

PICOPREP ORANGE®

New Zealand 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 this medicine".

What is in this leaflet?

Read this leaflet carefully before taking your medicine

This leaflet answers some common questions about PICOPREP ORANGE. It does not contain all the information that is known about PICOPREP ORANGE. 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 PICOPREP 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 is used for

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

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 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. 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.

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.

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.

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.

Before you take this medicine

When you must not take it

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

- Kidney failure or disease
- Gastrointestinal obstruction (a blockage in the stomach or bowel)
- Gastric retention (the stomach retaining its food)
- Bowel perforation (a hole in the stomach, small intestine or large 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)
- Stoma (a surgical opening from the large bowel through the lower abdomen or stomach to the outside)
- If your child is under the age of 9 years
- 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 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 PICOPREP ORANGE contact your doctor, prescriber or pharmacist.

Before you start to take this medicine

You must talk to your doctor, prescriber or pharmacist about using PICOPREP 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 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
- a heart condition
- diabetes

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.

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

PICOPREP ORANGE should only be taken by adults and children 9 years of age or 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 PICOPREP 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”)

Your doctor, prescriber and 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.

How to take this medicine

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, 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.

How much to take

It is important that you follow the instructions specifically given by your doctor, prescriber or pharmacist and ensure 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.

Usually, a total of TWO sachets will be required for the procedure. For some patients, THREE sachets will be required for the procedure.

How to prepare this medicine

Slowly mix the entire contents of one 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.

When to take this medicine

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 dosage regimen is detailed below if you have been prescribed **TWO** sachets:

1. One day prior to the examination (at approximately 3 pm or as advised by your doctor or prescriber), make up the PICOPREP ORANGE mixture as per the instructions above OR take pre-made chilled PICOPREP ORANGE mixture from 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 9 pm or as advised by your doctor or prescriber), mix the entire contents of the

second sachet of PICOPREP ORANGE, following the same instructions as the first sachet. Drink the contents of the mug followed by a glass (250 mL) of water. Continue drinking Recommended Clear Fluids, at least a glass per hour, until bedtime.

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

An example of a dosage regimen is detailed below if you have been prescribed **THREE** sachets:

1. One day prior to the examination (at approximately 1 pm or as advised by your doctor or prescriber), make up the PICOPREP ORANGE mixture as per the instructions above OR take pre-made chilled PICOPREP ORANGE mixture from 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 5 pm or as advised by your doctor or prescriber), make up the PICOPREP ORANGE mixture as per the instructions above OR take pre-made chilled PICOPREP ORANGE mixture from 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.
3. In the evening of the same day (at approximately 9pm or as advised by your doctor or prescriber), mix

the entire contents of the second sachet of PICOPREP ORANGE, following the same instructions as the first sachet. Drink the contents of the mug followed by a glass (250 mL) of water. Continue drinking Recommended Clear Fluids, at least a glass per hour, until bedtime.

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 PICOPREP ORANGE.

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

If you forget to take it

It is important for you to take PICOPREP 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 (telephone 13 11 26 in Australia or 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 PICOPREP ORANGE, 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 take too much PICOPREP ORANGE you may experience a

severe headache, and a fast or irregular heartbeat. **If you are not sure what to do, contact your doctor, prescriber or pharmacist.**

While you are using this medicine

Things you must do

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.

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 PICOPREP ORANGE.

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

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

You must drink the entire solution prepared from the PICOPREP ORANGE pack. Do not stop taking PICOPREP ORANGE or lower the dose, unless your doctor or prescriber tells you to do so.

Things you must 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.

Things to be careful of

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

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

Possible 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. 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.

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

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

Tell your doctor or prescriber 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 of possible side effects. 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 PICOPREP ORANGE is finished.

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

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

Storage and disposal

Storage

Keep PICOPREP 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 PICOPREP ORANGE or any other medicines, in a 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 PICOPREP ORANGE where children cannot reach it.

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

Disposal

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.

Product Description

What it looks like

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

Ingredients

Each sachet contains sodium picosulfate, magnesium carbonate hydrate and citric acid, as the active ingredients. It also contains natural orange flavour and natural Stevia sweetener.

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

Sponsor

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