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Evidence Update

Gastroenterology

Real-world usage study and survey of oral bowel cleansing for colonoscopy in Dudley, UK

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Evidence update: real-world usage study and survey of oral bowel cleansing for colonoscopy in Dudley, UK

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Foreword

As an endoscopy nurse, I come into regular contact with patients who need to take oral bowel preparation for their colonoscopy or sigmoidoscopy procedures. Oral bowel preparation taken correctly is vital to ensure that a patient's bowel is effectively prepared and clean enough for a thorough and high-quality examination. Therefore, patient compliance with taking the bowel preparation as prescribed is necessary.

In my experience many patients report that taking oral bowel preparation is the worst part of their endoscopy experience, stating it is worse than the actual endoscopic procedure itself. Some patients find that the volume of the preparation is difficult to manage, and they also complain about the flavour of the preparation. If a patient is unable to follow the oral bowel preparation regimen this can lead to an insufficiently cleansed bowel and the necessity of repeat or alternative investigations.

When I learnt about PLENVU®[1] (macrogol 3350, sodium ascorbate, ascorbic acid, sodium sulfate anhydrous, potassium chloride, sodium chloride)—a bowel preparation that offers a lower volume than MOVIPREP®[2] (macrogol 3350, sodium sulfate anhydrous, ascorbic acid, sodium ascorbate, sodium chloride, and potassium chloride) and KLEAN-PREP®[3] (macrogol 3350, anhydrous sodium sulfate, sodium bicarbonate, sodium chloride, potassium chloride), and with new flavours—I could see that there may be greater patient compliance, which could lead to greater efficacy of preparation. Therefore, I arranged a 3-month trial in the endoscopy unit where I am based. An audit of this trial would determine if patients were more compliant with a treatment that offered less volume to be consumed and different flavours. Efficacy of this preparation would also be reviewed to determine if the treatment was as efficient as the existing preparation being used.

We used PLENVU® alongside the existing oral bowel preparation and each patient who had taken PLENVU® preparation was asked to complete a satisfaction survey including reactions to the volume, the taste, and comparison to other oral bowel preparations they may have used before. We also recorded the endoscopists' opinion on the efficacy of the bowel preparation during the endoscopic procedures.

The importance of bowel cleansing for colonoscopy

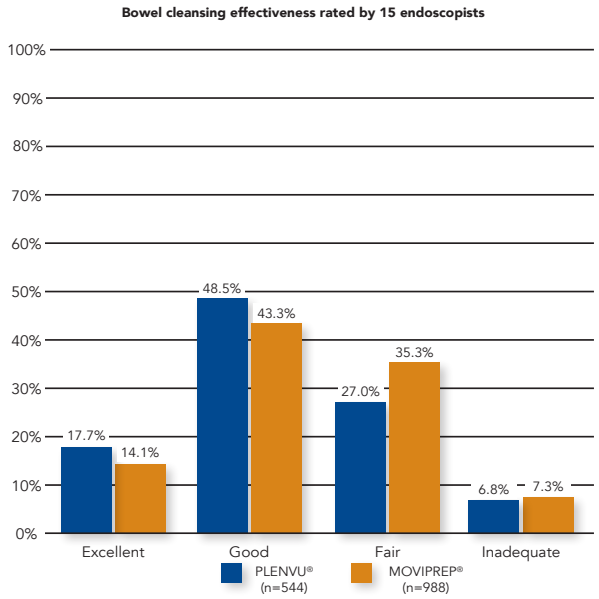
Bowel cleansing is vital to ensure a good quality endoscopic examination of the bowel and identify any lesions and potential cancers, yet an audit carried out in the UK showed that 22.2% of poor bowel preparation was a reason for incomplete colonoscopies, which led to missing lesions and more repeat procedures.[4] An adequate level of bowel cleansing is essential and important for the efficacy of colonoscopy. However, further costs and rescheduling/alternative procedures arise due to inadequate level of bowel cleansing.[5] The European Society of Gastrointestinal Endoscopy (ESGE) has proposed a minimum rate of adequate bowel preparation of ≥90% and a target standard rate of ≥95%.[6]

Patient perspectives on bowel preparations

Healthcare professionals working in the Colonoscopy Pre-Assessment Clinic will be well aware that, for patients scheduled to undergo colonoscopy, anxiety, and trepidation around the use of bowel preparation is commonplace. The taste and the volume of the bowel preparation treatments are two key concerns raised by patients. These issues may affect patients' compliance with bowel cleansing regimen required prior to colonoscopy and compromise outcomes from the procedure.

