

CONSUMER MEDICINE INFORMATION

WARNING

Life-threatening dehydration and/or electrolyte disturbances may occur in some "at risk" patients. Read the section headed "Before You Take Picolax"

What is in this leaflet

This leaflet answers some common questions about Picolax. 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 Picolax against the benefits they expect it will have for you. Read all of this leaflet carefully before you start taking this medicine.

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 Picolax is used for

Picolax is used to cleanse the lower bowel in preparation for endoscopic, barium enema, X-ray or surgical gastrointestinal examination. It does this by acting in the intestine and colon causing a watery bowel motion which evacuates the bowel. It is important to have an empty, clean bowel so that your doctor can see it clearly.

You should discuss with your doctor what is going to happen before you have the procedure. Your doctor however may prescribe Picolax for another purpose.

Ask your doctor if you have any questions about why Picolax has been prescribed for you or how you are to take it.

Before you take Picolax

When you must not take it

Do not take Picolax if you have:

- an **allergy** to any of the ingredients listed at the end of this leaflet
- **congestive heart failure** (the heart is unable to pump blood efficiently around the body)
- **gastric retention** (reduced ability of the stomach to empty)
- a **stomach ulcer** (gastric or duodenal ulcer)
- a **blockage of the intestine** (ileus)
- a **damaged intestinal wall** (toxic colitis)
- a **swollen large bowel** (toxic megacolon)
- **recently been sick or feel sick** (nausea or vomiting)
- **severe dehydration**
- a **swollen abdomen due to the collection of fluid** (ascites)
- **acute surgical abdominal conditions** (e.g. appendicitis)
- **perforated, damaged or obstructed bowel**
- **active inflammatory bowel disease** (e.g. Crohn's disease, Ulcerative colitis)
- **rhabdomyolysis** (damaged muscles that are leaking their contents into the blood)
- **severe kidney problems**
- **hypermagnesaemia** (too much magnesium in the blood)

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 Picolax after the expiry date printed on the sachet or if the sachet is torn or shows signs of tampering. If you are not sure whether you should start taking Picolax contact your doctor.

Before you start to take Picolax

You must talk to your doctor about taking Picolax if you:

- **are allergic to any medicines, foods, preservatives or dyes**
- **are elderly or physically weak**
- have or have had any of the following medical conditions or any other health problems:
 - **recent gastrointestinal surgery**
 - **kidney disease, heart disease, inflammatory bowel disease or diabetes.**
 - **water and/or electrolyte (sodium or potassium) imbalance** or are **taking medicines that might affect water and/or electrolyte balance** in the body, such as diuretics, corticosteroids or lithium
 - **epilepsy** or a **history of seizures**
 - **low blood pressure** (hypotension)
 - **problems with swallowing** or food coming back after eating
 - **are thirsty** or think you may be **mildly to moderately dehydrated**
 - **low sodium or potassium in the blood** (also known as hyponatraemia or hypokalaemia)

If you have any of the above you should discuss this with your doctor before taking Picolax.

Your doctor may not want you to take Picolax or may want you to take special precautions or take it in another way.

- **are pregnant**

Picolax 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 or have recently taken any other medicines, including:

- **any medicines you get without a prescription from your pharmacy, supermarket or health food shop.**
- **oral contraceptives, antibiotics, anti-epileptics, diabetes medicines and cardiac glycosides** (e.g. digoxin) as their effects may be modified.
- **diuretics, heart medicines, corticosteroids** (e.g. prednisolone) and **lithium** as they may affect electrolyte balance.
- **non-steroidal anti-inflammatory drugs (NSAIDs)** (e.g. aspirin and ibuprofen) used to treat pain and inflammation, **tricyclic antidepressants** (e.g. amitriptyline and imipramine), **selective serotonin reuptake inhibitors (SSRIs)** (e.g. fluoxetine, paroxetine and citalopram), **carbamazepine** (e.g. Tegretol) and **antipsychotic drugs** (e.g. haloperidol and risperidone) as these drugs may add to the electrolyte imbalance.
- other **laxatives**, including bulk-forming laxatives such as bran.
- **constipating drugs** (e.g. cholinergics, opioids) and oral **iron** preparations (including multivitamins) as these should be suspended a few days before the procedure.

