

PicoPrep

Sodium Picosulfate Powder for Oral Solution

Consumer Medicine Information

WARNING

Serious dehydration and/or electrolyte disturbance may occur in some "at risk" Patients.

Please read the section headed "Before you take PicoPrep"

What is in this leaflet?

This leaflet answers some common questions about PicoPrep. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking PicoPrep against the expected benefits 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 PicoPrep is used for?

PicoPrep is used to remove the bowel contents and cleanse it prior to the doctor's examination or surgery. It enables your doctor to see inside easily. It is sometimes used to clear the colon before a special x-ray of the kidneys. It does this by acting in the intestine and colon causing a watery stool or bowel motion which removes the bowel contents. This may be a little uncomfortable but is necessary for the examination.

It depends on what type of examination you are having as to

what procedure is to be used. One type is that a special instrument is inserted into the bowel that allows the doctor to see inside. Another is that you will be given an enema into the bowel containing a compound that shows up on x-rays.

You should discuss with your doctor what is going to happen before you have the procedure. Your doctor, however may prescribe PicoPrep for another purpose. Ask your doctor if you have any questions about why PicoPrep has been prescribed for you or how you are to take it.

Before you take PicoPrep

❖ When you must not take it

Those people who have the following: Gastrointestinal obstruction (a stomach blockage); gastric retention (the stomach retaining its food); bowel perforation (a hole in the large bowel); toxic colitis (a poisonous and inflamed large bowel); toxic mega colon (a poisonous and enlarged large bowel); ileus (a painful stoppage in the intestine); stoma (a surgical opening from the large bowel through the lower abdomen or stomach to the outside).

PicoPrep should only be taken by adults or children over the age of 9 years.

Do not take PicoPrep if you think any of the ingredients listed at the end of this leaflet may give you an allergy or cause you to have a reaction. Some of the symptoms of an allergic

reaction may include hives or an itchy skin rash, swelling of the face, lips or tongue, difficulty breathing, or faintness. It is very unlikely you will have an allergic reaction to PicoPrep.

The product contains a sweetener called aspartame which is present in only small amounts but which may upset persons who suffer from **PHENYLKETONURIA**. If you are one of these people, you must discuss this with your doctor.

Do not take PicoPrep if the packaging is torn or shows signs of tampering.

Do not take PicoPrep if the expiry date (EXP) printed on the pack has passed. If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure whether you should start taking PicoPrep contact your doctor.

❖ Before you start to take PicoPrep

You must talk to your doctor about using PicoPrep if:

1. **you are allergic to any medicines, foods, dyes or preservatives;**
2. **you are elderly;**
3. **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 problems (blood chemicals)
- a heart condition
- If you have any of the above, you should discuss your condition with your doctor before taking PicoPrep. Your doctor may not want you to take PicoPrep or may want you to take special precautions or take it in another way.

4. **you are pregnant.** PicoPrep should only be taken during pregnancy after you talk about it with your doctor as it is not known whether it will harm the unborn baby.

❖ Taking other medicines

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

Some medicines may interfere with PicoPrep, or be interfered by PicoPrep. These include: laxatives (especially saline ones); diuretics (water) tablets; heart medicines; antibiotics. These medicines may be affected by, or affect PicoPrep, or may affect how well it works, or whether you need to take different amounts of your medicine, or take a different medicine.

Your doctor and pharmacist may have more information on medicines to be careful with while taking PicoPrep.

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

How to take PicoPrep

Unless your doctor has given you specific instructions, please follow these dosage and dietary instructions.

Preparation of Solutions.

Dissolve the contents of one sachet in one full glass (approximately 250mls) of warm water. This may be chilled in a refrigerator prior to use if you prefer.

Where "glass" is mentioned, this should be at least 250mls.

Approved Clear Fluids

Water, clear salty fluids (e.g: strained chicken noodle soup), clear broth/bouillon, clear fruit juice, plain jelly, black tea or coffee (no milk), sports drinks, Gastrolyte, clear fruit cordials (clear lemon/lime), (no red/purple colourings).

(A good combination of these clear fluids, including 2-3 cups of strained chicken noodle soup, will give a variation in fluid intake.

Barley sugar may also be sucked if required.

Diabetics should discuss their requirements and dosage program with their doctor before commencing.

PicoPrep produces a watery stool or bowel motion that

empties and cleanses the bowel before examination or surgery. It should be prepared and taken according to the following directions unless otherwise directed by your doctor.

DOSAGE AND ADMINISTRATION (Note: The timing may be varied by your doctor)

PicoPrep should only be taken by adults and children over the age of 9 years.

Two days prior to the examination stop eating brown bread, red meat, cereals, vegetables, yellow cheese or anything with seeds in it. You may eat boiled or poached eggs, cottage cheese, white bread, low fat plain yoghurt, steamed white fish, boiled chicken, well cooked peeled pumpkin and potatoes. You may have clear jelly, skim milk and drink plenty of Approved Clear Fluids.

