Optimising bowel preparation before colonoscopy

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The importance of adequate bowel cleansing for effective colonoscopy

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A clean colon is required for a colonoscopy to be effective. Therefore, patients undergo a bowel preparation in advance of the procedure to clear the colon. Typically, this involves drinking 2 litres of polyethylene glycol or macrogol (PEG) solution, but dislike of the taste or having to drink such a large volume causes some patients not to adhere to this regimen. To address this, a PEG solution has been developed that requires patients to drink only 1 litre of bowel preparation in two flavours. The hope is this will increase patient adherence

This article outlines ways in which nurses can achieve adequate bowel cleansing to ensure safe and effective colonoscopy, supported by the latest evidence and expert-panel guidelines. The different bowel preparations available are outlined, with particular reference to PLENVU®* (macrogol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride) (Norgine), which reconstitutes to a smaller volume than the alternative PEG options.

What is colonoscopy?

Colonoscopy is a visual examination of the large bowel that uses a flexible tube to examine the whole of the colon. During the test, diagnostic samples can be taken and therapeutic removal of abnormal pathology, such as polyps, can be performed. To ensure a safe and adequate examination, the colon first has to be cleansed of stool. An oral bowel preparation is usually used for this.

Increasing demand

Demand for colonoscopy doubled between 2012 and 2017 (Shenbagaraj et al, 2019) as a result of the ageing population and the advent of bowel cancer screening, among other reasons. Colorectal cancer is the fourth most common cancer in the UK (Cancer Research UK, 2015). Adenomatous polyps arising in the bowel can develop into adenocarcinoma (Leslie et al, 2002). Detecting and removing adenomatous polyps at colonoscopy can interrupt the adenoma-carcinoma sequence and so reduce the incidence of cancer and the resulting number of deaths (Zauber et al, 2012).

Bowel cancer screening

Bowel cancer screening in the UK includes both flexible sigmoidoscopy and colonoscopy. In the bowel scope programme, all 55-year-olds are invited for a one-off flexible sigmoidoscopy (an endoscopic investigation of the left side of the bowel) (NHS, 2020). Polyps up to 1 cm in diameter can be removed during this procedure (NHS England, 2016). If polyps over this size are found, participants are invited to attend for a colonoscopy to remove the polyp, and to check the rest of the colon and remove other polyps if they are present. Colonoscopy is also offered if the polyp removed is a tubulovillous adenoma. The flexible sigmoidoscopy bowel scope test usually requires the patient to take a home-administered enema before the procedure.

In the colonoscopy screening programme, men and women between the ages of 60 and 74 years are sent home-testing kits every 2 years to check for faecal occult blood. Individuals who have a positive result are invited to attend for a colonoscopy (Public Health England, 2019). The faecal occult blood home test was replaced in June 2019 with the faecal immunochemical test, which is more sensitive to lower concentrations of blood and is specific for human blood. This means it can detect cancers and polyps earlier, and is not affected by red meat in the diet (Bowel Cancer UK, 2020). It is anticipated that this will increase the number of people referred for colonoscopy via the bowel cancer screening programme.

Colonoscopy is generally very safe but involves minor risks such as perforation, bleeding and discomfort (Rabeneck et al, 2008; Zauber et al, 2012; Gavin et al, 2013). Poor bowel preparation can mean that a full colonoscopy may not be able to be completed or that pathology may be missed (Harewood et al, 2003; Froehlich et al, 2005). Caecal intubation rate and polyp detection rate are key performance indicators for colonoscopy (Rees et al, 2016) and are associated with the quality of bowel preparation (Harewood et al, 2003; Froehlich et al, 2005). When screening a healthy asymptomatic population, it is particularly important that participants have

*SmPCs are available at https://www.medicines.org.uk/emc and https://www.medicines.ie

an adequately cleansed bowel so that they are not enduring the risks and discomfort of the procedure unnecessarily.

In addition to bowel cancer screening, colonoscopy may be used to investigate change of bowel habit, rectal bleeding or iron-deficiency anaemia. It is also used for assessment and surveillance of patients with adenomatous polyps, inflammatory bowel disease or a personal or significant family history of bowel cancer (Rutter et al, 2020). An adequately cleansed bowel is also essential for the colonoscopy to be effective in these indications.

How bowel preparations work

Oral bowel preparations work by preventing absorption of water from the colon, by drawing water into the colon or by increasing peristalsis. All of these should cause increased evacuation of the bowel contents, emptying the colon.

The ideal bowel preparation agent would be easy to administer, well tolerated, cleanse the bowel effectively and have few or no side effects (Connor et al, 2012). However, Connor et al also identified that there was no single agent suitable for all clinical scenarios.

