

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1 NAME OF THE MEDICINAL PRODUCT

KLEAN PREP 69g, sachet powder for oral solution

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of Klean-Prep contains the following active ingredients:

Macrogol 3350	59.000 g
Anhydrous Sodium Sulfate	5.685 g
Sodium Bicarbonate	1.685 g
Sodium Chloride	1.465 g
Potassium Chloride	0.7425 g

The content of electrolyte ions per sachet when made up to one litre of water is as follows:

Sodium	125 mM
Sulfate	40 mM
Chloride	35 mM
Bicarbonate	20 mM
Potassium	10 mM

Excipient with known affect:

Aspartame 49mg per sachet.

For the full list of excipients, see 6.1.

### 3 PHARMACEUTICAL FORM

Powder for oral solution.

A whitish powder which, when dissolved in water, gives a clear, colourless solution for oral administration.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

For colonic lavage prior to diagnostic examination or surgical procedures requiring a clean colon, eg colonoscopy, barium enema or colonic resection.

## 4.2 Posology and method of administration

**Adults:** Each sachet should be dissolved in 1 litre of water. The usual dose is up to 4 sachets taken at a rate of 250ml every 10 to 15 minutes until the total volume is consumed or rectal effluent is clear, or as directed by the physician.

The solutions from all 4 sachets should be drunk within 4 to 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 administration is by nasogastric tube, the usual rate should be 20 to 30ml/minute.

**Children:** There is no recommended dosage.

**Renal patients:** No dosage adjustment need be made.

## 4.3. Contraindications

Do not use in patients with known or suspected:

- hypersensitivity to the active substances or to any of the excipients listed in section 6.1
- gastrointestinal obstruction or perforation
- ileus
- gastric retention
- toxic colitis and toxic megacolon
- congestive cardiac failure (NYHA class III or IV)

## 4.4. Special warnings and precautions for use

The fluid content of Klean-Prep when reconstituted with water does not replace regular fluid intake and adequate fluid intake must be maintained.

No solid food should be eaten for at least 2 hours before taking Klean-Prep. The product should only be administered with caution to patients with impaired gag reflex, reflux oesophagitis, or those with diminished levels of consciousness and patients with ulcerative colitis.

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.

Unconscious, 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.

Although not expected due to the isotonic composition of the product, cases of electrolyte disturbances have been rarely reported in at-risk patients. Therefore, Klean-Prep should be used 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 also section 4.3), or those simultaneously treated with diuretics.

Convulsions associated with severe hyponatraemia in patients taking Klean-Prep have been reported (see section 4.8).

Patients may also develop confusional state/disorientation associated with hyponatraemia (see section 4.8).

Cases of seizures associated with use of macrogol 3350 with electrolytes for bowel preparation were observed in patients either with or without prior history of seizures. These cases were mostly associated with electrolyte abnormalities such as severe hyponatraemia (see section 4.8). Use caution when prescribing macrogol 3350 with electrolytes in patients with a history of seizures, at increased risk of seizure or at risk of electrolyte disturbance. In case of neurologic symptoms, fluid and electrolyte abnormalities should be corrected.

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

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.

Caution should be used in patients with an impaired gag reflex, reflux oesophagitis, or diminished levels of consciousness.

Cases of oesophageal rupture (Boerhaave syndrome) associated with excessive vomiting after intake (see section 4.8) of macrogol 3350 with electrolytes for bowel preparation has been reported post-marketing, mostly in elderly patients. Advise patients to stop administration and seek immediate medical assistance if they experience incoercible vomiting and subsequent chest, neck, and abdominal pain, dysphagia, hematemesis or dyspnoea.

Klean-Prep contains aspartame, which is metabolised to phenylalanine. This may be harmful for patients with phenylketonuria.

#### Ischaemic colitis

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.

Neither non-clinical nor clinical data are available to assess aspartame use in infants below 12 weeks of age.

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 patients with swallowing problems, who need the addition of a thickener to solutions to enhance an appropriate intake, interactions should be considered, see section 4.5.

## 4.5 Interaction with other medicinal products and other forms of interaction

The interaction of Klean-Prep with other medicinal products has not been studied. Theoretically, oral medication (e.g. oral contraceptive pill) taken one hour before, during and one hour after the administration of Klean-Prep may be flushed from the gastro-intestinal tract and not absorbed.

