1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

KLEAN-PREP 68,96 g sachets of powder for reconstitution

Intended for oral use only

2. QUALITATIVE AND QUATITATIVE COMPOSITION

Each 68,96 g sachet of KLEAN-PREP contains:

Macrogol 3350	59,00 g
Sodium sulphate anhydrous	5,685 g
Sodium bicarbonate	1,685 g
Sodium chloride	1,465 g
Potassium chloride	0,7425 g

When the contents of one sachet are reconstituted with 1 litre of water, the resulting solution contains:

Sodium	125 mmol/L
Sulphate	40 mmol/L
Chloride	35 mmol/L
Bicarbonate	20 mmol/L
Potassium	10 mmol/L

Contains sweetener: Aspartame 0,049 g

Sugar free

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Sachets of powder for reconstitution

KLEAN-PREP is white to cream, free-flowing crystalline powder with a faint characteristic odour of vanilla.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

KLEAN-PREP is indicated for

- Bowel preparation before colonoscopy, colonic surgery, radiological examination and other related procedures.

4.2. Posology and method of administration

Extended use is not recommended.

Iron tablets should be discontinued four days before hand and no constipating medicines (e.g. codeine) should be taken on the day of examination.

Eat no solid food from at least 2 hours before taking KLEAN-PREP until after the investigation.

However, clear fluids (tea or coffee without milk, soft drinks, clear soup) may be drunk during this time.

Adults

Each sachet should be dissolved in 1 litre of water.

The usual dose is 3 to 4 sachets, usually taken at a rate of 250 ml every 10 to 15 minutes until all the solution has been consumed, the rectal effluent is clear, or as directed by the physician. The solution is more palatable if chilled. The solution from all four sachets should be drunk within 4 to 6 hours.

KLEAN-PREP can either be given in the evening before or on the morning of the procedure. 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.

KLEAN-PREP is designed to cleanse the bowel and will cause diarrhoea-like watery bowel movements. The first of these liquid bowel movements should occur within 1 to 2 hours of starting to drink KLEAN-PREP solution.

No dosage changes need to be made for patients with renal insufficiency. If administered by nasogastric tube, the rate of administration should be 20 ml to 30 ml per minute (see section 4.4).

Special populations

Renal impairment

No dosage adjustment need be made.

Paediatric population

There is no recommended dosage.

Method of administration

For oral administration

4.3. Contraindications

KLEAN-PREP is contraindicated in:

- Patients with hypersensitivity to macrogol 3350, sodium sulphate anhydrous, sodium bicarbonate, sodium chloride, potassium chloride or to any of the excipients in KLEAN-PREP (section 6.1).
- Patients with gastrointestinal obstruction or perforation, ileus, gastric retention, acute intestinal or gastric ulceration, toxic colitis or toxic megacolon.
- Patients with congestive cardiac failure (NYHA class III of IV)
- Patients with a body mass of less than 20 kg or children under the age of 12 years.
- Pregnancy (see section 4.6).

4.4. Special warnings and precautions for use

Fluid intake

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

Solid food intake

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 or Crohn's disease.

Patients with concomitant conditions

KLEAN-PREP should be administered with caution to patients with an impaired gag reflex, reflux oesophagitis, those with diminished levels of consciousness and patients with ulcerative colitis or Crohn's disease.

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

Dysrhythmias

There have been reports of serious dysrhythmias 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 or semi-conscious patients or patients prone to aspiration

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 nasogastric tube, precautions should be taken to ensure that the tube is and remains appropriately placed. There have been reports of pulmonary oedema resulting from aspiration of macrogol lavage solutions, such as KLEAN-PREP, requiring immediate treatment.

Electrolyte disturbances

Although not expected, due to the isotonic composition of KLEAN-PREP, cases of electrolyte disturbances have been 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 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).

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

Debilitated patient baseline tests
In debilitated patients, patients with poor health, those with clinically significant renal impairment, dysrhythmia and those at risk of electrolyte imbalance, the medical practitioner should consider performing a baseline and post-treatment electrolyte, renal function test and ECG as appropriate.

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.
KLEAN-PREP contains 125 mmol (2,9 g) sodium per sachet of treatment and this must be taken into consideration in patients on a controlled sodium diet.

Excipients

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

4.5. Interaction with other medicines and other forms of interaction

All oral medicines (e.g. oral contraceptive tablet, anti-epileptics) should be given at least one hour prior to the administration of KLEAN-PREP.

It should be noted that any oral medicine administered within an hour of administration of KLEAN-PREP may be flushed from the gastrointestinal tract and not absorbed.

Iron tablets should be discontinued four days beforehand and no constipating medicines (e.g. codeine) taken on the day of examination (see section 4.2).

4.6. Fertility, pregnancy and lactation

The safety of KLEAN-PREP in pregnancy has not been established (see section 4.3).

Pregnancy

There is no experience of use during pregnancy.

Lactation

There is no data on the excretion of KLEAN-PREP in breast milk. As macrogol 3350, as in KLEAN-PREP is poorly absorbed, KLEAN-PREP may be taken if considered essential by the physician**.**

Fertility

No data are available

4.7 Effects on ability to drive and use machines

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

Since adverse reactions such as dizziness have been reported in patients taking KLEAN-PREP, patients should not drive, use machinery or perform any tasks that require concentration, until they are certain that KLEAN-PREP does not adversely affect their ability to do so (see section 4.8).

4.8.Undesirable effects

a) Tabulated list of adverse reactions

System organ class	**Frequency unknown** (cannot be estimated from the available data)
Immune system disorders	Allergic reactions including anaphylactic reaction, dyspnoea, skin reactions
Metabolism and nutrition disorders	Electrolyte disturbances, specifically hypokalaemia, hyponatraemia and dehydration.
Nervous system disorders	Convulsions, confusional state/disorientation, headaches and dizziness
Cardiac disorders	Transient increase in blood pressure, arrhythmia, palpitations.
Gastrointestinal disorders	Vomiting, nausea, abdominal pain, cramps, anal discomfort or irritation, abdominal distension, flatulence, borborygmi

Skin and subcutaneous tissue disorders	Allergic skin reactions including angioedema, urticaria, pruritus, rash, erythema.
General disorders and administrative 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 providers are asked to report any suspected adverse reactions to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

4.9.Overdose

Symptoms

In cases of accidental overdose, where diarrhoea is severe, conservative measures are usually sufficient.

Treatment

Generous amounts of fluid, especially fruit juices should be given. Monitoring and correction of electrolyte abnormalities.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A 11.5 Medicines acting on the gastrointestinal tract. Laxatives

Pharmacotherapeutic group: Medicines acting on gastro- intestinal tract

ATC code: A06AD65

Mechanism of action

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 facilitation of the defecation.

Pharmacokinetic properties

Macrogol 3350 is unchanged along the gut. It is virtually unabsorbed from the gastrointestinal 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 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 sulphate, the osmotic active ingredients included in the composition of the medicine.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Aspartame, vanilla flavour.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

36 months.

6.4. Special precautions for storage

Store in a cool, dry place, at or below 25 °C.

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

Keep in original packaging until required for use.

6.5. Nature and contents of container

KLEAN-PREP is filled into a Surlyn/aluminium/polyethylene/paper laminate sachet, which is then placed into either a cardboard carton or a polypropylene tub with a leaflet.

6.6. Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

8. REGISTRATION NUMBER

Z/11.5/340

9. DATE OF FIRST AUTHORISATION

08 December 1992

10. DATE OF REVISION OF TEXT

23 September 2021

Die Afrikaanse Professionele Inligting is op versoek beskikbaar. Mediese Blitslyn: 0800 118 088.

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