A number of different bowel preparations are available, and these are discussed below.

Magnesium carbonate with citric acid*

This is an osmotic agent that acts by drawing water into the colon through the bowel wall. The increased fluid in the bowel stimulates defaecation to help empty the bowel.** The patient only needs to drink a relatively small amount of fluid. The solution is osmotic, and so it draws fluid into the bowel, which can cause electrolyte and fluid disturbances. In addition, it can cause hypermagnesia, and so should be avoided in patients with stage 4 and above chronic kidney disease (Connor et al, 2012).

Picosulphate with magnesium*

These drugs work in two ways. The picosulphate stimulates peristalsis, while the magnesium works osmotically, again drawing water from inside the body into the bowel. The combined effects of increased peristalsis and increased water in the bowel lumen cause frequent bowel motions and help to empty the bowel.** Although the patient only needs to drink a small volume of solution, the preparation is osmotic and so will draw fluid into the bowel, increasing the risk of fluid and electrolyte imbalance (Connor et al, 2012).

Polyethylene glycols (PEG solutions)*

Polyethylene glycol (PEG) (KLEAN-PREP®*) (macrogol 3350, sodium sulphate, sodium bicarbonate, sodium chloride, potassium chloride) [Norgine], [MOVIPREP®*) (macrogol 3350, sodium sulfate, ascorbic acid, sodium ascorbate, sodium chloride, potassium chloride] [Norgine) and PLENVU®* solutions travel through the gut without being absorbed or drawing fluid into the bowel (Connor et al, 2012).** The large amount of fluid in the bowel should then soften the stool and stimulate defaecation. The risk of fluid and electrolyte imbalances is decreased (Connor et al, 2012). As outlined later in this article, with KLEAN-PREP®* and MOVIPREP®*, patients have been required to drink large volumes of solution. Despite this and their side-effect profile (*Table 1*), it has been suggested that PEG solutions may be the first-choice bowel preparation for many patients requiring a colonoscopy (Bechtold et al, 2016; Hassan et al, 2019). They must, of course, be consumed in accordance with the manufacturer's instructions for use.

Getting closer to the ideal bowel preparation

The problem with PEG solutions thus far has been the volume that patients have been required to drink. With KLEAN-PREP®*, patients need to drink 4 litres of PEG solution, which may reduce adherence (Ell et al, 2008; Hassan et al, 2013) and lead to suboptimal bowel preparation. Acceptability for patients improved with the advent of MOVIPREP®* (Ell et al, 2008), which requires only 2 litres of fluid and 1 litre of clear fluid to be consumed, although patients have still reported difficulties in drinking this amount. With the most recently introduced PEG solution, PLENVU®*, patients only need to drink 1 litre of PEG plus 1 litre of clear fluid. Per-protocol results of a phase III trial showed PLENVU®* had superior bowel cleansing efficacy compared with a 2-litre PEG solution (Bisschops et al, 2019).

There are risks associated with oral bowel preparations. In 2009, a rapid response report was issued by the UK National Patient Safety Agency because a death and over 200 patient safety incidents had been identified with use of oral bowel preparations. Risks of dehydration and electrolyte imbalance were highlighted. The National Patient Safety Agency (2009) recommended that safeguards be put in place to reduce the risks of bowel preparation. These included a clinical assessment for each patient, authorisation by a clinician, a safe system for the supply of bowel preparation to patients and provision of verbal and written explanations to patients on how to use the bowel preparations.

Following the National Patient Safety Agency (2009) rapid response report, the British Society of Gastroenterology published guidance for this procedure (Connor et al, 2012). Recommendations were made on the use of bowel preparations for different patient groups and circumstances.

PLENVU®*

PLENVU®* can be reconstituted at a lower volume than MOVIPREP®* because it has an increased amount of

***SmPCs are available at https://www.medicines.org.uk/emc and https://www.medicines.ie. KLEAN-PREP® is not distributed by Norgine in the Republic of Ireland. **Please refer to the SmPC for further information**