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

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

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

How to take Picolax

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet. **If you do not understand the instructions ask your doctor or pharmacist for help.** The success of your examination depends on the bowel being as clear as possible, otherwise the examination may need to be postponed and the preparation repeated.

If your doctor has not given you specific instructions, follow these dosage and dietary instructions

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

Two days before the examination - Low Residue Diet

Stop eating brown bread, red meat, cereals, yellow cheese, vegetables, fruit or anything with nuts or seeds in it.

You may eat boiled or poached eggs, cottage cheese, low fat plain yoghurt, white bread, steamed white fish, boiled chicken, well cooked peeled pumpkin and potato. You may have jelly (no red/purple colourings), low fat milk and Approved Clear Fluids*

One day before the examination – Approved Clear Fluids Diet

No solid foods, milk products or alcoholic beverages are allowed.

Drink only Approved Clear Fluids* (see below).

Approved Clear Fluids*

These are fluids that are not cloudy. Water, clear fruit juices (no pulp), clear cordials, soft drinks, jelly (yellow or orange), sports drinks or Gastrolyte[®]. Black tea or coffee sweetened to taste without milk, soy or whiteners. Clear soups, chicken or beef broth.

A combination of these clear fluids will give a variety of fluid intake. Do **not** have anything coloured **red** or **purple**.

Barley sugar is allowed.

Preparation of Solution

Slowly add the contents of one sachet of Picolax to a large glass of cold water (approximately 250mL). Stir gently until effervescence ceases.

Dosage Note:- Timing of sachets and time without food or drink before the examination may be varied by your doctor.

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

Two Sachet Preparation:

Two days before the examination follow the Low Residue diet above.

One day before the examination drink only Approved Clear Fluids*.

No solid foods, milk products or alcoholic beverages allowed.

1. **FIRST DOSE** (3.00 pm approximately) Slowly add the contents of one sachet of Picolax to a large glass of cold water (approximately 250mL). Stir gently until effervescence ceases.
Drink the solution slowly but completely, followed by a full glass of water. Continue drinking Approved Clear Fluids* (at least 250mL every hour) to ensure adequate hydration.
2. **SECOND DOSE** (9.00 pm approximately) Slowly add the contents of one sachet of Picolax to a large glass of cold water (approximately 250mL). Stir gently until effervescence ceases.
Drink the solution slowly but completely, followed by a full glass of water. Continue drinking Approved Clear Fluids* (at least 250mL every hour) to ensure adequate hydration.

Keep drinking approved clear fluids, at least 250 mL per hour, until 6 hours prior to the examination.

For some patients a third sachet may be required to ensure complete bowel emptying.

Three Sachet Preparation:

Two days before the examination follow the Low Residue diet above.

One day before the examination drink only Approved Clear Fluids*. No solid foods, milk products or alcoholic beverages allowed.

1. **FIRST DOSE** (1.00 pm approximately) Slowly add the contents of one sachet of Picolax to a large glass of cold water (approximately 250mL). Stir gently until effervescence ceases..
Drink the solution slowly but completely, followed by a full glass of water. Continue drinking Approved Clear Fluids* (at least 250mL every hour) to ensure adequate hydration.
2. **SECOND DOSE** (5.00 pm approximately) Slowly add the contents of one sachet of Picolax to a large glass of cold water (approximately 250mL). Stir gently until effervescence ceases..
Drink the solution slowly but completely, followed by a full glass of water. Continue drinking Approved Clear Fluids* (at least 250mL every hour) to ensure adequate hydration.
3. **THIRD DOSE** (9.00 pm approximately) Slowly add the contents of one sachet of Picolax to a large glass of cold water (approximately 250mL). Stir gently until effervescence ceases..
Drink the solution slowly but completely, followed by a full glass of water. Continue drinking Approved Clear Fluids* (at least 250mL every hour) to ensure adequate hydration.

