

Package Leaflet: Information for the user

Klean-Prep® Powder for oral solution

59g Macrogol 3350, 5.685g sodium sulphate, 1.685g sodium bicarbonate, 1.465g sodium chloride and 0.7425g potassium chloride.

Read all of this leaflet carefully before you start using 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 only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. 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
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1. What Klean-Prep is and what it is used for

Klean-Prep contains an ingredient called ‘Macrogol’ and a mixture of salts. It comes as a powder that you dissolve in water to make a drink.

Klean-Prep is used:

- To empty your bowel before a medical examination or bowel surgery
- As a laxative for short-term relief of constipation

2. What you need to know before you take Klean-Prep

Do not take Klean-Prep if:

- You are allergic (hypersensitive) to Macrogol or any of the other ingredients of this medicine (listed in Section 6)
- You have heart failure
- You have severe kidney problems
- You have an inflamed gut (toxic colitis)
- You have a stomach ulcer, or any ulcers in your gut
- Your gut has suddenly become bloated (toxic megacolon)
- You have an obstructed bowel or a hole in your bowel (perforated bowel)
- You have a gut problem where your gut contents move more slowly (ileus)
- Your stomach contents are not passing through to the gut properly (gastric retention)
- You weigh less than 20kg

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Klean-Prep.

Warnings and precautions

Talk to your doctor or pharmacist before taking Klean-Prep.

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

Check with your doctor or pharmacist before taking this medicine if:

- You have problems swallowing
- You have an illness called 'reflux' where acid from your stomach goes into your food pipe (oesophagus)
- You have an inflamed bowel (ulcerative colitis)
- You have an inflamed back passage (ulcerative proctitis)
- You have phenylketonuria, a rare problem passed down through families (inherited)

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Klean-Prep.

Other medicines and Klean-Prep

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription and herbal 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 so well.

If you need to thicken fluids in order to swallow them safely, Klean-Prep may counteract the effect of the thickener.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist before for advice before using this medicine.

Klean-Prep contains aspartame

This medicine contains 49.4mg aspartame in each sachet. Aspartame (E951) 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. Talk to your doctor before taking this medicine if you have phenylketonuria.

3. How to take Klean-Prep

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Do not eat solid food for at least 2 hours before taking Klean-Prep.
- When you start drinking Klean-Prep, you may feel bloated or uncomfortable. If this happens, drink it more slowly, or walk around until you feel better.
- About an hour after drinking Klean-Prep you should get diarrhoea so stay near a toilet. This is normal and shows that the medicine is starting to work.
- To make up this medicine you will need to measure out a litre of water. You can use a measuring jug for this. If your sachets come in a tub, you can fill this with water up to the one litre mark.

To empty your bowel before a medical examination or bowel surgery

- Up to 4 litres of solution (4 sachets) will be required
- The full amount of solution may be taken the evening before the procedure, or
- 2 litres (2 sachets) can be taken the evening before, followed by up to 2 litres (2 sachets) on the morning of the procedure.

How much to take

- Dissolve a sachet in one litre of water. This will fill four 250ml glasses.
- You need to drink one glass every 10 to 15 minutes.

- This means you should drink the litre (4 glasses) over about one hour.
- You may have difficulty drinking this fast. If this happens, take your time - there is no need to rush. Contact the hospital if you think that you will not finish drinking in time.
- Continue to drink one glass every 10 to 15 minutes until your diarrhoea fluid is clear.
- You will usually need to use four sachets dissolved as above in total (16 glasses).
- **If your diarrhoea fluid is clear after drinking three sachets, you don't need to take the fourth sachet.**

For short-term relief of constipation

How much to take

- Dissolve a sachet in one litre of water. This will fill four 250ml glasses.
- You need to drink one glass every 30 minutes.
- This means you should drink the litre over 2 hours (4 glasses).
- You may have difficulty drinking this fast. If this happens, take your time – there is no need to rush. You can do this over 4 to 6 hours.

Children

Do not use in children.

If you take more Klean-Prep than you should

If you take more Klean-Prep than you should, you may develop excessive diarrhoea, which can lead to dehydration. Take generous amounts of fluid, especially fruit juices. If you are worried contact your doctor or pharmacist

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may happen with this medicine:

Stop taking Klean-Prep and see a doctor straight away if you notice any of the following serious side effects, you may need urgent medical treatment:

- **Allergic reaction** – the signs may include swelling of the lips, face, tongue or throat, having difficulty breathing or collapsing. You could also notice an itchy, lumpy rash (hives).

Other side effects

- Tummy bloating, or flatulence (wind). When you start drinking Klean-Prep, you may feel bloated or uncomfortable. If this happens, drink it more slowly, or walk around until you feel better.
- Irritation around the back passage.
- Tummy cramps, being sick (vomiting) or chills.
- Headache or fits/shaking caused by changes in your salt levels.

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

HPRA Pharmacovigilance

Website: www.hpra.ie.

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

5. How to store Klean-Prep

- Keep out of the sight and reach of children.
- Do not use Klean-Prep after the expiry date printed on the sachet and outer box or tub. The expiry date refers to the last day of that month.
- Do not store Klean-Prep above 25°C. Keep the mixed (reconstituted) solution refrigerated and use within 48 hours.
- 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 main active ingredient is Macrogol 3350. Each sachet contains 59g Macrogol 3350, 5.685g sodium sulphate, 1.685g sodium bicarbonate, 1.465g sodium chloride and 0.7425g potassium chloride.
- The other ingredients are Aspartame and vanilla flavour.

What Klean-Prep looks like and contents of the pack

- Klean-Prep is a white to cream powder that you dissolve in water to make a drink. On mixing with water (reconstitution) the product gives a clear colourless solution with a flavour of vanilla.
- Klean-Prep is available as 2 or 4 sachets packed in a box. It is also available as 4 sachets packed in a tub fitted with a screw cap.

Marketing Authorisation Holder and Manufacturer

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