

PICOSALAX®

Powder for oral solution

Sodium picosulfate with Magnesium citrate

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 Picosalax".

What is in this leaflet

This leaflet answers some common questions about Picosalax. 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 Picosalax against the benefits they expect 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 Picosalax is used for

Picosalax is used for clearance of the bowel before x-ray, endoscopy or surgery.

Picosalax produces a watery stool or bowel motion which empties and cleans the bowel before the procedure.

Each dose of Picosalax usually produces a bowel movement within 2 to 3 hours, depending on your individual response.

Ask your doctor or pharmacist if you have any questions about why this medicine has been recommended for you.

Your doctor may have recommended it for another reason.

Before you take Picosalax

When you must not take it

Picosalax is not to be used as a routine laxative.

Picosalax is not for use in children under 9 years of age.

Do not take Picosalax if you have an allergy to:

- any medicine containing sodium picosulfate or magnesium citrate
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Picosalax if you are suffering from:

- heart failure
- perforation of the stomach or stomach obstruction

- delayed emptying of stomach contents into the small intestine
- holes in the lining of the stomach
- damage to the entire thickness of the intestinal wall
- severe distension in the colon
- blockage in the bowel
- nausea and vomiting
- inflammation of the appendix
- severe dehydration
- muscle damage causing muscle pains, vomiting, confusion
- high magnesium levels
- active inflammatory bowel disease
- severe kidney disease
- undiagnosed abdominal symptoms.

Do not take it after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- recent gastrointestinal surgery

- kidney problems
- heart problems
- inflammatory bowel disease
- electrolyte disturbances
- diabetes.

Tell your doctor if you are on potassium restricted diet.

Picosalax contains 195 mg potassium per sachet. This should be taken into consideration if you have reduced kidney function or you are on a controlled potassium diet.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Picosalax.

Taking other medicines

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

Some medicines and Picosalax may interfere with each other. These include:

- birth control medications (oral contraceptives)
- medicines used to treat infections (antibiotics)
- medicines used to help the kidneys get rid of salt and water by increasing the amount of urine produced (diuretics)
- corticosteroids
- medicines used to treat depression (antidepressants) or psychosis (antipsychotics)
- bulk-forming laxatives
- iron supplements
- medicines used to treat heart failure and the associated symptoms of shortness of breath when lying flat (e.g digoxin)
- medicines used to treat epilepsy (anti-epileptics)
- medicines used to treat diabetes

- medicines such as ibuprofen, used to treat pain and inflammation (NSAIDs)
- penicillamine.

These medicines may be affected by Picosalax or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Picosalax may prevent absorption of oral medication taken within one hour of its administration

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Picosalax

The following is a summary of how to take Picosalax and explains the different regimens that your doctor may tell you to follow. For FULL instructions on how to use Picosalax, please refer to the ‘Patient Information Leaflet’ enclosed with Picosalax.

The success of your examination depends on the bowel being as clear as possible. Otherwise, the examination may need to be repeated. So it is important to take all the medicine and follow all your doctor's instructions.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

How much to take

Adults and children 9 years and over

For adults and children 9 years and over, the usual dose is two sachets but the timing of each dose can vary and may depend on the time of your examination. The contents of each of two sachets may be taken several hours apart on the day before the

examination (DAY BEFORE regimen) or over two days (SPLIT-DOSE regimen). Your doctor will advise you which way to take your Picosalax.

In some circumstances, your doctor may choose to modify these dose instructions. Follow the doctor's instructions carefully.

How to take it

The sachets must be made up in water before drinking. The detailed instructions for reconstituting the sachets are in the carton.

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

It is important that you follow the instructions specifically given by the hospital and that you drink plenty of clear fluids.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Picosalax. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include profuse diarrhoea with dehydration and fluid/electrolyte imbalance.

While you are taking Picosalax

You should expect frequent, loose bowel movements at any time after taking a dose. Please ensure that you have access to a toilet at all times following each dose, until the effects wear off.

Things you must do

In order to replace the fluid lost from the body, it is important to drink plenty of clear fluids whilst the effects of Picosalax persist. In general you should try to drink at least 250 mL (approximately one large glass) of clear fluid every hour during the treatment day/days.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Picosalax.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Things you must not do

Do not take Picosalax to treat any other complaints unless your doctor tells you to.

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

Things to be careful of

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

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

This medicine helps most people who require a bowel preparation but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

- headache, tiredness
- nausea, vomiting
- griping
- sore anus
- severe diarrhoea
- allergic reactions
- rash
- convulsions
- mild ulcers in the small bowel.

If you experience one or more of these side effects, or any other undesirable effects, please tell your doctor or pharmacist.

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

After taking Picosalax

Storage

Keep this medicine in the pack until it is time to take it.

If you open the sachets too soon the powder may not keep well.

Keep this medicine in a cool dry place where the temperature stays below 30°C.

Do not store Picosalax or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

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 tells you to stop taking this medicine or the expiry date has passed, ask your

pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Picosalax sachets contain a white crystalline powder. It is supplied in boxes containing 2 sachets.

Ingredients

Each Picosalax sachet contains 10 mg of sodium picosulfate, 3.5 g of light magnesium oxide and 12 g of citric acid (forming magnesium citrate in solution) as the active ingredients. It contains the following inactive ingredients:

- potassium bicarbonate
- saccharin sodium
- orange flavour.

The orange flavour contains lactose (approximately 4.5 mg per sachet).

This medicine contains 195 mg potassium per sachet.

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

Supplier

Picosalax is supplied in Australia by:

Ferring Pharmaceuticals Pty Ltd
Suite 2, Level 1, Building 1
20 Bridge Street
Pymble NSW 2073
Australia

AUST R 138775

Picosalax powder for oral administration

This leaflet was prepared in August 2019.

PICOSALAX and FERRING are registered trademarks of Ferring B.V.