

Prepkit Orange™

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using Prepkit Orange?

Prepkit Orange contains both Picoprep Orange and Glycoprep Orange sachets. The active ingredients of Picoprep Orange are sodium picosulfate, citric acid and magnesium carbonate. The active ingredients of Glycoprep Orange are macrogol 3350 (polyethylene glycol), potassium chloride, sodium chloride and sodium sulfate. 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 and children 9 years of age and over.

For more information, see Section [1. Why am I using Prepkit Orange?](#) in the full CMI.

2. What should I know before I use Prepkit Orange?

Do not use if you have ever had an allergic reaction to Prepkit Orange or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant, intend to breastfeed or are breastfeeding.

For more information, see Section [2. What should I know before I use Prepkit Orange?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Prepkit Orange and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Prepkit Orange?

- Picoprep Orange: Mix the entire contents of each 20 g sachet in 250 mL of water at room (ambient) temperature using a suitable food grade container.
- Glycoprep Orange: Mix the entire contents of the Glycoprep Orange 70 g sachet in 1 litre of water at room (ambient) temperature using a suitable food grade container.
- It is important to follow the instructions your doctor, prescriber or pharmacist has provided to you.

More instructions can be found in Section [4. How do I use Prepkit Orange?](#) in the full CMI.

5. What should I know while using Prepkit Orange?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Prepkit Orange.• Drink plenty of recommended clear fluids whilst taking Prepkit Orange• Be close to toilet facilities whilst taking Prepkit Orange |
| Things you should not do | <ul style="list-style-type: none">• Do not give Prepkit Orange to anyone else• Do not take additional bowel preparation or laxative products unless stated by your doctor, prescriber or Pharmacist. |
| Looking after your medicine | <ul style="list-style-type: none">• Keep Prepkit Orange in a cool dry place where the temperature stays below 25°C• Once reconstituted, you may refrigerate for up to 24 hours. |

For more information, see Section [5. What should I know while using Prepkit Orange?](#) in the full CMI.

6. Are there any side effects?

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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING: Life threatening dehydration and/or electrolyte disturbances may occur in some people. Read the section with the heading “What should I know while using Prepkit Orange?”.

Prepkit Orange™

Active ingredient(s): *sodium picosulfate, citric acid, magnesium carbonate, macrogol 3350 (polyethylene glycol), sodium sulfate, potassium chloride and sodium chloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Prepkit Orange. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Prepkit Orange.**

Where to find information in this leaflet:

- [1. Why am I using Prepkit Orange?](#)
- [2. What should I know before I use Prepkit Orange?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Prepkit Orange?](#)
- [5. What should I know while using Prepkit Orange?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Prepkit Orange?

Prepkit Orange contains both Picoprep Orange and Glycoprep Orange sachets. The active ingredients of Picoprep Orange are sodium picosulfate, citric acid and magnesium carbonate. The active ingredients of Glycoprep Orange are macrogol 3350 (polyethylene glycol), sodium sulfate, potassium chloride and sodium chloride. Prepkit Orange is classified as a bowel preparation. 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. This results in watery stool or bowel motions which removes the bowel contents and ensures the bowel is clean before the examination or procedure. Picoprep Orange contains sodium picosulfate, citric acid and magnesium carbonate. Citric acid reacts with magnesium carbonate to form magnesium citrate. Sodium picosulfate and magnesium citrate 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.

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 and children 9 years of age and over.

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

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.

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 Prepkit Orange for another purpose.

2. What should I know before I use Prepkit Orange?

Warnings

Do not use Prepkit Orange if:

- you have severe dehydration (the symptoms of severe dehydration may include lethargy, excessive thirst, dizziness upon standing, rapid pulse, and not passing urine for protracted periods)
- you have had an allergy 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 immediately or go to the Emergency department at the nearest hospital**
- you have kidney failure or disease
- you have gastrointestinal obstruction (a blockage in the stomach or bowel)
- you have gastric retention (the stomach retaining its food)
- you have bowel perforation (a hole in the stomach, small intestine or large intestine)
- you have toxic colitis (a poisonous and inflamed large bowel)
- you have toxic megacolon (a poisonous and enlarged large bowel)
- you have ileus (a condition where the bowel does not work properly)
- you have inflammation of the bowel
- you have a body weight less than 20kg

- you have a stoma (a surgical opening from the large bowel through the lower abdomen or stomach to the outside)
- your child is under the age of 9 years
- 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.

