

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Klean-Prep Powder for oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Macrogol 3350	59.0000 g
Sodium Sulphate Anhydrous	5.6850 g
Sodium Bicarbonate	1.6850 g
Sodium Chloride	1.4650 g
Potassium Chloride	0.7425 g
Aspartame (E951)	0.0494 g

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

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

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder for oral solution.

A white granular powder for oral solution which on reconstitution gives a clear colourless solution with a characteristic flavour of vanilla.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For gastrointestinal lavage and preparation prior to diagnostic examination or surgery particularly for the large bowel. For use as a short term laxative in cases of constipation.

4.2 Posology and method of administration

Posology

Recommended Dosage

Adults Only:

For gastrointestinal lavage and preparation prior to diagnostic examination or surgery:

To reconstitute, dissolve the entire contents of one sachet of Klean-Prep in 1000ml of water, stirring in order to aid dissolution.

The usual dose of Klean-Prep is 4 litres of the reconstituted solution (four sachets) consumed at a rate of 200-250 ml every ten to fifteen minutes until either the rectal effluent appears clear, or the total volume of 4 litres is consumed. The required quantity of solution may be taken the evening prior to the split as follows: 2 litres the evening before the procedure followed by up to 2 litres on the morning of the procedure.

It is recommended that no food be consumed for at least 2 hours prior to taking Klean-Prep until after the completion of any related diagnostic or surgical procedure.

It is normally recommended to take the last glass at least 1 hour before the examination in order to ensure complete evacuation.

The resultant solution is more palatable if chilled. If administered by naso-gastric tube the usual rate should be 20 to 30 ml/minute.

For use as a short term laxative in Constipation:

As with all laxatives, prolonged use is not recommended. A course of treatment for constipation with Klean-Prep does not normally exceed two weeks, although this can be repeated if required. Dissolve the entire contents of one sachet in 1000ml of water, stirring to aid dissolution. The dose is one sachet in 1000mls to be consumed over 4-6 hours.

Paediatric population

There is insufficient experience of use in infants or children.

Renal impairment

No dosage changes need be made in patients with renal insufficiency.

4.3 Contraindications

1. Hypersensitivity to the active ingredients or to any of the excipients listed in section 6.1
2. Congestive heart failure (NYHA grades 3 and 4)
3. Severely impaired renal function
4. Known or suspected gastrointestinal obstruction or perforation, ileus, gastric retention, acute intestinal or gastric ulceration, toxic colitis, or megacolon
5. Use in patients less than 20 kg in weight.

4.4 Special warnings and precautions for use

Unconscious or semi-conscious patients or those prone to aspiration or regurgitation should be kept under observation, even if administration is via the naso-gastric route (see details in 4.2). When Klean-Prep is administered by nasogastric tube, precautions should be taken to ensure the tube is appropriately placed, especially if it is administered to elderly, fragile or debilitated patients. There have been a few reports of complications resulting from aspiration of macrogol lavage solutions (e.g. pulmonary oedema) requiring immediate treatment.

The product should only be administered with caution to patients with impaired gag reflex, oesophageal reflux, or with oesophagitis.

The benefit-risk ratio of Klean Prep should be considered before initiating treatment in patients with an increased risk of underlying renal impairment, i.e. patients with acute myocardial infarction or unstable angina, elderly patients or debilitated patients.

Klean Prep should be used with caution in patients with active inflammatory bowel disease.

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, cardiac impairment or those simultaneously treated with diuretics). These patients should maintain adequate hydration during treatment. Monitoring of baseline and post-treatment electrolytes is recommended.

Should distension or pain arise the rate of administration should be slowed down.

Klean-Prep contains aspartame, which is metabolized to phenylalanine.
This may be relevant when treating patients suffering from 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.

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 interactions

Oral medication taken within one hour of administration of Klean Prep may be flushed from the gastrointestinal tract and not absorbed.

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

There is no experience of use of Klean-Prep during pregnancy. The purpose and mechanism of use should be borne in mind if the physician is considering administration.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

The following listing of undesirable effects derives from clinical studies and marketing experience, with reporting rate classified as common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), and rare ($\geq 1/10,000$ to $< 1/1,000$).

The following undesirable effects have been reported divided by System Organ Class (SOC):

System Organ Class	Frequency	Adverse Reaction
Immune system disorders	Rare	Hypersensitivity Anaphylactic reaction including shock
Metabolism and nutrition disorders	Rare	Electrolyte imbalance Hyponatraemia Hypokalaemia
Respiratory, thoracic and mediastinal disorders	Rare	Dyspnoea
Gastrointestinal disorders	Common	Nausea Abdominal distension Flatulence Abdominal discomfort
	Uncommon	Abdominal pain Abdominal pain upper Vomiting Anal irritation
Skin and subcutaneous tissue disorders	Rare	Urticaria Rash Angioedema
General disorders and administration site conditions	Rare	Oedema Chills
Nervous system disorders	Rare	Headache
	Uncommon	Convulsions associated with hyponatraemia

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

HPRA Pharmacovigilance

Website: www.hpra.ie.

4.9 Overdose

In case of gross accidental overdose, 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

Pharmacotherapeutic group

The main ingredient in Klean-prep is Macrogol 3350, which acts as an osmotic laxative. The various salts are present to maintain the body's electrolyte balance. Klean-Prep acts as a bowel evacuant and cleanser.

Mechanism of Action

Macrogol 3350 is devoid of any pharmacological activity.

5.2 Pharmacokinetic properties

General Characteristics of the Active Substance(s)

Following intravenous dosage of Macrogol 3350, the major portion is excreted via the urine in 24 hours. Orally, doses pass through the alimentary tract with little absorption in a like interval.

Characteristics in Patients

Not relevant. When taken as directed, only minimal amounts of an oral dose are absorbed by the intact colon.

5.3 Preclinical safety data

Not relevant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aspartame (E951)
Vanilla flavour

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.
Reconstituted solution should be refrigerated (2-8°C) and used within 48 hours.

6.4 Special precautions for storage

Do not store above 25°C.
Reconstituted solution: See section 6.3.

6.5 Nature and contents of container

Klean-Prep is packed into foil sachets composed of, from the inside out:
18 g surlyn 1652, 0.008 mm aluminium, 40 g paper, 12 g polyethylene, print, varnish.

Cartons

Two or four sachets are packed in a cardboard outer.

Containers

Four sachets are packed in a polypropylene container fitted with a polypropylene screw cap.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No Special Requirements.

On reconstitution the product gives a clear colourless solution with a characteristic flavour of vanilla. Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Helsinn Birex Pharmaceuticals Limited
Damastown
Mulhuddart
Dublin 15
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0294/017/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 June 1988

Date of last renewal: 30 June 2008

10 DATE OF REVISION OF THE TEXT

October 2021