Table 1. Common side effects associated with bowel preparations (BNF, 2020)		
	Drug name	Side effects
	Citric acid with magnesium carbonate*	■ Common or very common: gastrointestinal discomfort; nausea; vomiting ■ Uncommon: dehydration; dizziness; electrolyte imbalance; headache
	Sodium picosulphate with magnesium*	■ Common or very common: gastrointestinal discomfort; headache; nausea ■ Uncommon: confusion; electrolyte imbalance; gastrointestinal disorders; seizures; skin reactions; vomiting
Polyethylene glycols (PEGs)	KLEAN-PREP®*	■ Frequency not known: angiodema; arrhythmia; chills; confusion; dehydration; dizziness; dyspnoea; electrolyte imbalance; fever; flatulence; gastrointestinal discomfort; headache; malaise; nausea; palpitations; seizure; skin reactions; thirst; vomiting
	MOVIPREP®* and PLENVU®*	■ Common or very common: chills; dehydration; dizziness; fever; gastrointestinal discomfort; headaches; hunger; malaise; nausea; sleep disorder; thirst; vomiting ■ Uncommon: arrhythmias; asthenia; drowsiness; dry mouth; dry throat; dysphagia; electrolyte imbalance; hot flush; pain; palpitations; temperature sensation altered ■ Frequency not known: flatulence; hyponatraemic seizure

ascorbate, which works synergistically with the PEG ingredient to achieve the laxative effect. PLENVU®* consists of two 500 ml doses. The first can either be taken on the evening before or the morning of the procedure and the second on the same morning, or both doses can be taken the evening before. The two doses should be separated by at least one hour. PLENVU®* is available in two flavours: mango and fruit punch, one for each dose.

In the Bisschops et al (2019) study, PLENVU®* was found, in the dose split between the evening and morning, to exceed the minimum standards required by the European Society of Gastrointestinal Endoscopy for adequate cleansing of the bowel (Kaminski et al, 2017). Additionally, Bisschops et al (2019) found that PLENVU®* resulted in improved cleansing of the right side of the bowel compared with MOVIPREP®*; this may help in the detection of high-risk sessile serrated adenomas, which require particularly high-quality bowel preparation to enable detection (Clark and Laine, 2016). Furthermore, Bisschops et al (2019) found high levels of patient adherence to and tolerability of PLENVU®*. Side-effects listed for PLENVU®*, as well as those of the other bowel preparations described above, are listed in *Table 1*.

Patient assessment

Whichever bowel preparation is used, it is essential that a full assessment of the patient takes place before prescription and administration. A nurse-led telephone or face-to-face assessment is an ideal way to do this. In turn, this will help ensure that the correct bowel preparation is prescribed and both verbal and written instructions are given to the patient.

A past medical history of congestive cardiac failure and/or renal or liver disease means that any bowel preparation should be prescribed with caution. In these patients, PEG solutions are usually the preferred option, although advice from renal physicians should be sought for patients on haemodialysis. Certainly, use of phosphate-type bowel preparations is strongly discouraged for this group of patients (Connor et al, 2012). Patients with ileostomies, bowel obstruction, toxic megacolon or severe inflammatory bowel disease should not be prescribed oral bowel preparation. Care should also be taken prescribing bowel preparation for patients with swallowing difficulties or a reduced level of consciousness. Patients with diabetes, hypertension, cardiovascular disease, haematuria, renal problems or a family history of kidney disease should have had their kidney function assessed using glomerular filtration rate within 3 months of a bowel preparation being administered (Connor et al, 2012).

Any patient assessment should also consider issues affecting the individual's mobility, as well as their toilet facilities. The bowel preparation will induce frequent visits to the toilet, and the patient will need to be able to access facilities quickly and easily. For some patients, it may be more appropriate to arrange hospital admission to support them to take the bowel preparation safely, conveniently and effectively. Older or frail patients may find the process of taking bowel preparation too difficult or inappropriate. In such cases, computed tomography (CT) examinations of the abdomen, such as CT with faecal tagging, might be considered instead.

Patient medications, including allergies and sensitivities, should be reviewed. Some medications will interact with bowel preparations. These are outlined in *Table 2*, which is adapted from Connor et al, 2012). Oral medications swallowed within one hour of taking the bowel preparation may not

***SmPCs are available at https://www.medicines.org.uk/emc and https://www.medicines.ie**

Table 2. Drugs that have the potential to interact with oral bowel preparations		
Drug type	Potential interaction	Action
Angiotensin-converting enzyme inhibitors*	Deterioration in renal function	If possible, discontinue on the day that the bowel preparation is taken and restart 72 hours after the procedure
Angiotensin II receptor blockers*		
Diuretics*	Increased risk of dehydration	Where possible, stop on the day of the procedure. Otherwise, check electrolytes. Polyethylene glycol (PEG) is preferable. Advise patient on risks of dehydration
Non-steroidal anti-inflammatory drugs*	Reduced kidney capacity to compensate for reduced renal perfusion	Stop during administration of the bowel preparation
Tricyclic antidepressants*	Increased risk of water retention and/or electrolyte imbalance	Check urea and electrolytes before administering bowel preparation
Selective serotonin reuptake inhibitors*		
Carbamazepine*		
Antipsychotic drugs*		
Adapted from Connor et al (2012)		

be properly absorbed, so medication times may need to be altered. Patients taking oral contraception should be advised to take additional precautions. Essential medications, such as immunosuppression for transplant recipients, may need to be given intravenously.