Keep drinking approved clear fluids, at least 250 mL per hour, until 6 hours prior to the examination.

If you forget to take it

It is important for you to take Picolax 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 131126 - this number is staffed 24 hrs a day) for advice, or go to casualty at your nearest hospital if you think you may have taken too much Picolax 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 Picolax you may experience a severe headache and palpitations (a rapid or irregular heartbeat).
If you are not sure what to do, contact your doctor or pharmacist.

While you are taking Picolax

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 Picolax. 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 Picolax.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Things you must not do

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

Things to be careful of

This preparation usually induces frequent, loose bowel movements within two to three hours of taking the first dose. You should remain within easy reach of toilet facilities and not plan any other activities until after the examination.

Oral medication taken within one hour of starting Picolax may be flushed from your gastrointestinal tract and not absorbed.

It is most important that you take adequate fluids to avoid dehydration. Drink approved clear fluids, at least 250mL every hour, until 6 hours prior to the examination.

Picolax may cause fatigue or dizziness, probably as a result of dehydration, and this may have a mild or moderate effect on the ability to drive or use machinery.

Things that would be helpful

Loose-fitting clothing is recommended. Consider using a plastic cover sheet as a mattress protector for the bed. Alcohol-free and fragrance-free wet wipes and soft toilet tissue may minimise the expected irritation from wiping. Frequent application of a protective cream, lanolin, petroleum jelly (Vaseline) or zinc cream will reduce discomfort. Arrange for someone to take you to and from the procedure. Replenish your system by drinking fluids after returning home from your procedure.

Side Effects

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

All medicines can have side effects. Picolax 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.

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

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

abdominal pain, abdominal fullness, bloating, nausea, thirst, headache, fatigue or anal discomfort. These are the more common side effects of Picolax.

Less frequent side-effects are vomiting or dizziness. Side effects usually last for a short time only.

Other rare side effects are hyponatraemia (low level of sodium in the blood) and other electrolyte disturbances. Symptoms relating to electrolyte disturbances include confusion, convulsions, muscle weakness, spasms or cramps. Orthostatic hypotension (low blood pressure upon standing up which may make you feel dizzy or unsteady).

If any of the following happen tell your doctor immediately or go to Accident and Emergency at your nearest hospital. Sudden signs of allergy such as shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.

Other side effects not listed may also occur in some patients. Do not be alarmed by the 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 its sachet until it is time to mix.

Keep Picolax 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.

Do not leave it on a window sill or in the car. 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 metres above the ground is a good place to store medicines.

Disposal

Ask your pharmacist what to do with any medication that is left over or the expiry date has passed.

Product Description

Picolax powder for solution is a white powder packed in a sachet containing 20g.

Ingredients

Each sachet of **Picolax** contains:

- Sodium picosulfate 10mg
- Magnesium carbonate 7.9g (equivalent to 3.36g Magnesium oxide (MgO))
- Citric acid-anhydrous 11.8g
- Lemon flavour
- Acesulfame potassium
- Povidone
- Silicon dioxide

Total Sodium content of a sachet of Picolax is 0.9mg

Picolax does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes

It is available in pack sizes of single, 2, 3, 50, 100 or 300 sachets

Registration

The Australian Registration number is AUST R 54113

Supplier

Dendy Pharmaceuticals Pty Ltd (ABN 32007180985)
41 / 148 Chesterville Road,
Moorabbin Vic 3189

All enquires: info@dendypharm.com.au Website: www.dendypharm.com.au
Telephone 03 95910567 during Office hours, Australian Eastern Standard Time. Fax 03 90384483

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