

PREPKIT ORANGE™

Consumer Medicine Information

WARNING

Life threatening dehydration and/or electrolyte disturbances may occur in some people. Read the section with the heading "Before you use this medicine kit".

What is in this leaflet

Read this leaflet carefully before taking your medicine

This leaflet answers some of the common questions people ask about PREPKIT ORANGE. It does not contain all the available information. It does not take the place of talking to your doctor, prescriber or pharmacist.

Ask your doctor, prescriber or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor, prescriber or pharmacist will have weighed the risks of you taking PREPKIT ORANGE against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine kit is used for

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

PREPKIT ORANGE is used to remove the bowel contents and

cleanse it prior to gastrointestinal examination (such as colonoscopy, barium enema x-ray examination), prior to intravenous pyelograms (IVP) or colorectal surgery, in adults 18 years and over.

PREPKIT ORANGE contains GLYCOPREP ORANGE and PICOPREP ORANGE sachets.

GLYCOPREP ORANGE contains macrogol 3350, which acts as a laxative in the intestine. Macrogol 3350 works by causing excess water to remain in your stool and stimulates bowel movements.

PICOPREP ORANGE contains sodium picosulfate and magnesium citrate, which both act as laxatives in the intestine.

Sodium picosulfate works by being broken down by intestinal bacteria and then acting on the lining in your intestine to stimulate bowel movements.

Magnesium citrate works similarly to GLYCOPREP ORANGE by causing excess water to remain in your stool and stimulates bowel movements.

This results in watery stool or bowel motions which removes the bowel contents and ensures the bowel is clean before the examination or procedure.

The bowel needs to be clean before the examination or procedure.

PREPKIT ORANGE produces watery stools or bowel motions within 1 to 4 hours after the first dose and may cause frequent

loose bowel motions depending on your individual response.

You should discuss with your doctor, prescriber or pharmacist what is going to happen before you have the examination or procedure. Your doctor or prescriber however, may prescribe GLYCOPREP ORANGE for another purpose.

Ask your doctor, prescriber or pharmacist if you have any questions about why this kit has been prescribed for you or how you are to take it.

Before you use this medicine kit

When you must not use it

Do not take this kit if you have, or have had, any of the following medical conditions:

- Gastrointestinal obstruction (a blockage in the stomach or bowel)
- Gastric retention (the stomach retains food and fluids)
- Bowel perforation (a hole in the stomach, large intestine or small intestine)
- Toxic colitis (a poisonous and inflamed large bowel)
- Toxic megacolon (a poisonous and enlarged large bowel)
- Ileus (a condition where the bowel does not work properly)
- Inflammation of the bowel
- A body weight less than 20 kg
- You are hypersensitive to or have had an allergic reaction to any of the ingredients

listed at the end of this leaflet.

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor, prescriber or pharmacist immediately or go to the Accident and Emergency department at the nearest hospital.

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

If you are not sure when you should start taking PREPKIT ORANGE, talk to your doctor, prescriber or pharmacist.

Before you start to take it

You must talk to your doctor, prescriber or pharmacist about using PREPKIT ORANGE if:

- you are allergic to any medicines, foods, dyes or preservatives;
- you are elderly;
- you have or have had any other health problems or medical conditions, including:
 - any stomach or bowel problems including ulcerative colitis (ulcers in the large bowel)
 - kidney disease
 - impaired kidney function (the kidneys not working properly)
 - difficulty in swallowing or food coming back after eating
 - diabetes
 - electrolyte disturbances
 - a heart condition
 - stoma (a surgical opening

from the large bowel through the lower abdomen or stomach to the outside).

If you have any of the above, you should discuss your condition with your doctor, prescriber or pharmacist before taking PREPKIT ORANGE. Your doctor, prescriber or pharmacist may not want you to take PREPKIT ORANGE or may want you to take special precautions or take it in another way.

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

PREPKIT ORANGE 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.

PREPKIT ORANGE should only be taken by adults 18 years and over.

Tell your doctor, prescriber or pharmacist 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, prescriber 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.