Check with your doctor or pharmacist 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 severe 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, electrolyte disturbances (such as high magnesium levels or low sodium levels), a heart condition, diabetes, or 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

- 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.

Use in children

- Prepkit Orange is not recommended for use in children under the age of 9 years as the safety and effectiveness has not been established.

Use in renal impairment

- If you have kidney disease or impaired kidney function, you may require additional monitoring. Please speak to your doctor, prescriber or pharmacist before using Prepkit Orange.

Use in elderly

- This medication can cause dehydration and electrolyte depletion. If you are elderly, it is important to ensure you are taking adequate fluids whilst taking Prepkit Orange. Please speak to your doctor, prescriber or pharmacist before using Prepkit Orange.

Use in diabetic patients

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

3. What if I am taking other medicines?

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

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

Some medicines may interfere with Prepkit Orange and affect how it works.

- Laxatives or other bowel cleansing preparations
- Medicines for heart conditions
- Medicines for diabetes
- Picoprep Orange may reduce the effect of medicines used to treat infections (antibiotics)
- Other medicines that may affect electrolyte balance
- Picoprep Orange may reduce the effect of birth control medicines (Oral contraceptive pills), particularly for low-dose contraceptive pills
- Iron supplements

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect 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.

4. How do I use Prepkit Orange?

How much to take / use

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

- They may differ from the information contained in this leaflet.
- Prepkit Orange contains 2 Picoprep Orange sachets and 1 Glycoprep Orange sachet.

- The treatment can be taken as either a single day regimen (day before) or split dose regimen (over 2 days) depending on the time of the clinical procedure.
- Your doctor, prescriber or pharmacist will have informed you of the dose that you should take and when to take it and which dosing schedule to follow.

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.

When to take / use Prepkit Orange

- Prepkit Orange should be used as per the instructions provided to you by your doctor, prescriber or Pharmacist.
- Your doctor, prescriber or pharmacist will have informed you of which dosing schedule to follow and when to take it.
- Commence drinking the prepared Prepkit Orange solution as directed by your doctor.
- The treatment can be taken as either a single day regimen (day before) or split dose regimen (over 2 days) (the times given are only suggestions, your doctor may tell you different times).
- If the procedure is scheduled for the afternoon, it is recommended that the Split-Dose regimen be used.

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

Single Day Regimen

Day Before Procedure

First Dose: *PICOPREP ORANGE® sachet (taken at 3 pm).* The solution should be ingested slowly but completely. This should be followed by one (1) glass of water and at least one (1) 250 mL glass every hour of water or Recommended Clear Fluids.

Second Dose: *GLYCOPREP ORANGE® sachet (taken at 6 pm).* One (1) to two (2) 250 mL glasses of the prepared solution should be taken every 15-20 minutes. This should be followed by adequate glasses of water or Recommended Clear Fluids. If nausea is experienced, the rate of intake of GLYCOPREP ORANGE® solution should be reduced.

Third Dose: *PICOPREP ORANGE® sachet (taken at 9 pm).* The solution should be ingested slowly but completely. This should be followed by one (1) glass of water and at least one (1) 250 mL glass every hour of water or Recommended Clear Fluids.

Split-dose Regimen (evening before and day of the procedure)

Day Before Procedure

First Dose: *PICOPREP ORANGE® sachet (taken at 6 pm).* The solution should be ingested slowly but completely. This should be followed by one (1) glass of water and at least one (1) 250 mL glass every hour of water or Recommended Clear Fluids.

Second Dose: *GLYCOPREP ORANGE® sachet (taken at 9 pm).* One (1) to two (2) 250 mL glasses of the prepared solution should be taken every 15-20 minutes. This should be followed by adequate glasses of water or Recommended Clear Fluids. If nausea is experienced, the rate of intake of GLYCOPREP ORANGE® solution should be reduced.

Day Of Procedure

Third Dose: *PICOPREP ORANGE® sachet taken approx. 2 to 5 hours prior to procedure).* The solution should be ingested slowly but completely. This should be followed by one (1) glass of water and at least one (1) 250 mL glass every hour of water or Recommended Clear Fluids.