Patients' language and communication issues should be assessed. An interpreter may be required, and the family may need to be involved to help the patient understand the instructions for taking the bowel preparation at home.

Patients with diabetes will need particular attention; the bowel preparation requires consumption of a clear fluid diet. Diabetic patients will thus need specific advice on how to adjust doses of medications and maintain safe blood sugar levels (Joint British Diabetes Societies for Inpatient Care, 2016).

Prescribing the bowel preparation

Once the full assessment has taken place, the decision regarding prescription of the bowel preparation should be made. This should take place after a full discussion with and explanation to the patient. It is essential that the patient understands fully the risks and benefits of undergoing the colonoscopy procedure before taking the bowel preparation; if the patient undertakes the bowel preparation before learning of the risks and then declines the procedure, they will have undergone the risks and inconvenience of bowel preparation unnecessarily.

The patient needs to understand how to take the bowel preparation correctly and follow all the dietary instructions. The tolerability associated with taking the lower-volume PLENVU®* may help improve adherence. Additionally, the fact that this preparation comes in two flavours may make it easier: if the patient finds one flavour unpalatable, they may find the second more acceptable.

Dietary considerations

Patients will benefit from eating a low-fibre diet for a few days before commencing bowel preparation (Hassan et al, 2019). Examples of low-fibre foods that should be encouraged and high-fibre foods that should be avoided are outlined in *Table 3*.

Patients are asked to stop eating a solid diet while they are taking the bowel preparation and to remain on clear fluids. Instructions will usually tell the patient to stop taking solid foods from a specified time on the day before the procedure. Typical advice is listed in *Table 4*. Guidance may differ between endoscopy units, and this should be borne in mind when advising patients.

Patient advice

The instructions for taking the preparation should be given both verbally and in writing. Patients should be given contact numbers to call if they feel unwell while taking the bowel preparation. They should be advised that they may get some abdominal pain, nausea and vomiting, as well as diarrhoea. They should also be advised to look out for signs of dehydration, including dizziness or confusion.

Preparations may be more palatable for patients if chilled before drinking. Patients should also be encouraged to drink plenty of clear fluids in addition to the bowel preparation and informed when mandatory fluids need to be consumed.

Owing to the frequency of the bowel motions caused by the

*SmPCs are available at https://www.medicines.org.uk/emc and https://www.medicines.ie

Table 3. An example of low-fibre diet advice given to patients in advance of bowel preparation	
Three days before the procedure	
You need to follow a low-fibre diet for at least 3 days before the procedure to help your bowel empty properly for the colonoscopy. A low-fibre diet consists of foods that are easy to digest and avoids foods containing high fibre	
High-fibre foods to avoid	Bread: wholemeal, high bran, granary, highfibre or half wholegrain
	Wholemeal pittas, chapatis, crumpets, scones and muffins
	Cereal bars, digestive biscuits, fruit cake, fig rolls
	Wholemeal lasagna or pasta
	Brown rice
	High-fibre or bran crispbreads and crackers
	Wholemeal, wholegrain bran or high-fibre cereals, porridge and muesli
	Nuts
	Vegetables and salad
	Fruit: fresh, frozen, cooked and dried
	Beans, lentils and chickpeas
	Potatoes with skins on
Low-fibre foods you can eat	White cereals such as cornflakes or rice-based cereals
	White rice and pasta
	Plain white biscuits, such as rich tea, custard creams, Nice or malted milk
	White bread, crumpets and scones (without dried fruit)
	Well-cooked tender meat, fish, cheese or egg
	Stewed fruit
	Potatoes without the skin

preparations, patients should be advised to stay near a toilet. Additionally, the frequent bowel motions may mean some patient get anal soreness. Application of a barrier cream may help reduce or prevent this.

Conclusion

The ageing population and the bowel cancer screening programme have increased demand for colonoscopy. However, for colonoscopy to be safe and effective, consumption of a high-quality oral bowel preparation is required. Risks have been identified with oral bowel preparations, and therefore recommendations for their use have been put in place.