Some medicines may interact with PREPKIT ORANGE. These include:

- Laxatives or other bowel cleansing preparations
- Medicines for heart conditions
- Medicines for diabetes
- Antibiotics
- Other medicines that may

affect electrolyte balance

- Oral contraceptive pills (“the pill”)
- Iron supplements

PREPKIT ORANGE may affect any medication, taken orally, one (1) hour before and after taking PREPKIT ORANGE.

Your doctor, prescriber or pharmacist will have more information on medicines to be careful with or avoid while taking PREPKIT ORANGE.

If you have not told your doctor, prescriber or pharmacist about any of the above, tell them before you start taking PREPKIT ORANGE.

How to take this medicine kit

Follow all directions given to you by your doctor, prescriber 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, prescriber or pharmacist for help.

PREPKIT ORANGE will produce numerous bowel motions within a short period of time. Ensure you have toilet facilities within easy access from when you start to take PREPKIT ORANGE.

Do not have any food after the first dose of PREPKIT ORANGE. You must only consume the Recommended Clear Fluids while taking PREPKIT ORANGE and until after the procedure.

Recommended Clear Fluids include water, soups (e.g. strained chicken noodle soup), broth/bouillon, pulp-free fruit juices (e.g. apple, pear, white grape), black tea or coffee (no milk), electrolyte replacing drinks, nutritional supplements, carbonated beverages, clear cordials (e.g. lemon/lime), plain

jelly, sorbet, boiled sweets, and gums/jubes. Sugar, salt, and sweetener can be used. No red or purple colouring. Barley sugar may be sucked if required.

Do not drink alcoholic beverages.

If you are diabetic, discuss your requirements, and your diet and dosage program with your doctor, prescriber or pharmacist before commencing.

How much to take

It is important that you follow the instructions specifically given by your doctor, prescriber or pharmacist and that you drink plenty of Recommended Clear Fluids.

Your doctor, prescriber or pharmacist will have informed you of the dose that you should take and when to take it.

How to prepare this medicine kit

PICOPREP ORANGE

Slowly mix the entire contents of the PICOPREP ORANGE sachet in approximately 250 mL of warm water (not boiling). Use a large container (approx. 500 mL) as the solution will be effervescent (fizz and bubble). Stir gently until the effervescence ceases. The solution will appear cloudy and may be hot. Allow solution to cool before drinking. You also have the option of chilling the prepared PICOPREP ORANGE mixture in the refrigerator for up to 24 hours prior to drinking.

GLYCOPREP ORANGE

Mix the entire contents of the GLYCOPREP ORANGE sachet in 1 litre of water at ambient temperature using a suitable food grade container. Stir gently. The solution will appear cloudy. You also have the option of chilling the prepared GLYCOPREP ORANGE mixture in the refrigerator for up to 24 hours prior to drinking.

When to take this medicine kit

It is important that you follow the instructions specifically given by your doctor, prescriber or pharmacist and that you drink plenty of Recommended Clear Fluids.

Your doctor, prescriber or pharmacist will have informed you of the dose that you should take and when to take it.

An example of a dosing regimen is detailed below:

1. One day prior to the examination (at approximately 3 pm or as advised by your doctor or prescriber), prepare the PICOPREP ORANGE mixture as per the instructions in “**How to prepare this medicine kit**” or if prepared earlier and chilled, take the mixture out of the refrigerator. Drink the contents of the mug followed by a glass of water. Continue drinking Recommended Clear Fluids, at least a glass per hour.
2. In the evening of the same day (at approximately 6 pm or as advised by your doctor or prescriber), prepare the GLYCOPREP ORANGE sachet as per the instructions in “**How to prepare this medicine kit**” or if prepared earlier and chilled, take the mixture out of the refrigerator. Drink the mixture completely. Ideally drink approximately 1 to 2 glasses every 15-20 minutes until completed. If you become nauseated, reduce the rate of intake. Continue drinking Recommended Clear Fluids, at least a glass per hour until bedtime.

