

Prepkit-C®

Consumer Medicine Information

WARNING

Life threatening dehydration and/or electrolyte disturbances may occur in some people. Read the section with the heading “Before you take Prepkit-C”. PHENYLKETONURICS ARE WARNED THAT THIS PRODUCT CONTAINS PHENYLALANINE.

What is in this leaflet

This leaflet answers some of the common questions people ask about Prepkit-C.

It does not contain all the information that is known about Prepkit-C. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking Prepkit-C against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Prepkit-C is used for

Prepkit-C is used for bowel cleansing in conjunction with intravenous pyelograms (IVP), abdominal x-ray examinations, surgery and colonoscopy.

The bowel needs to be clean before your doctor can examine it properly.

Prepkit-C produces watery stools or bowel motions within 2 to 3 hours after the first administration and may cause frequent loose bowel motions during the night.

This medicine belongs to a group of medicines called Bowel Preparations.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you take Prepkit-C

When you must not take it

Do not take Prepkit-C if you have an allergy to:

- Any of the ingredients listed at the end of this leaflet
- Any similar medicines to Prepkit-C

Some symptoms of an allergic reaction may include:

- Shortness of breath
- Wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body
- Skin rash, itching or hives

Do not take Prepkit-C if you have, or have had, any of the following medical conditions:

- Gastrointestinal obstruction or blockage
- Gastric retention
- A hole in the stomach, large intestine or small intestine

- Toxic megacolon, a type of bloating
- A condition known as Paralytic Ileus where the small bowel doesn't work properly
- Inflammation of the bowel
- A body weight less than 20kg

Caution should be exercised in “at risk” patients such as the elderly who are more at risk of dehydration as electrolyte depletion may occur, people with impaired kidney function, diabetes or heart condition. Consult your doctor before use.

Ensure you receive adequate fluids during the administration of Prepkit-C

Prepkit-C is not recommended in children as the safety and effectiveness in children has not been established.

Do not take Prepkit-C after the expiry date printed on the pack, or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure when you should start taking Prepkit-C, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- Ulcerative Colitis
- Kidney problems
- Heart problems

- Diabetes
- Dehydration
- Phenylketonuria
- Stoma
- Undiagnosed stomach pain

It may not be safe for you to take Prepkit-C if you have these conditions.

Tell your doctor or pharmacist if you are pregnant, intend to become pregnant or are breast-feeding.

Prepkit-C is not generally recommended for use in pregnant women unless the benefits outweigh the risk to the unborn baby. Your doctor will discuss the benefits and possible risks with you.

Tell your doctor if you are diabetic.

The liquid diet recommended with this medication may affect your blood glucose levels and adjustment of your diabetic medication may be required.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

These include:

- Medicines for heart condition
- Iron medications
- Other medicines that may affect electrolyte balance
- Other bowel cleansing preparations

These medicines may be affected by Prepkit-C, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Medications that are taken just before or during the course of Prepkit-C may not be absorbed. This is due to the increased movement in the digestive tract and the watery diarrhoea that is caused by Prepkit-C.

These include:

- Oral contraceptives ('the pill')
- Antibiotics
- Medicines for diabetes

Your doctor or pharmacist will have more information on medicines to be careful with or avoid while taking Prepkit-C.

How to take Prepkit-C

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box or in this leaflet, ask your doctor or pharmacist for help.

Prepkit-C will produce numerous bowel motions within a short period of time. Ensure you have bathroom facilities within easy access from when you start to take Prepkit-C.

How much to take

Prepkit-C contains only enough medication for one treatment.

How to take it

It should be prepared and taken according to the directions in this leaflet unless otherwise directed by your doctor.

Preparation for the procedure begins two days prior to the procedure by stopping all iron containing medication.

Dietary changes also occur two days prior to the procedure. Refer to the Patient Instructions on the back of this leaflet for details.

Prepkit-C is taken the day before the procedure unless otherwise stated by your doctor.

Recommended Clear Fluids

include water, strained fruit juice without pulp (apple, white grape, pineapple, pear), clear broth, tea or coffee without milk or cream, clear

sugar-free cordials such as lemon or lime (no red or purple colourings), plain sugar-free jelly (no red or purple colourings) and clear ice blocks.

Do not drink carbonated beverages.

Do not drink alcoholic beverages.

REMEMBER you need to be close to toilet facilities whilst you are taking Prepkit-C.

Bowel movements may continue for several hours after the last dose of Prepkit-C has been taken.

If you take too much (overdose)

Overdosage is unlikely as Prepkit-C contains only enough medication for one treatment.

However in the event of an overdose, dehydration is likely and immediate action should be taken to restore electrolyte balance with appropriate fluid replacement.

