



Package Leaflet: Information for the User

KLEAN-PREP 69g Sachet Powder for Oral Solution

(Macrogol 3350, Sodium sulphate anhydrous, Sodium bicarbonate, Sodium chloride and Potassium chloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet:

1. What Klean-Prep is and what it is used for
2. What you need to know before you take Klean-Prep
3. How to take Klean-Prep
4. Possible side effects
5. How to store Klean-Prep
6. Contents of the pack and other information

1. WHAT KLEAN-PREP IS AND WHAT IS IT USED FOR

Klean-Prep is dissolved in water, it is a bowel cleansing agent. This means it flushes everything out of your intestines (gut) through a laxative action so that they are completely empty and clean.

You are taking Klean-Prep because you are going to have one of these procedures:

- Colonoscopy
- Barium enema
- Gut surgery

For all of these, it is important that your gut is clean so the procedure is more likely to be a success.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE KLEAN-PREP

Do not take Klean-prep if you suspect or your doctor suspects:

- you are allergic (hypersensitive) to the active substances or any of the other ingredients of Klean-Prep (listed in section 6).
- you have a blockage of the gastrointestinal obstruction or perforation of the wall of the bowel
- you have ileus (loss of muscle tone in the gut)



- you have gastric retention
- you have toxic colitis and toxic megacolon
- you have congestive cardiac failure (Heart Failure)

Warnings and Precautions

The fluid content of Klean-Prep when reconstituted with water does not replace regular fluid intake and adequate fluid intake should be maintained.

If you are in poor health or have a serious medical condition, you should be particularly aware of the possible side effects listed in section 4. Contact your doctor or pharmacist if you are concerned.

You should tell your doctor before taking Klean-Prep if you have any of the following;

- have a problem swallowing
- have reflux oesophagitis (which is a condition where acid from the stomach enters the oesophagus (gullet))
- have reduced levels of consciousness
- have an inflammatory bowel disease such as ulcerative colitis (which can cause abdominal pain and bloody diarrhoea).
- are prone to regurgitation (which is the return of food from the stomach into the oesophagus (gullet) and mouth) or aspiration (which is breathing in of food and/or fluid into the airways). These patients will need to be carefully monitored during administration.
- have heart problems including irregular heartbeats or palpitations.
- have kidney problems

Some patients taking Klean-Prep have developed very low levels of sodium in the blood and as a result may experience convulsions, confusion or disorientation.

If you experience sudden abdominal pain or rectal bleeding when taking Klean-Prep for bowel preparation, contact your doctor or seek medical advice immediately.

Other medicines and Klean-prep

Do not take other oral medicines during and at least one hour before and after taking Klean-Prep because they may be flushed through your digestive system and not work as well. If taking oral contraceptives, you may need to use additional forms of contraception (e.g. condom) to prevent pregnancy.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, such as diuretics (that increase the amount of urine passed), laxatives (to help you pass stool or do a poo) and also medicines obtained without a prescription.

If you use products to thicken fluids in order to swallow them safely, taking Klean-Prep may counteract this thickening effect.



Klean-Prep with food and drink

Do not take any solid food for at least two hours before you take Klean-Prep.

Pregnancy, breast-feeding and fertility

There are no data on the use of Klean-Prep during pregnancy or lactation and it should only be used if considered essential by your physician.

So if you are pregnant or breastfeeding, think you may be pregnant or are planning a baby, ask your doctor or pharmacist for advice before taking Klean-Prep.

Driving and using machines

Klean-Prep does not affect your ability to drive or use machines.

Important information about some of the ingredients of Klean-Prep

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.

This medicinal product contains 10mM of potassium per litre. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

This medicine contains 49.4mg of Aspartame per sachet (68.96g).

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

Always take Klean-Prep exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- The usual dose is up to 4 sachets taken at a rate of 250ml every 10 to 15 minutes until the total volume is consumed or rectal effluent is clear, or as directed by the physician. The solution from all 4 sachets should be drunk within 4 to 6 hours.