3. In the evening of the same day (at approximately 9 pm or as advised by your doctor or prescriber), prepare the PICOPREP ORANGE mixture as per the instructions in “**How to prepare this medicine kit**” or if prepared earlier and chilled, take the mixture out of the refrigerator. Drink the contents of the mug followed by a glass of water. Continue drinking Recommended Clear Fluids, at least a glass per hour.

No food or drink should be taken for two (2) hours prior to the examination.

REMEMBER you need to be close to toilet facilities whilst you are taking PREPKIT ORANGE.

Bowel movements may continue for several hours after the last dose of PREPKIT ORANGE has been taken.

If you forget to take it

It is important for you to take PREPKIT ORANGE exactly as prescribed. If you forget to take a dose, contact your doctor or prescriber as soon as possible as the time of the examination may need to be changed.

If you take too much (overdose)

Immediately telephone your doctor, prescriber, pharmacist or the Poisons Information Centre on 0800 764 766 in New Zealand for advice or go to the Accident and Emergency department (Casualty) at your nearest hospital if you think you may have taken too much of a medicine, even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these services handy.

If you are not sure what to do, contact your doctor, prescriber

or pharmacist.

While you are using this medicine kit

Things you must do

PREPKIT ORANGE 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, prescriber or pharmacist to answer any questions you may have.

If you are taking any other medicines, whether they require a prescription or not, talk to your doctor, prescriber or pharmacist before taking PREPKIT ORANGE. Tell all doctors, prescribers and pharmacists who are treating you that you are going to take PREPKIT ORANGE.

Tell your doctor or prescriber if, for any reason, you have not taken PREPKIT ORANGE exactly as prescribed.

Things you must not do

Do not give PREPKIT ORANGE to anyone else, even if they have the same condition as you.

Do not take any additional bowel preparation or laxative products unless otherwise stated by your doctor.

Things to be careful of

Because of the watery bowel motion caused by PREPKIT ORANGE you should not plan any other activities until after the examination.

It is most important that you take adequate fluids whilst using PREPKIT ORANGE.

Possible side effects

Tell your doctor, prescriber or pharmacist as soon as possible

if you do not feel well while you are taking PREPKIT ORANGE.

All medicines can have side effects. PREPKIT ORANGE may have unwanted side effects in some people. 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, prescriber or pharmacist to answer any questions you may have.

Tell your doctor, prescriber or pharmacist if you notice any of the following and they worry you:

- Nausea (feeling sick)
- Vomiting
- Stomach pain
- Stomach bloating
- Anal irritation
- Skin reactions
- Runny nose

Do not be alarmed by this list of possible side effects. You may not experience any side effects.

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

However, these side effects usually disappear when treatment with PREPKIT ORANGE is finished.

If you get any side effects, do not stop taking PREPKIT ORANGE without first talking to your doctor, prescriber 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.

Storage and disposal

Storage

Keep PREPKIT ORANGE in a cool dry place where the temperature stays below 25°C.

If you prefer to have your bowel preparation chilled, cover the mixture and place in a

refrigerator prior to drinking for no more than 24 hours.

Do not store PREPKIT ORANGE 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 ORANGE 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 medicine kit with:

- one (1) GLYCOPREP ORANGE 70 g sachet containing a white to creamy yellow powder with an odour characteristic of oranges and
- two (2) PICOPREP ORANGE 20 g sachets containing a white to creamy yellow powder with an odour characteristic of oranges.

Ingredients

Each GLYCOPREP ORANGE 70 g sachet contains macrogol 3350 (polyethylene glycol) 52.9 g, potassium chloride 740 mg, sodium chloride 2.6 g and sodium sulfate 5.6 g, as active ingredients. Total sodium content in 70 g sachet is 2.86 g. It also contains ascorbic acid, silicon dioxide, natural orange flavour and natural Stevia sweetener.

Each PICOPREP ORANGE 20 g sachet contains sodium picosulfate 10.3 mg, magnesium carbonate hydrate 7.4 g and citric acid 12.2 g,

as the active ingredients. It also contains natural orange flavour and natural Stevia sweetener.

PREPKIT ORANGE does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes or sulfites.

PREPKIT ORANGE does not contain any preservatives.

Sponsor

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