New Zealand Datasheet

1 PRODUCT NAME
KLEAN-PREP®

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each sachet of KLEAN-PREP contains the following active ingredients:

Macrogol 3350 (Polyethylene glycol 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

Contains aspartame.

3 PHARMACEUTICAL FORM
KLEAN-PREP is a whitish powder which, when dissolved in water, gives a clear, colourless solution for oral administration.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
KLEAN-PREP is indicated for colonic lavage prior to diagnostic examination or surgical procedures requiring a clean colon, e.g. colonoscopy, barium enema or colonic resection.

4.2 Dose 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 250 mL 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 care should be taken in the rate of administration (see section 4.4).

Children: There is no recommended dosage for children.

Renal patients: No dosage adjustment need be made.

4.3 Contraindications
Use in patients with:

- Hypersensitivity to the active substances or to any of the excipients.

- Congestive cardiac failure (NYHA class III and IV).

- Known or suspected gastrointestinal obstruction or perforation, ileus, gastric retention, toxic colitis or toxic megacolon.

4.4 Special warnings and precautions for use

KLEAN-PREP contains aspartame, which is metabolised to phenylalanine. This may be relevant when treating patients suffering from phenylketonuria.

The fluid content of KLEAN-PREP when re-constituted with water does not replace regular fluid intake and adequate fluid intake must be maintained.

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.

Although not expected due to isotonic composition of the product, cases of electrolyte disturbances have been reported rarely in at-risk patients. Therefore KLEAN-PREP should be used with care in patients at risk of electrolyte disturbances such as patients with renal failure, cardiac impairment (NYHA class I and II) or those simultaneously treated with diuretics.

Convulsions associated with severe hyponatraemia in patients taking KLEAN-PREP have been reported. Patients may also develop confusional state/disorientation associated with hyponatraemia.

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.

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.

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 severe acute ulcerative colitis.

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.

Unconscious, semi-conscious patients or patients prone to aspiration or regurgitation should be observed during administration especially if this is via the nasogastric route. When KLEAN-PREP is administered by naso-gastric tube, precautions should be taken to ensure that the tube is appropriately placed. There have been reports of pulmonary oedema resulting from aspiration of macrogol lavage solutions requiring immediate treatment.

No solid food should be eaten for at least 2 hours before taking KLEAN-PREP.

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

KLEAN-PREP should be used with caution in patients with severe acute inflammatory bowel disease.

Ischaemic colitis
Post-marketing cases of ischaemic colitis, including serious cases, 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.

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.

4.5 Interaction with other medicines and other forms of interaction
Oral medication (e.g. oral contraceptive pill) taken one hour before, during and one hour after administration of KLEAN-PREP may be flushed from the gastro-intestinal tract and not absorbed.

KLEAN-PREP may have a potential interactive effect when used with starch-based food thickeners. The polyethylene glycol (PEG) 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
Pregnancy
KLEAN-PREP 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.

Lactation
There are no data on the excretion of macrogol 3350 in breast milk. As macrogol 3350 is poorly absorbed, the preparation may be taken during lactation if considered essential by the physician.

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 undesirable effects are predominantly gastrointestinal in nature. Should distension or pain arise, the rate of administration should be slowed down or temporarily stopped until symptoms subside. Abdominal cramps, vomiting and anal discomfort occur less frequently. These effects normally subside rapidly.

The following adverse reactions have been observed in post-marketing experience.

System Organ Class	Adverse Reaction
Immune system disorders	Allergic reactions.
	Anaphylactic reaction, dyspnoea, skin reactions (see below).
Metabolism and nutrition disorders	Electrolyte disturbances, specifically hypokalaemia and hyponatraemia, dehydration.
Nervous System Disorders	Seizures, convulsions confusional state/disorientation, headaches, dizziness.
Cardiac Disorders	Transient increase in blood pressure, arrhythmia, palpitations.
Gastrointestinal disorders	Oesophageal rupture (Borheaave syndrome), vomiting, nausea, abdominal pain, abdominal distension, flatulence, anal discomfort.
Skin and subcutaneous tissue disorders	Urticaria.
	Other allergic skin reactions including angioedema, 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 medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions via https://pophealth.my.site.com/carmreportnz/s/.

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.

In case of accidental overdosage, symptomatic treatments and supportive care are suggested. For information on the management of overdose, contact the National Poisons Centre on 0800 764 766.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Osmotically acting laxatives, ATC Code: A06AD

Actions
Macrogol 3350 acts by virtue of its osmotic action 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 potentially 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. Sodium sulfate showed negative results in genotoxicity and reproductive toxicity studies, and both sodium chloride and potassium chloride are present at a similar level to normal daily intake from the diet.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Vanilla flavour, Aspartame

6.2 Incompatibilities

None are known.

6.3 Shelf life

Sachets: 3 years, Solution: 24 hours

6.4 Special precautions for storage

Sachets: Store in a dry place and below 25°C. Reconstituted solution: Store in a refrigerator (2°C – 8°C)

6.5 Nature and contents of container

Sachets containing 69 g white powder, in a box of 4 sachets.

6.6 Special precautions for disposal

No special precautions required.

The solution should be used within 24 hours. Any unused portion should be discarded.

7 MEDICINE SCHEDULE

Pharmacist Only Medicine

8 SPONSOR

Sponsor:
CARSL Consulting PO Box 766
Hastings
Ph (06) 875 0979

For Norgine Pty Limited

Distributor:
Pharmacy Retailing (NZ) Ltd
Trading as Healthcare Logistics 58 Richard Pearse Drive Airport Oaks
PO Box 62-027
Mt Wellington Auckland
Telephone: (09) 918 5100
Fax: (09) 918 5101

9 DATE OF FIRST APPROVAL

30 April 1992

10 DATE OF REVISION OF THE TEXT

18 March 2025

KLEAN-PREP and Norgine are trademarks.

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
4.4 and 4.8	Addition of warnings and side effects for seizure and oesophageal rupture.