

PICOSALAX® Powder for Oral Solution

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 taking PICOSALAX?

PICOSALAX contains the active ingredient sodium picosulfate with magnesium citrate. PICOSALAX is used for clearance of the bowel before x-ray, endoscopy or surgery.

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

2. What should I know before I take PICOSALAX?

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

Talk to your doctor 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 take PICOSALAX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PICOSALAX 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 take PICOSALAX?

- 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 sachets must be made up in water before drinking.

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

5. What should I know while taking PICOSALAX?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking PICOSALAX.• 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.
Things you should not do	<ul style="list-style-type: none">• 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.
Driving or using machines	<ul style="list-style-type: none">• This medicine is not expected to affect your ability to drive a car or operate machinery.
Looking after your medicine	<ul style="list-style-type: none">• Store it in a cool dry place, where the temperature stays below 30°C, away from moisture, heat or sunlight• Keep this medicine in the pack until it is time to take it.

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

6. Are there any side effects?

All medicines can have side effects. Most of them are minor and temporary but some may need medical attention.

Tell your doctor if you experience any side effects, including rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing. These are very serious side effects. You may need urgent medical attention.

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 "Before you take Picosalax".

PICOSALAX® Powder for Oral Solution

Active ingredient(s): *sodium picosulfate with magnesium citrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PICOSALAX. **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 PICOSALAX.**

Where to find information in this leaflet:

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

1. Why am I taking PICOSALAX?

PICOSALAX contains the active ingredient sodium picosulfate with magnesium citrate.

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.

2. What should I know before I take PICOSALAX?

Warnings

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

- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions especially the following:
 - recent gastrointestinal surgery
 - kidney problems
 - heart problems
 - inflammatory bowel disease
 - electrolyte disturbances
 - diabetes
- take any medicines for any other condition

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 if you are pregnant or intend to become pregnant.

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

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.

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

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.

Some medicines may interfere with PICOSALAX and affect how it works. 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.

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

4. How do I 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 take 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.

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 PICOSALAX

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 PICOSALAX

If you think that you have taken too much PICOSALAX, 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.

You may need urgent medical attention.

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

5. What should I know while 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 should 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 any doctor, dentist or pharmacist you visit that you are taking PICOSALAX.

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 should 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.

Driving or using machines

This medicine is not expected to affect your ability to drive a car or operate machinery.

Looking after your medicine

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.

Store it in a cool dry place, where the temperature stays below 30°C, away from moisture, heat or sunlight;

For example, do not store it:

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

Heat and dampness can destroy some medicines.

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

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

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 about side effects.

Side effects

Side effects	What to do
Common side effects (affect more than 1 in 100 users): <ul style="list-style-type: none">• headache• nausea• vomiting• griping• sore anus• high magnesium levels in the blood (hypermagnesaemia) Uncommon side effects - affect less than 1 in 100 users): <ul style="list-style-type: none">• tiredness• rash• mild ulcers in the small bowel	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Uncommon side effects (affect less than 1 in 100 users): <ul style="list-style-type: none">• Hypersensitivity or allergic reactions (uncommon side effects - affect less than 1 in 100 users):<ul style="list-style-type: none">○ 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• Severe diarrhoea• Convulsions	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 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.

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

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

Other side effects not listed here may occur in some people.

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

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.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What PICOSALAX contains

Active ingredient (main ingredient)	sodium picosulfate light magnesium oxide citric acid (forming magnesium citrate in solution)
Other ingredients (inactive ingredients)	potassium bicarbonate saccharin sodium orange flavour
Potential allergens	The orange flavour contains lactose (approximately 4.5 mg per sachet). This medicine contains 195 mg potassium per sachet.

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

What PICOSALAX looks like

PICOSALAX is a white crystalline powder. It is supplied in boxes containing 2 sachets.
Picosalax powder for oral administration (Aust R 138775).

Who distributes PICOSALAX

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

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