The therapeutic effect of drugs with a narrow therapeutic index or short half-life may be particularly affected.

Klean-Prep may result in a potential interactive effect if used with starch-based food thickeners. The macrogol ingredient counteracts the thickening effect of starch, effectively liquefying preparations that need to remain thick for people with swallowing problems.

#### 4.6. Fertility, Pregnancy and lactation

The preparation should only be used during pregnancy and lactation if considered essential by the physician. There is no experience of use during pregnancy. The purpose and mechanisms of use should be borne in mind if the physician is considering administration.

#### 4.7 Effects on ability to drive and use machines

There is no known effect on the ability to drive and use machines.

#### 4.8. Undesirable effects

The most commonly experienced undesirable effects are gastrointestinal in nature. The following Adverse Events have been observed in post-marketing experience and therefore the frequencies are not known:

<b>System Organ Class</b>	<b>Adverse reaction</b>
Immune system disorders	Allergic reactions including anaphylactic reaction, dyspnoea, skin reactions (see below)
Metabolism and nutrition disorders	Electrolyte disturbances, specifically Hypokalaemia, hyponatraemia and dehydration.
Nervous System Disorders	Seizures, convulsions (see section 4.4), confusional state/disorientation (see section 4.4), headaches and dizziness
Cardiac disorders	Transient increase in blood pressure, arrhythmia, palpitations.
Gastrointestinal disorders	Oesophageal rupture (Boerhaave syndrome), vomiting, nausea, abdominal pain, anal discomfort, abdominal distension, flatulence.
Skin and subcutaneous tissue disorders	Allergic skin reactions including angioedema, urticaria, pruritus, rash, erythema.
General disorders and administration site conditions	Rigors, malaise, pyrexia and thirst.

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions

via Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App store.

#### 4.9 Overdose

In case of gross accidental overdosage, where diarrhoea is severe, conservative measures are usually sufficient; generous amounts of fluid, especially fruit juices, should be given.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

#### **ATC Code: A06A D**

Macrogol 3350 exerts its effects by virtue of its osmotic effect in the gut, which induces a laxative effect. Electrolytes are present in the formulation and are exchanged across the intestinal barrier (mucosa) with serum electrolytes and water to prevent the occurrence of potential clinically significant variations of net electrolyte or net water balance.

Macrogol 3350 increases the stool volume, which triggers colon motility via neuromuscular pathways. The physiological consequence is an improved propulsive colonic transportation of the softened stools and a facilitation of the defecation.

### **5.2. Pharmacokinetic properties**

Macrogol 3350 is unchanged along the gut. It is virtually unabsorbed from the gastro-intestinal tract. Any macrogol 3350 that is absorbed is excreted via the urine.

Osmotically-acting bowel preparations lead to a copious diarrhoea, resulting in extensive elimination of most of the product via the faeces. They can also lead to changes in electrolyte balance in the body, often with depletion of sodium and potassium. The additional sodium and potassium included in the Klean-Prep formulation help to balance the electrolytes. While some absorption of sodium takes place, the bulk of sodium is expected to be excreted in the faeces as the sodium salts of sulfate, the osmotic active ingredients included in the Klean-Prep composition.

### 5.3 Preclinical safety data

Preclinical studies provide evidence that macrogol 3350 has no significant systemic toxicity potential.

## **6.1 List of excipient(s)**

Vanilla flavour	
Aspartame	0.049 g per sachet

### 6.2 Incompatibilities

None are known

- 6.3 Shelf life  
Sachets: 3 years  
Solution after reconstitution: 24 hours
- 6.4 Special precautions for storage  
Sachets: Store in a dry place. Do not store above 25°C.  
Reconstituted solution: Store in a refrigerator (2 – 8°C)
- 6.5 Nature and contents of container  
Sachets containing 69gm white powder, in a box of 4 sachets
- 6.6 Special precautions for disposal

The solution should be used within 24 hours.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## **7. MARKETING AUTHORISATION HOLDER**

Norgine Limited  
New Road, Tir-Y-Berth, Hengoed,  
Wales, CF82 8SJ  
United Kingdom

## **8 MARKETING AUTHORISATION NUMBER(S)**

PL 00322/0068

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

14/08/1991 / 12/02/2004

## **10 DATE OF REVISION OF THE TEXT**

23/05/2025