

Package leaflet: Information for the patient

Plenvu powder for oral solution

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

[For medicines available **only on prescription**]

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

[For medicines available **without a prescription**]

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Plenvu is and what it is used for
2. What you need to know before you take Plenvu
3. How to take Plenvu
4. Possible side effects
5. How to store Plenvu
6. Contents of the pack and other information

1. What Plenvu is and what it is used for

Plenvu contains the combination of active substances macrogol 3350, sodium ascorbate, sodium sulfate anhydrous, ascorbic acid, sodium chloride and potassium chloride.

Plenvu is a laxative.

Plenvu is intended for adults 18 years of age and older prior to any clinical procedure requiring a clean bowel.

Plenvu cleans your bowel by causing you to have diarrhoea.

2. What you need to know before you take Plenvu

Do not take Plenvu:

- if you are allergic (hypersensitive) to the active substances or any of the other ingredients of Plenvu (listed in

section 6)

- if you have a blockage in your bowel (bowel obstruction)
- if you have an opening in the wall of your stomach or bowel (bowel perforation)
- if you have paralysis of the gut (ileus)
- if you experience problems with food and fluid emptying from your stomach (e.g. gastric paresis, gastric retention)
- if you suffer from phenylketonuria. This is a hereditary inability of the body to use a particular amino acid. Plenvu contains a source of phenylalanine
- if your body is unable to produce enough glucose-6-phosphate dehydrogenase
- if you have a very dilated bowel (toxic megacolon)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Plenvu if any of the below are applicable to you. If you:

- have heart problems and/or heart rhythm problems
- have kidney problems and/or dehydration
- have heart failure, severe kidney problems or are taking blood pressure medicine
- have stomach or bowel problems, including bowel inflammation
- have problems with swallowing (see also Food and drink with Plenvu)
- have a high or low blood salt level (e.g. sodium, potassium)
- have any other medical conditions (e.g. seizures)
- have epilepsy or a history of convulsions

Plenvu should not be given to patients with impaired consciousness without medical supervision.

If you are in poor health or have a serious medical condition, you should be particularly aware of the possible side effects listed in section 4. Contact your doctor, pharmacist or nurse if you are concerned.

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

If you experience (blood) vomiting followed by sudden chest, neck or abdominal pain, difficulty swallowing or difficulty breathing when taking Plenvu, stop taking medicine and promptly contact your doctor.

Children and adolescents

Plenvu is not recommended for use in children under 18 years of age.

Other medicines and Plenvu

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines (including oral contraceptives).

Medicines taken by mouth could be flushed through the gastrointestinal tract and may not be absorbed properly when taken one hour before, during and one hour after you have taken Plenvu.

If taking oral contraceptives you may need to use additional forms of contraception (e.g. condom) to prevent pregnancy.

Food and drink with Plenvu

On the day before the clinical procedure you can eat a light breakfast followed by a light lunch:

For the **Two-day split dosing schedule**, OR the **Day before dosing schedule** you must finish eating lunch at least 3 hours before you start taking Plenvu, after which you may only consume clear fluids. For the **Morning only dosing**

schedule you may have clear soup and/or plain yogurt for dinner (which should be completed by approximately 20.00H). You may only consume clear fluids from after dinner on the evening before the clinical procedure.

Note: For information regarding the dosing schedules refer to section 3. No breakfast is allowed on the morning of the clinical procedure.

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 prescribed amounts of clear fluids.

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

Important:

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

Consumption of all fluids should be stopped at least:

- two hours before the clinical procedure when under general anaesthesia, or
- one hour before the clinical procedure without general anaesthesia.

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

Pregnancy, breast-feeding and fertility

There are no data on the use of Plenvu during pregnancy or breast-feeding and is therefore not recommended. It should only be used if considered essential by the doctor. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking Plenvu.

Driving and using machines

Plenvu does not affect your ability to drive or use machines.

Plenvu contains sodium, potassium and a source of phenylalanine

This medicinal product contains 458.5 mmol (10.5 g) sodium per course of treatment. This is to be taken into consideration by patients on a controlled sodium diet.

This medicinal product contains 29.4 mmol (1.1 g) potassium per course of treatment. This should be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet. Plenvu contains a source of phenylalanine which may be harmful for people with phenylketonuria. It also contains ascorbate which may be harmful for people with glucose-6-phosphate dehydrogenase deficiency.

3. How to take Plenvu

[For medicines available **only on prescription**]

Always take this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

[For medicines available **without a prescription**]

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

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 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

Dose 1 taken in the evening before the clinical procedure and Dose 2 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

Dose 1 and Dose 2 taken in the morning of the day of the clinical procedure; the second dose should be taken a minimum of 2 hours after the start of the first dose, **or**

Day before dosing schedule

Dose 1 and Dose 2 taken in the evening of the day before the clinical procedure; the second dose should be taken a minimum of 2 hours after the start of the first dose.

