

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.

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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:

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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 Pharmaceuticals Limited
Moorhall Road
Harefield
Middlesex
UB9 6NS
Tel: 01895 826606
E-mail: medinfo@norgine.com

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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.