How to prepare Prepkit Orange

Picoprep Orange Sachets x 2

- Mix the entire contents of the first 20 g sachet in 250 mL of water at room (ambient) temperature using a suitable food grade container. Use a large container (approximately 500 mL) as the solution will be effervescent (fizz and bubble). Stir gently until the effervescence ceases. Repeat this for the second sachet. The solution will appear cloudy and may be hot. Allow solution to cool prior to drinking.

Glycoprep Orange Sachet x 1

- Mix the entire contents of the Glycoprep Orange sachet in 1 litre of water at room (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
- If you prefer to have your bowel preparation chilled, cover all mixtures and place in a refrigerator prior to drinking for no more than 24 hours.

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 use too much Prepkit Orange

If you think that you have used too much Prepkit Orange, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Prepkit Orange?

Things you should do

- No food or drink should be taken for two (2) hours prior to the examination.
- 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.
- It is most important that you take adequate fluids whilst using Prepkit Orange.

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.
- Because of the watery bowel motion caused by Prepkit Orange you should not plan any other activities until after the examination.

Prepkit Orange can lead to serious (life-threatening or harmful) 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.

- Remind any doctor, dentist or pharmacist you visit that you are using Prepkit Orange.
- Ask your doctor, prescriber or pharmacist to answer any questions you may have.

Tell all doctors, prescribers and pharmacists who are treating you that you are going to take Prepkit Orange.

Tell your doctor, prescriber or pharmacist if, for any reason, you have not taken Prepkit Orange exactly as prescribed.

Things you should not do

- Do not give Prepkit Orange to anyone else, even if they have the same procedure as you.
- Do not take any additional bowel preparation or laxative products unless otherwise stated by your doctor, prescriber or pharmacist.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Prepkit Orange affects you.

Prepkit Orange may cause dizziness in some people.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Do not drink alcohol whilst taking Prepkit Orange. Alcohol may add to the dehydrating effect of Prepkit Orange.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly. 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.

Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 25°C; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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.

- If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.
- Do not use this medicine after the expiry date.

6. Are there any 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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

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

Side effects

| Less Serious Side effects | What to do |
|--|--|
| Gastrointestinal <ul style="list-style-type: none">• Nausea• Vomiting• Bloating• Abdominal Cramps• Anal Irritation Dermatology <ul style="list-style-type: none">• Skin Reactions Other <ul style="list-style-type: none">• Runny Nose• Headache• Dizziness | Speak to your doctor or pharmacist if you have any of these side effects and they worry you. Usually, they are transient and will subside once the preparation is finished. |

| Serious/ rare side effects | What to do |
|--|--|
| <ul style="list-style-type: none">• Allergic reactions, hypersensitivity• Severe life-threatening dehydration, convulsion• Electrolyte disturbance | Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. If the side effects are severe, you may need urgent medical attention. If you get any side effects, do not stop taking Prepket Orange without first talking to your doctor, prescriber or pharmacist.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Prepket Orange contains

Glycoprep Orange sachet x 1

| | |
|---|--|
| Active ingredient (main ingredient) | macrogol 3350 potassium chloride sodium sulfate sodium chloride |
| Other ingredients (inactive ingredients) | ascorbic acid silicon dioxide Natural Orange flavour Sweetesse Stevia™ 97 |
| Potential allergens | none |

Picoprep Orange sachet x 2

| | |
|---|--|
| Active ingredient (main ingredient) | sodium picosulfate magnesium carbonate hydrate citric acid |
| Other ingredients (inactive ingredients) | Natural Orange flavour Sweetesse Stevia™ 97 |
| Potential allergens | none |

Do not take this medicine if you are allergic to any of these ingredients.

Prepket Orange does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes or sulfites.

Prepket Orange does not contain any preservatives.

What Prepket Orange looks like

Prepket Orange is a medicine kit which contains:

- 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.
(AUST R 370153)

Who distributes Prepket Orange

Fresenius Kabi Australia Pty Ltd.

Level 2, 2 Woodland Way

Mount Kuring-Gai NSW 2080

Tel: 1300 732 001

This leaflet was prepared in April 2023.