On the day before your examination, no solid foods or milk products are allowed. Drink only Approved Clear Fluids (see above) for breakfast, lunch and dinner.

1. On the day prior to the examination, drink Approved Clear Fluids only.
2. Commencing on the day before the examination (at approximately **3 pm**), dissolve the entire contents of one sachet of PicoPrep in a glass (250 mls) of warm water. If preferred chill in a refrigerator before drinking. Drink the contents of the glass followed by a glass of water. Continue drinking Approved Clear Fluids, at least a glass per hour the more the better to ensure adequate body hydration.
3. In the evening of the same day (at approximately **9pm**),

repeat the above with another sachet of PicoPrep ie: dissolve in a glass of warm water, chill if preferred, then drink contents followed by a glass of water. Continue drinking Approved Clear Fluids, at least a glass per hour until six (6) hours prior to the examination.

No food or drink should be taken for six (6) hours prior to the examination.

If a third sachet is required:

1. On the day prior to the examination, drink Approved Clear Fluids only.
2. Commencing on the day before the examination (at approximately **1pm**), dissolve the entire contents of one sachet of PicoPrep in a glass (250 mls) of warm water. If preferred chill in a refrigerator before drinking. Drink the contents of the glass followed by a glass of water. Continue drinking Approved Clear Fluids, at least a glass per hour the more the better to ensure adequate body hydration.
3. In the evening of the same day (at approximately **5pm**), repeat the above with another sachet of PicoPrep, that is, dissolve in a glass of warm water, chill if preferred, then drink contents followed by a glass of water. Continue drinking Approved Clear Fluids, at least a glass per hour the more the better to ensure adequate body hydration.
4. In the evening of the same day (at approximately **9pm**), repeat the above again with the third sachet of PicoPrep ie: dissolve in a glass of warm water, chill if preferred, and drink the contents followed by a glass of water. Continue drinking Approved

Clear Fluids at least a glass per hour until six (6) hours prior to the examination.

No food or drink should be taken for six (6) hours prior to the examination.

Follow all directions given to you by your doctor or pharmacist carefully. If you do not understand the instructions, ask your doctor or pharmacist for help.

The first bowel motion should occur approximately 2 to 3 hours after commencing dose. Onset may be sooner in individual patients.

❖ **If you forget to take it**

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

Do not double a dose to make up for the dose you have missed.

❖ **If you take too much (overdose)**

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to casualty at your nearest hospital if you think you may have taken too much PicoPrep, even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these places handy.

If you take too much PicoPrep you may experience a severe headache, and a fast or irregular heartbeat. **If you are not sure what to do, contact your doctor or pharmacist.**

While you are taking PicoPrep

❖ **Things you must do:**

- If you are about to be started on any new medicines, tell your doctor or pharmacist that you are to take PicoPrep.
- Do not take any other medicines, whether they require a prescription or not, without first telling your doctor.
- Tell all doctors and pharmacists who are treating you that you are to take PicoPrep.
- Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

❖ **Things you must not do:**

- Only take half the dose or none at all.
- Give the medicine to anyone else.

❖ **Things to be careful of:**

- Because of the watery bowel motion caused by PicoPrep you should not plan any other activities until after the examination.
- It is most important that you take adequate fluids whilst using PicoPrep.
- Be careful driving or operating machinery until you know how PicoPrep affects you.

Side Effects

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

All medicines can have side effects. PicoPrep 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 or pharmacist any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

Nausea; abdominal fullness; or a feeling of gas in the stomach. These are the more common side effects of PicoPrep.

Less frequent side effects are: abdominal cramps; vomiting; anal irritation. All side effects usually last for a short time only.

Other side effects not listed may also occur in some patients. Do not be alarmed by this list of possible side effects. You may not experience any of them. Tell your doctor if you notice anything else that is making you feel unwell. Ask your doctor or pharmacist if you don't understand anything in this list.

Storage

Keep your medicine in the sachet until it is time to mix and take a dose. Keep PicoPrep in a cool, dry place where it stays below 30°C. Do not store it, or any other medicines, in a bathroom or near a sink. Heat and dampness can destroy some medicines.

Keep this medicine where young children cannot reach it. A locked cupboard at least one-and-a half

meters above the ground is a good place to store medicines.

Product Description

PicoPrep is a white powder and is available in a packet with two or three sachets.

INGREDIENTS

PicoPrep powder for solution contains:

10mg of sodium picosulfate;
3.5g of magnesium oxide;
12.0g of citric acid; and,
36mg of aspartame.

PicoPrep does not contain lactose, sucrose, gluten, tartrazine, any azo dyes or "sulfur" medicines.

REGISTRATION

The Australian registration number is AUST R 20508

SUPPLIER

Fresenius Kabi Australia Pty Limited
(ABN 39 109 383 593)
964 Pacific Highway
Pymble NSW 2073

Date Revised : 26 October 2010