 25°C. It may

also be stored in the refrigerator (2°C to 8°C). Do not keep it for more than 24 hours.

Do not store Plenvu or any other medicines in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Store it in a cool dry place away from moisture, heat or sunlight.

When to discard your medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Do not be alarmed by this list of possible side effects. You may not experience any of them.

If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

It is normal to get diarrhoea when you take Plenvu. If you do not have a bowel movement within 6 hours of taking Plenvu, stop the intake and contact your doctor immediately.

Less serious/common side effects

Common side effects (may affect up to 1 in 10 people) include:

Less serious side effects	What to do
<ul style="list-style-type: none">• Dehydration.• Nausea (feeling sick).• Vomiting.	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

Uncommon side effects

Additional uncommon side-effects (may affect up to 1 in 100 people) include:

Uncommon side effects	What to do
<ul style="list-style-type: none"> Abdominal bloating and pain. Aches and pains. Allergic reaction. Chills. Fatigue. Headache or migraine. Hot flushes. Increased blood glucose level in diabetic patients. Increased heart rate. Palpitations. Soreness of the anus. Sleepiness. Temporary increase in blood pressure. Temporary increase in liver enzymes. Thirst. Various salt (electrolyte) imbalances and weakness. You also may be feeling generally unwell. 	<p>Speak to your doctor or pharmacist if you have any of these less uncommon side effects and they worry you.</p>

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Serious/rare side effects

As with other medicines there is a small risk of serious allergic reactions. Stop your intake and tell your doctor immediately or go to the Accident & Emergency department of your nearest hospital if you notice any of the following side effects, as these may be symptoms of a severe allergic reaction:

Serious side effects	What to do
<ul style="list-style-type: none"> Extreme fatigue Palpitations Sudden or severe itching, skin rash, hives. Shortness of breath, asthma, wheezing. Swelling of your face, lips or tongue (which may make swallowing or breathing 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

difficult), ankles or other part of your body.	
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Tell your doctor immediately if you have any of these symptoms of a loss of too much body fluid (dehydration) while taking Plenvu:

Serious side effects	What to do
<ul style="list-style-type: none"> Confusion. Dizziness. Excessive thirst. Headache. Urinating less often than normal or dark coloured urine. Vomiting. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Also, tell your doctor right away if you have severe stomach-area (abdomen) pain.

If you experience sudden abdominal pain or rectal bleeding when taking Plenvu for bowel preparation, contact your doctor or seek medical advice immediately.

Rarely, serious heart rhythm problems may occur (i.e. heart may feel like it's pounding, fluttering or beating irregularly, often for a few seconds or possibly a few minutes) with the use of laxatives for bowel preparation, especially in patients with underlying heart disease or salts disturbance.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Plenvu contains

Active ingredients (main ingredients)	Macrogol 3350 Sodium sulfate Sodium chloride Potassium chloride Sodium ascorbate Ascorbic acid
Other ingredients (inactive ingredients)	Sucralose (E955) Aspartame (E951) Mango flavouring Fruit punch flavouring Citric acid Maltodextrin
Potential allergens	Macrogol 3350

What it looks like

What Plenvu contains

Dose 1 Sachet contains the following active substances:

Macrogol 3350	100 g
Sodium sulfate	9 g
Sodium chloride	2 g
Potassium chloride	1 g

The concentration of electrolyte ions when the first dose is made up to 500 mL of solution is as follows:

Sodium	160.9 mmol/500 mL
Sulfate	63.4 mmol/500 mL
Chloride	47.6 mmol/500 mL
Potassium	13.3 mmol/500 mL

Dose 1 also contains 0.79 g of sucralose (E955).

Dose 2 (Sachets A and B) contains the following active substances:

Sachet A:

Macrogol 3350	40 g
Sodium chloride	3.2 g
Potassium chloride	1.2 g

Sachet B:

Sodium ascorbate	48.11 g
Ascorbic acid	7.54 g

The concentration of electrolyte ions when the second dose (Sachets A and B) is made up to 500 mL of solution is as follows:

Sodium	297.6 mmol/500 mL
Ascorbate	285.7 mmol/500 mL
Chloride	70.9 mmol/500 mL
Potassium	16.1 mmol/500 mL

Dose 2 (Sachet A) also contains 0.88 g of aspartame (E951).

The other ingredients in Plenvu are: sucralose (E955), aspartame (E951) mango flavouring, fruit punch flavouring, citric acid, and maltodextrin.

Do not take this medicine if you are allergic to any of these ingredients.

What Plenvu looks like

Plenvu is a powder for oral solution.

Australian Registration No.: AUST R 298344.

Who distributes Plenvu

Plenvu is supplied in Australia by:

Norgine Pty Ltd
Suite 3.01 Building A
20 Rodborough Road
Frenchs Forest NSW 2086
AUSTRALIA
Phone: 1800 766 936
www.norgine.com.au

Plenvu is supplied in New Zealand by:

Pharmacy Retailing (NZ) Ltd
Trading as Healthcare Logistics
58 Richard Pearse Drive
Mangere, Auckland
Phone: 0800 404 178 (Medical Information)

This leaflet was prepared in July 2023.

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