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

Do not eat while taking Plenvu and until after your clinical procedure.

For information regarding the timing of meals before taking Plenvu refer to [section 2](#).

How to prepare Plenvu Dose 1

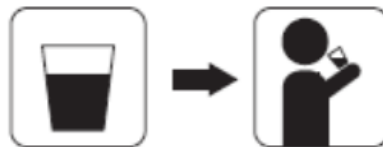
1. Open the carton and remove the Dose 1 sachet.
2. Pour the contents of Dose 1 into a measuring container that can hold 500 ml of fluid.
3. Add water to make up to 500 ml and stir until all the powder has dissolved. This may take up to approximately 8 minutes.



How to drink Plenvu Dose 1

Drink the 500 ml Dose 1 and 500 ml of clear fluid over a period of 60 minutes. Alternating between the reconstituted solution and 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

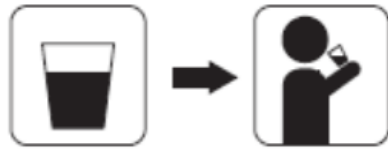
1. When you are ready to take Dose 2 pour the contents of Dose 2 Sachet A and Dose 2 Sachet B into a measuring container that can hold 500 ml of fluid.
2. Add water to make up to 500 ml and stir until all the powder has dissolved. This may take up to

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 and 500 ml of clear fluid over a period of 60 minutes. Alternating between the reconstituted solution and clear fluid is acceptable.



Additional clear fluid may be drunk throughout the bowel preparation process, i.e. before, during, and after you take Plenvu, but you must stop drinking 1-2 hours prior to your clinical procedure. Drinking clear fluids will help prevent fluid loss (dehydration).

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 clear, and this will help you to have a successful examination. You should allow sufficient time after your bowel movements have subsided to travel to the clinic/hospital.

If you take more laxatives than you should

If you take Plenvu before or after taking other laxative products you may develop excessive diarrhoea, which can lead to dehydration. Take generous amounts of clear fluid. If you are worried contact your doctor or go to the nearest hospital accident and emergency department straight away.

If you forget to take Plenvu

- If you forget to take Plenvu as instructed, take 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.

4. Possible side effects

Like all medicines Plenvu can cause side effects, although not everybody gets them. 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.

If you have any of the following side effects **stop** taking Plenvu and tell your doctor immediately, as these may be symptoms of a severe allergic reaction:

- Extreme fatigue
- Palpitations
- Rash or itching
- Shortness of breath
- Swelling of your face, ankles or other part of your body

Stop taking Plenvu and immediately contact a doctor if you notice any of the following side effects:

- Seizure

Tell your doctor immediately if you have any of these symptoms while taking Plenvu as these may indicate a loss of too much body fluid (dehydration):

- Dizziness
- Headache
- Urinating less often than normal
- Vomiting

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

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 cardiac disease or salts disturbance. Talk to your doctor if the symptoms continue.

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

- Dehydration
- Nausea (feeling sick)
- Vomiting

Uncommon side effects (may affect up to 1 in 100 people)

- 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
- Weakness

Not known side effects (frequency cannot be estimated from the available data)

- Oesophageal rupture due to vomiting

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Plenvu

Keep this medicine out of the sight and reach of children.

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. Prior to opening do not store above 25°C.

Keep prepared solutions below 25°C and drink it within 24 hours. The solutions may be stored in a refrigerator. The solutions must be covered.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Plenvu contains

Dose 1 sachet contains the following active substances:

Macrogol 3350	100 g
Sodium sulfate anhydrous	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
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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

Excipients with known effect

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

The other ingredients are:

Mango flavour containing glycerol (E422), flavouring preparations, gum acacia (E414), maltodextrin (E1400) and natural flavouring substances; and fruit punch flavour containing flavouring preparations, gum acacia (E414), maltodextrin (E1400) and flavouring substances. For further information refer to section 2.

What Plenvu looks like and contents of the pack

This pack contains three sachets: Dose 1, Dose 2 Sachet A, and Dose 2 Sachet B.

Plenvu powder for oral solution is available in packs containing 1 treatment and in packs containing 40, 80, 160 and 320 treatments. Not all pack sizes may be marketed.

Marketing authorisation holder:

To be completed nationally.

Manufacturer:

To be completed nationally.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names: Belgium, Bulgaria, Czech Republic, Croatia, Denmark, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Luxembourg, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Sweden, United Kingdom (Northern Ireland): PLENVU

Austria, Netherlands, Spain: PLEINVUE

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