

New Zealand Datasheet

Name of Medicine

KLEAN-PREP

Each sachet of KLEAN-PREP contains the following active ingredients:

Polyethylene Glycol 3350 59.000g; Anhydrous Sodium Sulphate 5.685g; Sodium Bicarbonate 1.685g; Sodium Chloride 1.465g; Potassium Chloride 0.7425g.

The content of electrolyte ions per sachet when made up to one litre of water is as follows: Sodium 125 mM; Sulphate 40 mM; Chloride 35 mM; Bicarbonate 20 mM; Potassium 10 mM

Presentation

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

Uses

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.

Pharmacokinetics

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

Indications

KLEAN-PREP is indicated for colonic lavage prior to diagnostic examination or surgical procedures requiring a clean colon, eg colonoscopy, barium enema or colonic resection.

Dosage and 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 Warnings and Precautions).

Children: There is no recommended dosage for children.

Renal patients: No dosage adjustment need be made.

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.

Warnings and Precautions

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

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.

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.

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.

Caution should be used in the administration of KLEAN-PREP to elderly, fragile or debilitated patients.

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

Use in Pregnancy and Lactation

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.

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.

Effects on Ability to Drive and Use Machines

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

Adverse 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	Frequency	Adverse Reaction
Immune system disorders	Rare	Allergic reactions.
	Not known	Anaphylactic reaction, dyspnoea, skin reactions (see below).
Metabolism and nutrition disorders	Not known	Electrolyte disturbances, specifically hypokalaemia and hyponatraemia. These occur more commonly in patients taking concomitant medication affecting the kidneys such as ACE inhibitors and diuretics.
Nervous System Disorders	Not known	Convulsions associated with severe hyponatraemia, headaches.
Gastrointestinal disorders	Not known	Vomiting, nausea, abdominal pain, abdominal distension, flatulence, anal discomfort.
Skin and subcutaneous tissue disorders	Rare	Urticaria.
	Not known	Other allergic skin reactions including angioedema, pruritus, rash, erythema.
General disorders and administration site conditions	Not known	Rigors.

Transient increases in blood pressure have been observed in association with bowel preparations.

Interactions

Oral medication (e.g. oral contraceptive pill) taken within one hour of administration of KLEAN-PREP may be flushed from the gastro-intestinal tract and not absorbed.

Overdosage

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.

Pharmaceutical Precautions

Shelf Life

Sachets: 3 years, Solution: 24 hours

Special Precautions for Storage

Sachets: Store in a dry place and below 25°C.

Reconstituted solution: Store in a refrigerator (2°C – 8°C)

Medicine Classification

Pharmacist Only Medicine

Package Quantities

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

Further Information

Preclinical Safety Data

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

Instruction for Use/Handling

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

List of Excipients

Vanilla flavour Aspartame

Incompatibilities

None are known.

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