Picoprep Orange®

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> 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 <u>full CMI</u>. Read before using this medicine.

1. Why am I using Picoprep Orange?

Picoprep Orange contains the active ingredients sodium picosulfate, citric acid and magnesium carbonate. Picoprep 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 <u>1. Why am I using Picoprep Orange?</u> in the full CMI.

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

Do not use if you have ever had an allergic reaction to Picoprep 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 or are breastfeeding.

For more information, see Section 2. What should I know before I use Picoprep Orange? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Picoprep 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 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.
- It is important to follow the instructions your doctor, prescriber or pharmacist has provided to you.

More instructions can be found in Section <u>4. How do I use Picoprep Orange?</u> in the full CMI.

5. What should I know while using Picoprep Orange?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Picoprep Orange. Drink plenty of recommended clear fluids whilst taking Picoprep Orange Be close to toilet facilities whilst taking Picoprep Orange
Things you should not do	 Do not give Picoprep 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	 Keep Picoprep 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 Picoprep Orange? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Picoprep 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 Picoprep Orange?".

Picoprep Orange®

Active ingredient(s): sodium picosulfate, citric acid and magnesium carbonate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Picoprep 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 Picoprep Orange.

Where to find information in this leaflet:

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

1. Why am I using Picoprep Orange?

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. Picoprep Orange is classified as a bowel preparation. Sodium picosulfate works by being broken down by intestinal bacteria and then acting on the lining in your intestine to stimulate 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 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.

Picoprep Orange produces watery stools or bowel motions within 2 to 3 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 medicine has been prescribed for you or how you are to take it

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

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

Warnings

Do not use Picoprep 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 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 (e.g.

high magnesium level), a heart condition and diabetes.

• you are taking any medicines for any other condition.

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

Caution should be exercised in "at risk" (See "Before you start to take this medicine") patients such as the elderly who are more at risk of life-threatening dehydration as electrolyte depletion may occur.

Picoprep Orange should only be taken by adults and children 9 years of age or over.

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 <u>6. Are there any side effects?</u>

Pregnancy and breastfeeding

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

 Picoprep Orange is not generally recommended for use in pregnant women unless the benefits outweigh the risk to the unborn baby. Your doctor, prescriber or pharmacist will discuss the benefits and possible risks with you.

Use in children

 Picoprep Orange is not recommended 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 Picoprep 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 Picoprep Orange. Please speak to your doctor, prescriber or pharmacist before using Picoprep 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.

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

Some medicines may interfere with Picoprep 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
- Oral medication taken within one hour of the commencing Picoprep Orange, may be flushed from the gastrointestinal tract and not absorbed.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Picoprep Orange. Your doctor, prescriber or pharmacist may have more information on medicines to be careful with while taking Picoprep Orange.

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

4. How do I use Picoprep 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.

- Usually, a total of two (2) sachets each containing 20 g of Picoprep Orange will need to be prepared and consumed. Some patients will require three (3) sachets to be prepared and consumed.
- 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, contact your doctor, prescriber or pharmacist for help. Picoprep 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 Picoprep Orange.

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

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

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 which dosing schedule to follow and when to take it.
- Commence drinking the prepared Picoprep Orange solution as directed by your doctor.
- You can take this preparation as a single day regimen (day before) or a split dose regimen (over 2 days) (<u>the</u> <u>times given are only suggestions, your doctor may tell</u> <u>you different times</u>).
- If the procedure is scheduled for the afternoon, it is recommended that the Split-Dose regimen be used.

Single Day Regimen- Two Sachet Regimen

Day Before Procedure

<u>First Dose</u>: 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.

<u>Second Dose:</u> 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.

Single Day Regimen- Three Sachet Dose

Day Before Procedure

<u>First Dose:</u> PICOPREP ORANGE[®] sachet (taken at 1 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.

<u>Second Dose</u>: PICOPREP ORANGE[®] sachet (taken at 5 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.

<u>Third Dose</u>: 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)- Two Sachet Dose

Day Before Procedure

First Dose: PICOPREP ORANGE[®] sachet (taken at 7 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.

Day Of Procedure

<u>Second Dose</u>: 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.

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

Day Before Procedure

First Dose: PICOPREP ORANGE[®] sachet (taken 3- 5pm). 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.

<u>Second Dose</u>: 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.

<u>Day Of Procedure</u>

<u>Third Dose:</u> 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 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. Use a large container (approximately 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 prior to drinking.
- 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.

If you use too much Picoprep Orange

If you think that you have used too much Picoprep 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 Picoprep 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 Picoprep Orange.
- It is most important that you take adequate fluids whilst using Picoprep Orange.

REMEMBER you need to be close to toilet facilities whilst you are taking Picoprep Orange

- Bowel movements may continue for several hours after the last dose of Picoprep Orange has been taken.
- Because of the water bowel motion caused by Picoprep Orange, you should not plan any other activities until after the examination.

Picoprep Orange can lead to life-threatening dehydration and electrolyte disturbances. You must ensure that you drink the recommended amount of liquid to replace the fluid that may be lost during bowel emptying.

Remind any doctor, dentist or pharmacist you visit that you are using Picoprep Orange.

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

Things you should not do

- Do not give Picoprep 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 Picoprep Orange affects you.

Picoprep Orange may cause dizziness in some people.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Alcohol may add to the dehydrating effect of Picoprep 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, prescriber or pharmacist tells you to stop taking Picoprep 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 Picoprep 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.

Side effects

Life threatening dehydration and/or electrolyte disturbances may occur in some people.

Less serious side effects	What to do
Gastrointestinal • Nausea • Vomiting • Bloating • Abdominal Cramps • Anal Irritation	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.
Other • Headache • Dizziness	

Serious/rare side effects	What to do
 Aallergic reactions, hypersensitivity Severe life-threatening dehydration, convulsions Electrolyte disturbances 	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 Picoprep 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 Picoprep Orange contains

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

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

This medicine does not contain lactose, sucrose, gluten, tartrazine, or any other azo dyes or sulfites.

What Picoprep Orange looks like

Picoprep Orange is a sachet containing 20 g of a white to creamy yellow powder with an odour characteristic of oranges. It is available in a carton containing two or three sachets.

(AUST R 363537).

Who distributes Picoprep Orange

Fresenius Kabi Australia Pty Ltd. Level 2, 2 Woodland Way Mount Kuring-Gai NSW 2080 Tel: 1300 732 001

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