

UK PRESCRIBING INFORMATION: Plenvu powder for oral solution (Macrogol 3350 + Sodium ascorbate + Ascorbic acid + Sodium sulfate anhydrous + Potassium chloride + Sodium chloride)

Please refer to the full Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Plenvu powder for oral solution is administered in two doses. Dose one is made up of 1 sachet containing: macrogol 3350 100g, sodium sulfate anhydrous 9g, sodium chloride 2g, potassium chloride 1g. Dose 2 is made up of 2 sachets (A and B). Sachet A contains: macrogol 3350 40g, sodium chloride 3.2g, potassium chloride 1.2g. Sachet B contains: sodium ascorbate 48.11g, ascorbic acid 7.54g.

Indication: For bowel cleansing in adults, prior to any procedure requiring a clean bowel.

Dosage and administration: For oral use. **Adults and elderly:** A course of treatment consists of two separate non-identical 500ml doses of Plenvu. At least 500ml of additional clear fluid must be taken with each dose. Treatment can be taken according to a two-day or one-day dosing schedule. Two-day dosing schedule: First dose taken the evening before the procedure. Second dose in the early morning of the day of the procedure. Morning only dosing schedule: Both doses taken the morning of the procedure. The two doses should be separated by a minimum of 1 hour. Day before dosing schedule: Both doses taken the evening before the procedure. The two doses should be separated by a minimum of 1 hour. No solid food should be taken from the start of the course of treatment until after the clinical procedure. Consumption of all fluids should be stopped at least 2 hours prior to a procedure under general anaesthesia or 1 hour prior to a procedure without general anaesthesia. **Children:** Not recommended for use in children below 18 years of age. **Patients with renal or hepatic impairment:** No special dosage adjustment is deemed necessary in patients with mild to moderate renal or hepatic impairment.

Patients should be advised to allow adequate time after bowel movements have subsided to travel to the clinical unit.

Contraindications: Hypersensitivity to the active substances or to any of the excipients, gastrointestinal obstruction or perforation, ileus, disorders of gastric emptying (gastroparesis, gastric retention), phenylketonuria, glucose-6-phosphate dehydrogenase deficiency, toxic megacolon.

Warnings and precautions: The fluid content of reconstituted Plenvu does not replace regular fluid intake. Adequate fluid intake must be maintained. As with other macrogol containing products, allergic reactions including rash, urticaria, pruritus, angioedema and anaphylaxis are a possibility. Caution should be used with administration to frail or debilitated patients, in patients with impaired gag reflex, with the possibility of regurgitation or aspiration, or with diminished levels of consciousness, severe renal impairment, cardiac failure (grade III or IV of NYHA), those at risk of arrhythmia, dehydration or severe acute inflammatory bowel disease.

In debilitated fragile patients, patients with poor health, those with clinically significant renal impairment, arrhythmia and those at risk of electrolyte imbalance, the physician should consider performing a baseline and post-treatment electrolyte, renal function test and ECG as appropriate.

Any suspected dehydration should be corrected for before use of Plenvu.

There have been rare reports of serious arrhythmias including atrial fibrillation associated with the use of ionic osmotic laxatives for bowel preparation, predominantly in patients with underlying cardiac risk factors and electrolyte disturbance.

If patients develop any symptoms indicating arrhythmia or shifts of fluid/electrolytes during or after treatment, plasma electrolytes should be measured, ECG monitored and any abnormality treated appropriately.

If patients experience severe bloating, abdominal distension, or abdominal pain, administration should be slowed or temporarily discontinued until the symptoms subside.

Post-marketing cases of ischaemic colitis, including serious, have been reported in patients treated with macrogol for bowel preparation. Macrogol should be used with caution in patients with known risk factors for ischaemic colitis or in case of concomitant use of stimulant laxatives (such as bisacodyl or sodium picosulfate). Patients presenting with sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis should be evaluated promptly.

The sodium content, 458.5mmol (10.5g), should be taken into consideration for patients on a controlled sodium diet. The potassium content, 29.4mmol (1.1g), should be taken into consideration by patients with reduced kidney function or those on a controlled potassium diet.

Interactions: Medicinal products taken orally within one hour of starting colonic lavage with Plenvu may be flushed from the gastrointestinal tract unabsorbed. The therapeutic effect of drugs with a narrow therapeutic index or short half-life may be particularly affected.

Fertility, pregnancy and lactation: There are no data on the effects of Plenvu on fertility in humans. There were no effects on fertility in studies in male and female rats.

It is preferable to avoid the use of Plenvu during pregnancy.

It is unknown whether Plenvu active ingredients/metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to abstain from Plenvu therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Effects on ability to drive and use machines: Plenvu has no influence on the ability to drive and use machines.

Undesirable effects: Diarrhoea is an expected outcome.

Common: vomiting, nausea, dehydration. Uncommon: abdominal distension, anorectal discomfort, abdominal pain, drug hypersensitivity, headache, migraine, somnolence, thirst, fatigue, asthenia, chills, pains, aches, palpitation, sinus tachycardia, transient increase in blood pressure, hot flush, transient increase in liver enzymes, hypernatraemia, hypercalcaemia, hypophosphataemia, hypokalaemia, decreased bicarbonate, anion gap increased/ decreased, hyperosmolar state.

Refer to the SmPC for a full list and frequency of adverse events.

UNITED KINGDOM:

Price and pack sizes: £12.43 (3 sachet)

Legal category: Pharmacy medicine

MA Number: PL 20011/0040

MA Holder: Norgine Pharmaceuticals Limited, Norgine House, Widewater Place, Moorhall Road, Harefield, Uxbridge, UB9 6NS, UK

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**Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Norgine Pharmaceuticals Ltd on:
Tel: +44 (0)1895 826 606
Email: medinfo@norgine.com**