Many patients struggle to tolerate the quantities of fluid involved in bowel preparation regimens, which can entail several litres of liquid consumed over a relatively short period of time. Some individuals complain that the taste of the bowel preparation itself is extremely unpalatable and will resort to strategies, such as flavouring with squash or drinking through a straw. The need to adhere to a low-residue diet can also have a negative impact on patients' everyday life in the run up to the colonoscopy procedure.

Figure 1: Showing the study results for both PLENVU® and MOVIPREP®



Study and patient survey

PLENVU® is the first 1 litre PEG preparation to become available. It consists of a taste-optimised combination of two different formulations, designed to maximise adherence and to work synergistically for bowel cleansing. PLENVU® has two flavours—dose one is mango and dose two is fruit punch.[7]

This study at the Dudley Group NHS Foundation was undertaken to compare PLENVU® to MOVIPREP® in terms of both efficacy and patient satisfaction. The effectiveness of the two different bowel cleansing preparations was compared by the treating endoscopists and a patient survey carried out to gauge patients' opinions of the new treatment.[8]

During this study, all non-bowel cancer screening programme (BCSP) patients were supplied with PLENVU® unless another preparation was specifically requested by the referrer; all BSCP colonoscopy patients used MOVIPREP® distributed by a specialist screening practitioner.[8] Both PLENVU® and MOVIPREP® were prescribed and used in accordance with the recommendations laid out in their summaries of product characteristics.[1,2]

Efficacy

A Unisoft analysis was carried out over a 7-month period from 1 January 2019 onwards, looking at 544 cases where PLENVU® was used as bowel preparation, and 988 cases where MOVIPREP® was used. The efficacy of the bowel preparation was rated as excellent, good, fair, or inadequate by 15 endoscopists, using the standard endoscopy reporting tool. Of these 15 endoscopists; seven were gastroenterology consultants, one gastroenterology registrar, and seven colorectal surgical consultants.[8]

Overall, study results showed that both PLENVU® and MOVIPREP® performed similarly and were equally effective in preparing the bowel for colonoscopy (Figure 1). PLENVU® was rated as good or excellent by endoscopists in 66% (360/544) of cases, compared with 57% (567/988) for MOVIPREP®. In total, 27% (147/544) of endoscopists judged the bowel cleansing of PLENVU® as fair and only 6.8% (37/544) rated it as inadequate, which compares favourably to MOVIPREP®, which was rated fair in 35% (349/988) of cases and inadequate in 7.3% (72/988).[8] Both PLENVU® (93.2%) and MOVIPREP® (92.7%) achieved the ESGE minimum rate of ≥90% adequate bowel preparation.[6]

Patient survey

The patient satisfaction survey provided a snapshot of opinion from 33 patients who received PLENVU® for bowel preparation prior to colonoscopy. The patients were asked some questions:[6]

- Question 1: did you follow the 3-day low-residue diet plan?
- Question 2: did you take all of the PLENVU®?
- Question 3: did you find the instructions for taking the preparation easy?
- Question 4: did you like the flavour of the PLENVU®?

Out of 33 patients, 30 patients (91%) adhered to the low-residue diet required prior to colonoscopy. In the three cases (9%) where patients did not, this was due to short-notice appointments and only one of those patients failed to achieve a good bowel preparation.[8]

The vast majority of patients successfully completed dosing of the PLENVU® bowel preparation prior to their colonoscopy. Overall, 31 out of 33 patients (94%) took all of the preparation as required. One patient (3%) left half of the second dose and the preparation was inadequate and required rebooking. Thirty patients (>90%) found the instructions for taking the PLENVU® preparation easy to understand.[8]

When directly questioned about whether they liked the flavour of PLENVU®, 19 patients (58%) answered no. Despite the negative feedback on taste expressed by some patients, it is important to note that around half of those questioned (the remaining 42% of patients) were satisfied with the flavour of PLENVU®.

Adverse events

Of the 33 patients surveyed, specific complaints reported by patients included isolated incidents of nausea, vomiting, and heaving. One patient (3%) was sick after completing both doses and one patient (3%) left 200 ml due to heaving, however, both

preparations were rated 'fair' and the procedure was complete.