Table 4. Typical dietary instructions when taking bowel preparation
The day before the test: **2 pm**
Do not eat any more solid food after this time. You should drink plenty of clear fluids; water is best
You are allowed:
Water
Tea and coffee without milk (you can have sugar)
Bovril or Oxo
Clear, thin soups with vegetables and meat strained out
Smooth fruit juice (no bits)
Squash or cordial

These risks include electrolyte imbalance and dehydration. Previously, PEG solutions involved patients drinking large volumes of fluids, which has affected tolerance and adherence. The introduction of lower-volume PEG solutions might improve this situation, with the latest preparation, PLENVU®*, requiring 1 litre of solution to be ingested.

A full assessment of each patient is essential to help ensure effective bowel preparation and to minimise risks to the patient. The bowel preparation must be prescribed and administered correctly. Furthermore, it is essential that patients are given clear instructions, both verbally and in writing, so that they know how to take the preparation correctly, how to recognise any adverse reactions early and when to seek assistance.

The introduction of the low-volume PEG solution PLENVU®* offers effective bowel preparation in a form that is intended to be easy for patients to take. When combined with correct assessment and patient preparation, the safety and effectiveness of the bowel preparation will be optimised. It seems that we are getting closer to the ideal bowel preparation. The rest of this supplement comprises case studies describing the use of PLENVU®* as a bowel preparation in patients attending a cancer screening centre.

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Case studies

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CASE STUDY 1

A 55-year-old woman required a colonoscopy following the removal of three adenomas during a bowel scope screening test. She had no complex comorbidities and, other than diabetes, was relatively fit and healthy. This was her first colonoscopy.

The patient complied with the bowel preparation regimen and said the instructions were 'easy to follow…but the taste was not that good'. She said the solution started to take effect after 30 minutes.

Water immersion was performed during the colonoscopy for insertion. The nurse said that, although views were clear, the colon was 'very loopy'. The problem was resolved by putting the patient in a prone position. The colonoscopy was completed with good bowel preparation, overall.

CASE STUDY 2

Following previous removal of adenomas, a 56-year-old woman was scheduled to have her annual surveillance colonoscopy as part of the bowel cancer screening programme.

For her previous colonoscopy, which had taken place a year earlier, she had taken MOVIPREP®* as the bowel preparation. She said there had been too much to drink and so she was happy to try PLENVU®* this time instead.

The patient complied with the new bowel preparation regimen. She found the first dose easy to take, but said the second dose had a 'very strong taste' and did not make her go to the toilet more often than had been the case with MOVIPREP®* a year previously.

The colonoscopy was straightforward, with an easy

insertion to the caecum and very clean. Two polyps were removed.

Overall, the patient said PLENVU®* was easier to use than MOVIPREP®* and required less water.

CASE STUDY 3

A 55-year-old woman was due to have her first colonoscopy after a bowel scope screening test identified a 25 mm polyp. PLENVU®* was chosen because of her age and hypertension being her only comorbidity.

The patient found the instructions for use on PLENVU®* 'very easy to follow'. She said it tasted strong 'like Lemsip', but that the taste of the second dosage was 'not good'. She said PLENVU®* started working after 2 hours, and she was up all night going to the toilet.

The colonoscopy was straightforward, with minimal need for additional bowel cleansing and irrigation from the endoscopist. Five polyps were identified and removed.

CASE STUDY 4

A 61-year-old man was scheduled for a surveillance colonoscopy. He last had a colonoscopy 3 years earlier, about which he could remember little, although he did say it 'was fine'. He was willing to try another preparation. His only comorbidity was hypertension.

The patient said the instructions for use for PLENVU®* were 'easy to understand' and the drink itself 'was good'. The specialist screening practitioner stated that preparation with PLENVU®* was excellent and the colonoscopy to the terminal ileum was straightforward. The findings were considered normal.

CASE STUDY 5

A 55-year-old man presented for his first colonoscopy after his bowel scope screening test identified a 10 mm rectal polyp. His comorbidities were hypertension and atrial fibrillation, but he was otherwise fit and in good health.

The patient complied with the PLENVU®* regimen, saying it was 'easy to use' but 'overly sweet'. The colonoscopy was successful: intubation took 4 minutes, minimal washing was required and there were excellent views. Several biopsies were taken, and a polypectomy was performed.

CASE STUDY 6

Following abnormal faecal immunochemical test (FIT) results, a 64-year-old man was referred for his first colonoscopy. He had no relevant comorbidities; hypercholesterolaemia was noted.

The patient complied with the PLENVU®* bowel preparation regimen, commenting that it was 'easy to take'. He said that, although it made him feel a little sick at first, he soon got used to it. The bowel preparation was successful, and little cleansing was required during the colonoscopy. Several polyps were removed.

CASE STUDY 7

A male patient of screening age needed a colonoscopy following abnormal FIT results. The patient had last had a colonoscopy 4–5 years previously. As far as he could recollect, the bowel preparation had been 'fine' and he had complied with the regimen, which had been effective.

