

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

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

Macrogol 3350

Sodium sulphate anhydrous

Sodium bicarbonate

Sodium chloride

Potassium chloride

Contains sweetener: Aspartame 0,049 g

Sugar free

Read all of this leaflet carefully before you start taking KLEAN-PREP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- KLEAN-PREP has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. What KLEAN-PREP is and what it is used for

KLEAN-PREP is a bowel cleansing medicine. KLEAN-PREP flushes everything out of your intestines (gut) through a laxative action so that your gut is completely empty and clean. You may need KLEAN-PREP because you are going to have a procedure or surgery where you need a clean gut.

2. What you need to know before you take KLEAN-PREP

Do not take KLEAN-PREP

- if you are hypersensitive (allergic) to macrogol 3350, sodium sulphate anhydrous, sodium bicarbonate, sodium chloride, potassium chloride or any of the other ingredients of KLEAN-PREP.
- if you have an obstruction, blockage, ulceration or perforation in the wall of your gut.
- if you have loss of muscle tone in the gut that leads to a blockage (ileus).
- if you have a dilation of your colon and signs of toxicity in your system (toxic colitis and megacolon)
- if you have heart failure.
- if you are pregnant.

KLEAN-PREP should not be given to a child weighing less than 20 kg or children under the age of 12 years.

Warnings and precautions

Take special care with KLEAN-PREP:

- If you have an impaired gag reflex or trouble swallowing.

- If you have a condition where acid from the stomach enters the food pipe (reflux oesophagitis).
- If you have a reduced level of consciousness.
- If you have a chronic, inflammatory bowel disease called ulcerative colitis or if you suffer from inflammation of last part of small bowel as this is known as Crohn's disease.
- If you have heart problems including irregular heartbeats. You are more at risk of developing an irregular heartbeat If you have imbalances of electrolytes in your body.
- If you are prone to regurgitation (which is the return of food from the stomach into the food pipe and mouth) or aspiration (which is breathing in food and/or fluid into your airways).
- If you have kidney problems.
- If you have a history of fits or convulsions.
- If at any time during KLEAN-PREP administration, you feel confused or disorientated.
- If you are in poor health or have serious medical conditions, your doctor may want to do special tests on you before you take KLEAN-PREP.
- You will be carefully monitored during KLEAN-PREP administration.

Children and adolescents

There is no experience with KLEAN-PREP administration in children.

Other medicines and KLEAN-PREP

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

If you are taking other medicines take them at least one hour before taking KLEAN-PREP or at least one hour afterwards because they may be flushed through your digestive system and not work well.

Tell your doctor if you are taking any of the following medicines:

- Iron tablets (e.g. ferrous sulphate): medicine to supplement the amount of iron in your body.
- Analgesics (e.g. codeine): medicine used to relieve pain.
- Oral contraceptives: medicine used to prevent pregnancy.
- Diuretics: medicine used to reduce the amount of fluid in your body or to treat high blood pressure.
- Anti-epileptics: medicine used to treat epilepsy.

Food and drink intake and KLEAN-PREP

KLEAN-PREP dissolved in water does not replace your regular fluid intake. Make sure that you maintain adequate fluid intake.

You should not eat any solid food for at least 2 hours before taking KLEAN-PREP until after the investigation or procedure.

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

Pregnancy, breastfeeding and fertility

You should not take KLEAN-PREP if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, or you think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machines

KLEAN-PREP is not expected to influence your ability to drive, use machinery or perform any tasks that require concentration.

It is not always possible to predict to what extent KLEAN-PREP may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which KLEAN-PREP affects them (see section 4).

KLEAN-PREP contains aspartame

This medicine contains 0,049 g aspartame in each 68,96 g sachet of KLEAN-PREP.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take KLEAN-PREP

Do not share medicines prescribed for you with any other person.

Always take KLEAN-PREP exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults:

1. Empty the contents of each sachet in 1 litre of clean water and stir until the powder is completely dissolved. You can chill the solution before drinking it.
2. Drink one glassful (250 ml) of the KLEAN-PREP solution every 10 to 15 minutes until all of the solution has been consumed.
3. Repeat this procedure with each sachet (3 to 4 sachets) until all four sachets have been mixed with water and the solution drunk. The solution from all four sachets should be drunk within 4 to 6 hours.
4. KLEAN-PREP can either be taken in the evening before or on the morning of the procedure.
5. Alternatively, you can divide the dose, for example, taking 2 sachets during the evening before the examination or procedure, and the remaining 2 sachets on the morning of the examination.

KLEAN-PREP is designed to cleanse the gut 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 the KLEAN-PREP solution.

If you experience nausea, vomiting, stomach bloating or pain during KLEAN-PREP administration, the rate at which you are taking KLEAN-PREP may need to be reduced or temporarily stopped.

Your doctor will tell you how long your treatment with KLEAN-PREP will last. Do not stop treatment early. If you have the impression that the effect of KLEAN-PREP is too strong or too weak for you, tell your doctor or pharmacist.

If you take more KLEAN-PREP than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of KLEAN-PREP

Do not take a double dose to make up for forgotten individual doses. If you have missed a dose of KLEAN-PREP, take the dose that you have missed as soon as you remember.

However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take several doses, contact your doctor without delay.

4. Possible side effects

KLEAN-PREP can have side effects.

Not all side effects reported for KLEAN-PREP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking KLEAN-PREP, please consult your healthcare provider for advice.

If any of the following happens, stop taking KLEAN-PREP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching (skin reaction).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to KLEAN-PREP. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- fits (convulsions), confusion or disorientation,
- irregular heartbeat (palpitations).

These are all serious side effects. You may need urgent medical attention.

Side effects with an unknown frequency

- disturbances in your electrolytes such as low levels of potassium and sodium, dehydration,
- headaches, dizziness,
- temporary increase in blood pressure,
- vomiting, nausea, stomach pain and cramps, anal discomfort or irritation, swollen stomach, wind (flatulence),
- hives,
- cold with shivering (rigors), tiredness, fever, thirst,
- a rumbling or gurgling noise made by the movement of fluid and gas in the intestine (borborygmi).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.



Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

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

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of KLEAN-PREP

5. How to store KLEAN-PREP

STORING AND DISPOSING OF KLEAN-PREP

Store all medicines out of reach of children.

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 KLEAN-PREP in its original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What KLEAN-PREP contains

The active substance per sachet of KLEAN-PREP is macrogol 3350, sodium sulphate anhydrous, sodium bicarbonate, sodium chloride and potassium chloride.

The other ingredients are aspartame and vanilla flavour.

Contains sweetener: Aspartame 0,049 g

Sugar free

What KLEAN-PREP looks like and contents of the pack

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

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

Holder of Certificate of Registration

PHARMACARE LIMITED

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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