Comparing with the clinical trial data

Overall, results from this study correspond closely with findings from Phase III trials of PLENVU®. Phase III clinical studies have evaluated PLENVU® using both the Harefield Cleansing Scale (HCS) and Boston Bowel Preparation Study (BBPS), and these studies have shown that it is effective for overall bowel and right-sided colon cleansing.[9,10] In the MORA study, a randomised, blinded, multicentre, parallel-group trial, PLENVU® was directly compared with the standard PEG-based bowel preparation with ascorbate (2LPEG) in 849 patients undergoing colonoscopy. PLENVU® demonstrated superior colon cleansing efficacy—achieving overall cleansing success rates of 97.3% when given as an evening/morning regimen and 92.7% when used morning-only in the per protocol population.[7]

Results from the MORA Phase III trial looking at patient perceptions and opinions of PLENVU® also align with those reported in this study. Based on patient diary responses in the MORA trial, the overall tolerability and acceptability of PLENVU® was similar to the 2LPEG bowel preparation with self-reported adherence rates of around 90% across all treatment groups. The vast majority of patients in the Phase III trial (92–94%) said that PLENVU® was not very difficult to drink and almost all (97–99%) found the product instructions easy to follow. On the issue of taste, approximately 95% of patients in the Phase III study rated the taste of PLENVU® as 'not very unacceptable' and the same proportion felt that taking the same bowel preparation again would be acceptable. Overall, 93% of patients on the split-dosing PLENVU® regimen and 90% on the morning-only dose managed to complete their bowel preparation process without significant interference with normal daily activities, compared with 88.5% of patients in the 2LPEG group.[7]

In the Phase III study, the overall safety profile of PLENVU® was also comparable to that of 2LPEG. Treatment-related adverse events were mostly gastrointestinal, but were typically mild or moderate in severity and only transient.[7]

Most patients regard bowel preparation as an extremely unpleasant part of the overall colonoscopy experience. Both patients' satisfaction and their compliance with the prescribed bowel preparation regimen may, therefore, be improved by availability of a lower volume and more palatable oral cleansing treatment. Compliance with the bowel cleansing preparation is crucial in order to ensure the diagnostic success of the colonoscopy. In this real-world study, PLENVU® showed equivalent, if not slightly better, bowel cleansing efficacy to MOVIPREP® as assessed by endoscopists, with 66% classing it as good or excellent compared with 57% for MOVIPREP®.

Key points

- Effective bowel preparation is vital for a good quality endoscopic procedure
- Poor bowel preparation may mean pathology and lesions are missed
- Poor bowel preparation will require either repeat procedures or alternative investigations
- Full patient compliance with a low-residue diet is necessary for maximum effectiveness of oral bowel cleansing
- Full patient compliance with oral bowel cleansing preparation is needed to ensure the bowel is optimally cleansed
- Patients should seek advice from a healthcare professional if they experience problems or have any questions with the low-residue diet or bowel cleansing preparation.

References

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Conflicts of interest

Samantha Horley received an honorarium from Norgine Pharmaceuticals Limited.

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

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: November 2020

Company reference: UK-GE-PLV-2000020

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

UK PRESCRIBING INFORMATION: Moviprep and Moviprep Orange

(Macrogol 3350, sodium sulfate 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 100g; sodium sulfate anhydrous 7.5g; sodium chloride 2.691g and potassium chloride 1.015g. Sachet B contains ascorbic acid 4.7g and sodium ascorbate 5.9g.

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.

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.

Moviprep/Moviprep Orange contains 363.2 mmol (8.4g) of sodium per course of treatment (two litres) equivalent to 420% of the WHO recommended maximum daily intake of 2g 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 (2.6g) per course of treatment) of sodium is absorbed. It also contains 28.4 mmol (1.1g) 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 decreased, 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

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

Date of preparation: November 2020

Company reference: UK-GE-MPR-2000004

United Kingdom

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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 49mg 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.

Contra-indications, warnings etc:

Contra-indications: 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 contra-indications), 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.

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.

This medicinal product contains 125 mmol (2.9 g) sodium per sachet of treatment. To be taken into consideration by patients on a controlled sodium diet.

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 : £10.48

Marketing Authorisation Number: PL 00322/0068

For further information contact:

NORGINE

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Date of preparation: September 2020

Code: UK-GE-KLE-2000002

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple store. Adverse events should also be reported to Medical Information at Norgine Pharmaceuticals Ltd on 01895 826606.

Guidelines in practice