Contact the Poisons Information Centre for any further information.

While you are taking Prepkit-C

Things you must do

Prepkit-C can lead to serious dehydration and electrolyte disturbances. You must ensure that you drink the recommended amount of liquid to replace the large amounts of fluid that may be lost during bowel emptying.

Ask your doctor or pharmacist to answer any questions you may have.

Things you must not do

Do not take any additional bowel preparation or laxative products.

Do not give Prepkit-C to anyone else, even if they have the same condition as you.

Do not stop taking Prepkit-C or lower the dose without checking with your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Prepkit-C.

Prepkit-C helps most people that require bowel cleansing, but it may have unwanted side effects in a few people. All medicines can have some unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

The following is a list of possible side effects. Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Nausea (feeling sick)
- Vomiting
- Stomach pain
- Stomach bloating
- Anal irritation

Do not be alarmed by this list. You may not experience any of them.

If the effects are severe, you may need medical treatment.

However these side effects usually disappear when treatment with Prepkit-C is finished.

If you get any side effects, do not stop taking Prepkit-C without first talking to your doctor or pharmacist.

Other side effects not listed may also occur in some patients. Tell your doctor or pharmacist if you notice anything unusual that is making you feel unwell.

Nephrocalcinosis and renal impairment may occur following the use of this medicine.

Further information

Storage

Keep Prepkit-C in a cool dry place where the temperature stays below 25°C.

Do not store Prepkit-C or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking Prepkit-C or it has passed the expiry date, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

A composite pack containing a 70g sachet of white powder labelled Glycoprep-C, two 15.5g sachets of white powder labelled PicoPrep and a Consumer Medicine Information leaflet.

Ingredients

Each Prepkit-C carton contains the following products:

Glycoprep-C

Each sachet labelled Glycoprep-C contains a white powder for solution composed of macrogol 3350, sodium chloride, potassium chloride, sodium sulfate anhydrous, ascorbic acid,

citric acid anhydrous, aspartame and lemon flavour.

PicoPrep

Each sachet labelled PicoPrep contains a white powder for solution composed of sodium picosulfate as the active. It also contains magnesium oxide, citric acid and aspartame.

Prepkit-C does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Prepkit-C does not contain any preservative.

Australian Registration Number

AUST L 210263

Sponsor

Supplied in Australia by:

Fresenius Kabi Australia Pty Ltd
964 Pacific Highway
Pymble NSW 2073
Ph: 1300 361 004

Supplied in New Zealand by:

Fresenius Kabi New Zealand Limited
60 Pavilion Drive
Airport Oaks, Auckland 2022
New Zealand
Freecall: 0800 144 892

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This leaflet was prepared in August 2015.

Patient instructions

Directions for taking Prepkit-C unless otherwise directed

2 Days prior to procedure

	<p>Stop taking all iron containing medication. Continue regular medications.</p> <p>Stop eating brown bread, red meat, cereals, vegetables and fruit. Do not have anything with seeds in it. No cheese.</p> <p>You may eat eggs, steamed white fish, boiled chicken, cheese, low fat plain yoghurt, white bread, white rice, clear jelly, skim milk and well cooked pumpkin potato.</p>
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1 Day prior to procedure

	<p>Preparation of the Glycoprep-C Solution Dissolve the contents of the 70g sachet in one (1) litre using a suitable food container. Refrigerate prior to use if preferred. No FOOD or MILK products allowed. Drink only recommended clear fluids.</p> <p>During the day drink at least one glass (approx. 250mL) of clear fluids each hour to maintain hydration. Continue to drink recommended clear fluids until bedtime.</p>
3pm	<p>Add the contents of ONE sachet of PicoPrep to a glass of water (approx. 250mL) and stir until dissolved. Note the solution may become hot. Chill for half an hour if preferred. Drink mixture slowly but completely.</p>
6pm	<p>Commence drinking the Glycoprep-C solution which was previously prepared. Ideally drink approximately every 15-20 minutes until completed. Drink the mixture slowly but completely. If you become nauseated, reduce the rate of intake.</p>
9pm	<p>Add the contents of the SECOND sachet of PicoPrep to a glass of warm water (approx. 250mL) and stir until dissolved. Note the solution may become hot. Chill for half an hour if preferred. Drink mixture slowly but completely. Continue drinking adequate glasses of recommended clear fluids until bedtime.</p>

On the day of procedure

	<p>NO FOOD to be taken. NO DRINK should be taken for six (6) hours prior to procedure.</p>
	<p>Patient:</p> <p>Appointment Date: _____</p> <p>Appointment Time: _____</p> <p>Type of Procedure: _____</p>