If you have a morning appointment at the hospital

- take Klean-Prep during the afternoon and evening of the day before your appointment. This will take about 4 to 6 hours altogether.

If you have an afternoon appointment,

- take 2 sachets on the evening before your appointment, and the remaining 2 sachets the next morning. This takes about 2-3 hours each time.

To take Klean-prep:

1. Empty the contents of one sachet of Klean-Prep into 1 litre (1 $\frac{3}{4}$ pints) of water.
2. Stir until the solution is clear.
3. Drink 1 glassful ($\frac{1}{4}$ litre or $\frac{1}{2}$ pint) of Klean-Prep about every fifteen minutes until you have



drunk it all.

4. Make up and take the next sachets in the same way. You should be starting to have watery bowel movements so stay near a toilet. If after three sachets you are passing only clear liquid, there is no need to take the final sachet.

What else do I need to know?

You should start opening your bowels 1 to 2 hours after starting to take Klean-Prep. If you have not had a bowel movement after taking 2 sachets, wait until you go to the toilet before you continue with Klean-Prep. If you have slept the night and still not have had any bowel movements, contact the hospital for advice.

If you take more Klean-Prep than you should, drink lots of liquids especially fruit juices.

If you forget to take Klean-Prep, take the next dose as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist

4. POSSIBLE SIDE EFFECTS

Like all medicines, Klean-Prep can have side effects, although not everybody gets them. The following side effects have sometimes been seen but it is not known how often they occur because the frequency cannot be estimated from the available data:

- Feeling sick, a feeling of fullness in your stomach, bloating and wind may all be experienced. You may experience abdominal cramps, vomiting or soreness of the anus (bottom). If you get a feeling of nausea (feeling sick), swelling of the stomach, or stomach pain, or you start to vomit, you should drink Klean-Prep more slowly or stop drinking it for a few minutes until you feel better.
- People can be allergic to Klean-Prep, and may get an itchy skin rash (nettle rash or hives) or reddening of the skin. They may also experience swelling of the face, lips, tongue and throat, and may also have difficulty in breathing and become breathless. If you experience any of these reactions you should contact a doctor immediately for advice.
- A reduction in levels of sodium and potassium in the blood. This is more common in people who are taking medicines which affect the kidneys, such as diuretics
- Convulsions (fits), confusion/disorientation linked with extremely low levels of sodium in the blood.
- Dehydration or feeling thirsty
- Headaches or dizziness
- Shivering or fever may occur.
- Malaise (general unwellness)
- Brief increase in blood pressure that may be linked to bowel preparations. Irregular heartbeats or palpitations.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google



Play or Apple App store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE KLEAN-PREP

Keep this medicine out of the sight and reach of children.

Store Klean-Prep sachets in a dry place. Do not store above 25°C.

After you have dissolved Klean-Prep in the water, the solution may be stored in the fridge (2°C - 8°C). Do not keep it for more than 24 hours.

Do not use this medicine after the expiry date which is stated, after “EXP” on the carton. The expiry date refers to the last day of the month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Klean-Prep contains

The active substances are Macrogol 3350, Sodium Sulphate, Sodium Bicarbonate, Sodium Chloride and Potassium Chloride. Each sachet contains:

Macrogol 3350	59.0g
Sodium Sulphate	5.685g
Sodium Bicarbonate	1.685g
Sodium Chloride	1.465g
Potassium Chloride	0.743g

The other ingredients are aspartame and vanilla flavour.

What Klean-Prep looks like and contents of the pack

Each sachet contains 69g Klean-Prep and 4 sachets come in one box.

Marketing Authorisation Holder

Norgine Limited, Norgine House, Widewater Place, Moorhall Road, Harefield, Uxbridge, UB9 6NS, UK.

Manufacturer

Helsinn-Birex Pharmaceuticals Ltd., County Dublin, Ireland.

The leaflet was last revised in October 2023

Other sources of information

If you need the information on this leaflet in an alternative format, such as large print, or Braille please ring 0800 198 5000.