The patient had no relevant comorbidities. PLENVU®* was selected because he was regarded as at low risk, being relatively young and fit, with no comorbidities.

The patient said that PLENVU®* tasted 'better' than the previous bowel preparation he had used. It took about 3 hours to take effect.

The intubation time was 7 minutes, during which 300 ml was suctioned. Thirteen polyps were removed.

CASE STUDY 8

A 55-year-old woman was due to have her first colonoscopy after a polyp was observed during bowel scope screening. Her only relevant comorbidity was hypertension.

The patient complied with the bowel preparation regimen, commenting that PLENVU®* was easy to drink, although she said it was 'too sweet' for her, resulting in her taking it with a lot of water. This did not make her feel nauseous.

The bowel preparation for this patient was considered good. Two 50 ml syringe washes were used to cleanse the bowel, and the colon was observed to be wet and bubbly. Clear views were achieved. Two polypectomies were performed, after which withdrawal took 13 minutes.

*SmPCs are available at https://www.medicines.org.uk/emc and https://www.medicines.ie

UK AND IE PRESCRIBING INFORMATION: Moviprep and Moviprep Orange
(Macrogol 3350, sodium sulphate anhydrous, ascorbic acid, sodium ascorbate, sodium chloride and potassium chloride)

PLEASE REFER TO THE FULL SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) BEFORE PRESCRIBING.

Presentation: Powder for oral solution contained in two separate sachets, A and B. Sachet A contains macrogol 3350 100 g; sodium sulfate anhydrous 7.5 g; sodium chloride 2.691 g and potassium chloride 1.015 g. Sachet B contains ascorbic acid 4.7 g and sodium ascorbate 5.9 g.

Uses: Bowel cleansing prior to any clinical procedure requiring a clean bowel.

Dosage and administration: For oral use. ***Adults and older people:*** A course of treatment consists of two litres of Moviprep/Moviprep Orange. A litre consists of one sachet A and one sachet B dissolved together in water to make one litre of solution. The reconstituted solution should be drunk over a period of one to two hours. This process should be repeated with a second litre to complete the course. A further litre of clear fluid is recommended during the course of treatment.

This course of treatment can be taken either as divided or as single doses and timing is dependent on whether the clinical procedure is conducted with or without general anaesthesia as specified below:

For procedures conducted under general anaesthesia:

1. Divided doses: one litre in the evening before and one litre in the early morning of the day of the clinical procedure. Ensure consumption of Moviprep/Moviprep Orange as well as any other clear fluids has finished at least two hours before the start of the clinical procedure.
2. Single dose: two litres in the evening before the clinical procedure or two litres in the morning of the clinical procedure. Ensure consumption of Moviprep/Moviprep Orange as well as any other clear fluids has finished at least two hours before the start of the clinical procedure.

For procedures conducted without general anaesthesia:

1. Divided doses: one litre in the evening before and one litre in the early morning of the day of the clinical procedure. Ensure consumption of Moviprep/Moviprep Orange as well as any other clear fluids has finished at least one hour before the start of the clinical procedure.
2. Single dose: two litres in the evening before the clinical procedure or two litres in the morning of the clinical procedure. Ensure consumption of Moviprep/Moviprep Orange has finished at least two hours before the start of the clinical procedure. Ensure consumption of any clear fluids has finished at least one hour before the clinical procedure.

Patients should be advised to allow for appropriate time to travel to the colonoscopy unit.

No solid food should be taken from the start of the course of treatment until after the clinical procedure.

Children: Not recommended below 18 years of age.

Contraindications: Known or suspected hypersensitivity to any of the ingredients, gastrointestinal obstruction or perforation, disorders of gastric emptying, ileus, phenylketonuria, glucose-6-phosphate dehydrogenase deficiency, toxic megacolon which complicates very severe inflammatory conditions of the intestinal tract including Crohn's disease and ulcerative colitis. Do not use in unconscious patients.

Warnings and precautions: Diarrhoea is an expected effect. Administer with caution to fragile patients in poor health or patients with serious clinical impairment such as impaired gag reflex, or with a tendency to aspiration or regurgitation, impaired consciousness, severe renal insufficiency (creatinine clearance <30 ml/min), cardiac impairment (NYHA grade III or IV), those at risk of arrhythmia (e.g. those on treatment for cardiovascular disease or who have thyroid disease), dehydration, severe acute inflammatory bowel disease.

Dehydration, if present, should be corrected before using Moviprep/Moviprep Orange. The reconstituted Moviprep/Moviprep Orange does not replace regular fluid intake and adequate fluid intake must be maintained.

Semi-conscious patients or patients prone to aspiration or regurgitation should be closely monitored during administration, particularly if this is via a nasogastric route. If symptoms indicating arrhythmia or shifts of fluid or electrolytes occur, plasma electrolytes should be measured, ECG monitored and any abnormality treated appropriately. 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. The possibility of serious arrhythmias, predominantly in those with underlying cardiac risk factors and electrolyte disturbance cannot be ruled out. If patients experience symptoms which make it difficult to continue the preparation, they may slow down or temporarily stop consuming the solution and should consult their doctor. Moviprep Orange is not recommended for patients with glucose-galactose malabsorption.

Moviprep/Moviprep Orange contains 363.2 mmol (8.4 g) of sodium per course of treatment (two litres) equivalent to 420% of the WHO recommended maximum daily intake of 2 g of sodium for an adult. To be taken into consideration by patients on a controlled sodium diet. Only a proportion (up to 112.4 mmol (2.6 g) per course of treatment) of sodium is absorbed. It also contains 28.4 mmol (1.1 g) of potassium per two litres. To be taken into consideration in patients with reduced kidney function or patients on a controlled potassium diet.

Interactions: Oral medication should not be taken within one hour of administration as it may be flushed from the GI tract and not absorbed.

Fertility, pregnancy and lactation: There are no data on the effects on fertility. There are no data on the use in pregnancy or lactation so it should only be used if judged essential by the physician.

Effects on ability to drive and use machines: No influence on the ability to drive and use machines

Side effects: ***Very common:*** abdominal pain, nausea, abdominal distension, anal discomfort, malaise and pyrexia. ***Common:*** sleep disorder, dizziness, headache, vomiting, dyspepsia, rigors, thirst and hunger. ***Uncommon:*** dysphagia, abnormal liver function tests and discomfort. ***Not known:*** allergic reaction including anaphylactic reaction, dyspnoea and allergic skin reactions including angioedema, urticaria, pruritus, rash, erythema; electrolyte disturbances including blood bicarbonate decrease, hyper- and hypocalcaemia, hypophosphataemia, hypokalaemia and hyponatremia and changes in the blood chloride levels; dehydration; convulsions associated with severe hyponatraemia; transient increase in blood pressure; arrhythmia, palpitations; flatulence and retching.

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

UNITED KINGDOM

Price and pack sizes: Lemon- or orange-flavoured powder in sachets, 1 treatment pack (2 x sachet A + 2 x sachet B) £10.36.
Legal category: Pharmacy medicine.
MA Number: PL 20011/0039 (Moviprep); PL 20011/0006 (Moviprep Orange).
MA Holder: Norgine Pharmaceuticals Limited, Norgine House, Widewater Place, Moorhall Road, Harefield, Uxbridge, UB9 6NS, UK.

IRELAND

Price and pack sizes: Lemon- or orange-flavoured powder in sachets, 1 treatment pack (2 x sachet A + 2 x sachet B) €13.26.
Legal category: Product subject to medical prescription which may be renewed.
MA Number: PA 1336/001/001 (Moviprep); PA 1336/001/002 (Moviprep Orange).
MA Holder: Norgine BV, Antonio Vivaldistraat 150, 1083 HP Amsterdam, The Netherlands.

Additional information is available on request or in the SmPC. For further information contact: Norgine Pharmaceuticals Limited, Norgine House, Moorhall Road, Harefield, Middlesex, UB9 6NS, UK. Tel: +44(0)1895 826606. Email: medinfo@norgine.com

Date of preparation: Jan 2020
Company reference: UK/MPR/0120/0197

United Kingdom
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

Ireland
Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie; E-mail: medsafety@hpra.ie. Adverse events should also be reported to Norgine Pharmaceuticals Ltd on: Tel: +44 (0)1895 826 606. Email: medinfo@norgine.com

Klean-Prep Prescribing information

REFER TO FULL SUMMARY OF PRODUCT CHARACTERISTICS (SMPC) BEFORE PRESCRIBING

Presentation: A box containing four 69-gram sachets, containing a whitish powder. Each sachet contains: 59.000g macrogol 3350; 5.685g anhydrous sodium sulphate; 1.685g sodium bicarbonate; 1.465g sodium chloride; 0.7425g potassium chloride. Also contains aspartame and vanilla flavour.

Uses: Colonic lavage prior to diagnostic examination or surgical procedures requiring a clean colon e.g. colonoscopy, barium enema or colonic resection.

Dosage and administration:

Adults (including the elderly): The contents of one sachet to be dissolved in 1 litre of water. Usual dose is up to 4 sachets taken at a rate of 250ml every 10- 15 minutes until the total volume is consumed or rectal effluent is clear, or as directed by the physician. The solution from all 4 sachets should be drunk within 4–6 hours. Alternatively, administration may be divided, for example, taking 2 sachets during the evening before the examination, and the remaining 2 sachets on the morning of the examination. If administered by nasogastric tube, the rate of administration should be 20-30ml/minute.

Children: There is no recommended dosage.

Contraindications, warnings etc:

Contraindications: Known or suspected gastro-intestinal obstruction or perforation, ileus, gastric retention, toxic colitis, toxic megacolon. Congestive cardiac failure (NYHA class III or IV) and hypersensitivity to any of the ingredients.

Warnings: No solid food should be taken for at least 2 hours before taking Klean-Prep. Administer with caution in patients with impaired gag reflex, reflux oesophagitis, those with diminished levels of consciousness and patients with ulcerative colitis. Unconscious or semi-conscious patients or patients prone to aspiration or regurgitation should be observed during administration, especially if this is via the nasogastric route. There have been reports of pulmonary oedema resulting from aspiration of macrogol lavage solutions requiring immediate treatment.

Use with care in patients at risk of electrolyte disturbance, such as patients with renal failure, mild (NYHA class I and II) congestive cardiac impairment (see contraindications), or those simultaneously treated with diuretics.

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

Klean-Prep contains aspartame, which may be harmful for patients with phenylketonuria.

In debilitated 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.

Interactions: Oral medications taken within 1 hour of administering Klean-Prep may be flushed from the gastrointestinal tract and not absorbed.

Pregnancy and lactation: There is no experience of use in pregnancy, this should only be used if considered essential by the physician.

Side effects: The most commonly experienced undesirable effects are gastrointestinal in nature e.g. vomiting, nausea, abdominal pain, anorectal discomfort, abdominal distension and flatulence.

Should nausea, vomiting, abdominal pain or distension arise, the rate of administration should be slowed down or temporarily stopped until the symptoms subside.

Allergic reactions including anaphylactic reaction, dyspnoea, skin reactions e.g. angioedema, urticaria, pruritus, rash, erythema may occur.

Other effects include rigors and convulsions associated with severe hyponatraemia, headaches, transient increase in blood pressure, arrhythmia, palpitations.

Refer to the Summary of Product Characteristics (SmPC) for full list and frequency of adverse events.

Pharmaceutical Particulars: Store in a cool dry place below 25°C.

The reconstituted solution should be refrigerated (2–8°C) and be used within 24 hours.

LICENSING AND LEGAL CATEGORY:
Legal category: P
Packs: One pack of Klean-Prep contains a single treatment
Cost: £9.98

Marketing Authorisation Number: PL 00322/0068

NORGINE

For further information contact: Norgine Pharmaceuticals Limited, Norgine House, Moorhall Road, Harefield, Middlesex, United Kingdom UB9 6NS. Telephone: +44(0)1895 826606. Email: medinfo@norgine.com

Date of preparation: April 2020

Code: UK-GE-KLE-2000001

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

KLEAN-PREP® is not distributed by Norgine in the Republic of Ireland

UK AND IE 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 100 g, sodium sulfate anhydrous 9 g, sodium chloride 2 g, potassium chloride 1 g. Dose 2 is made up of 2 sachets (A and B). Sachet A contains: macrogol 3350 40 g, sodium chloride 3.2 g, potassium chloride 1.2 g. Sachet B contains: sodium ascorbate 48.11 g, ascorbic acid 7.54 g.

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 500 ml doses of Plenvu. At least 500 ml 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.

The sodium content, 458.5 mmol (10.5 g), should be taken into consideration for patients on a controlled sodium diet. The potassium content, 29.4 mmol (1.1 g), 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

IRELAND
Legal category: Product subject to medical prescription which may be renewed
MA Number: PA 1336/005/001
MA Holder: Norgine BV, Hogehilweg 7, 1101CA Amsterdam ZO, The Netherlands

Additional information is available on request or in the SmPC. For further information contact: Norgine Pharmaceuticals Limited, Norgine House, Moorhall Road, Harefield, Middlesex, United Kingdom UB9 6NS. Telephone: +44(0)1895 826606. Email: medinfo@norgine.com

Date of preparation: March 2019

Company reference: UK/PLV/0319/0147

United Kingdom
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

Ireland
Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. Adverse events should also be reported to Norgine Pharmaceuticals Ltd on:
Tel: +44 (0)1895 826 606
Email: medinfo@norgine.com

Job code: UKE-GE-PLV-2000002

Date of preparation: June 2020