

Picolax[®]

Powder for oral solution

Sodium Picosulfate / Magnesium Oxide / Citric Acid

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet

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1. What Picolax[®] is and what it is used for

Picolax[®] is a powder that contains sodium picosulfate, a laxative that works by increasing the activity of the intestine. Picolax[®] also contains magnesium citrate, another type of laxative that works by holding back fluid in the bowel to provide a wash-out effect.

Picolax[®] is used in adults, adolescents and children from the age of 1 year to clear the bowel before an x-ray examination, endoscopy or surgery when judged clinical necessary.

2. What you need to know before you take Picolax[®]

Do not take Picolax[®] if you:

- are allergic to sodium picosulfate / magnesium oxide / citric acid or any of the other ingredients of this medicine (listed in section 6)
- have reduced ability of the stomach to empty (gastric retention)
- have stomach or intestinal ulcers
- have severe problems with your kidneys
- have a blockage or perforation of your bowel
- are currently suffering from feeling or being sick
- have a condition requiring abdominal surgery such as acute appendicitis
- have been told by a doctor that you have congestive heart failure (the heart is unable to pump blood efficiently around the body)
- have active inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- have been told by your doctor that you have too much magnesium in your blood
- are very thirsty or may be severely dehydrated
- have been told by your doctor that you have damaged muscles that are leaking their contents to your blood
- have a condition called:
 - ileus (intestinal blockage or failure of normal bowel movements),
 - toxic colitis (damage to the intestinal wall)
 - toxic megacolon (expansion of the large bowel)

In these conditions, the movement of the contents of the bowel may be impaired or prevented. Symptoms include nausea, vomiting, diarrhoea, abdominal pain, tenderness or swelling, colicky pain and fever.

Warnings and precautions

Talk to your doctor or pharmacist before taking Picolax[®]:

- if you have recently had abdominal surgery
- if you have a heart disease or kidney problems
- if you have inflammatory bowel disease such as ulcerative colitis or Crohn's disease
- if you are taking Picolax[®] prior to surgery involving the bowel

You should make sure to drink a sufficient amount of fluid and electrolytes during the course of the treatment. This is particularly important if you are younger than 18 years, elderly or physically weak.

If you have an early time of the day procedure, you might need to take the second dose during night and possible sleep disturbance may occur.

Other medicines and Picolax[®]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is especially important to tell your doctor if you are taking:

- bulk forming laxatives e.g. bran
- prescribed oral medication, especially if it is regularly prescribed as their effects may be modified e.g. contraceptives, antibiotics, antidiabetics, iron, penicillamine or antiepileptics. These medicines should be taken at least 2 hours before and not less than 6 hours after administration of Picolax[®]
- prescribed medication that may affect water and/or electrolyte balance e.g. water tablets, steroids, lithium, digoxin, antidepressants, carbamazepine or anti-psychotics

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are trying to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Picolax[®] has no effect on the ability to drive and use machines. However, you should make sure that you have access to a toilet at all times following each dose, until the effect wears off.

Picolax[®] contains potassium, lactose and sodium

Each sachet contains 5 mmol (or 195 mg) potassium. You should discuss this with your doctor if you have kidney problems or you have been put on a controlled potassium diet.

This medicine also contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially 'sodium-free'.

3. How to take Picolax[®]

Always take Picolax[®] exactly as your doctor has told you. Check with your doctor if you are not sure.

Picolax[®] powder should be dissolved in a cup of cold water (approximately 150ml). Stir for 2-3 minutes and then drink the solution. Sometimes the solution becomes warm as Picolax[®] dissolves. If this happens, wait until it cools sufficiently before drinking it.

Adults (including elderly) and children 9 and over

The recommended dose is one sachet taken 10 to 18 hours before your procedure and one sachet taken 4 to 6 hours before your procedure. The first sachet taken, should be followed by at least five 250 ml drinks of clear liquids (not only water) spread over several hours and the second sachet taken, should be followed by at least three 250 ml drinks of clear liquids (not only water) spread over several hours. You may drink clear liquids (not only water) until 2 hours before your procedure. Do not drink only water.

Children (under 9 years)

For the timing of dosing in children, refer to the instructions given for adults. A measuring spoon is provided with the product.
From 1 and below 2 years: first dose is 1 spoonful, second dose is 1 spoonful
From 2 and below 4 years: first dose is 2 spoonfuls, second dose is 2 spoonfuls
From 4 and below 9 years: first dose is 1 sachet (taken as described under 'adults'), second dose is 2 spoonfuls
9 years and above: adult dose.

To measure the dose with the measuring spoon:

- Fill the spoon with a heap of powder from the sachet
- Pass the flat back of a knife across the top of the measuring spoon
- The powder left in the measuring spoon is one spoonful (4g of powder)
- Pour the powder from the spoon into a cup of water. The cup should contain:
 - Approximately 50 ml of water if you are measuring one spoonful of powder
 - Approximately 100 ml of water if you are measuring two spoonfuls of powder
- Stir in the cup for 2-3 minutes
- Drink the solution. Sometimes the solution becomes warm as Picolax® dissolves. If this happens, wait until it cools sufficiently before drinking it
- Discard any remaining powder from the sachet

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

In order to replace fluid lost from the body, it is important to drink plenty of clear liquids (not only water) throughout the treatment with Picolax® until the bowel movements have ceased. In general, you should try to drink clear liquids (not only water) when you are thirsty. Do not drink only water.

Clear liquids should include a variety of fruit juice without pulp, soft drinks, clear soup, tea, coffee (without milk, soy or cream) and water. Do not drink only water.

The success of your hospital procedure that you undergo depends on the bowel being as clear as possible. The procedure may need to be repeated if you do not achieve a clear bowel. You should always follow the dietary instructions given by your doctor.

If you take more Picolax® than you should

If you have taken more Picolax® than you should, contact your doctor immediately or go to the casualty department at your nearest hospital.

If you forget to take Picolax®

Please consult your doctor, nurse or pharmacist for advice.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor immediately in case of the following side effects as these might be severe:

- allergic reaction including such as rash, redness of skin, hives, itching, swelling of the throat, and/or difficulty breathing (uncommon)
- change in consciousness, such as loss or reduced level of consciousness (uncommon)
- confusion/disorientation (uncommon)
- syncope/fainting (uncommon)
- dizziness/light-headedness (uncommon)
- seizures (uncommon)
- abdominal pain (common)
- vomiting (common)

Other known side effects of Picolax® are described below:

Common (affects less than 1 in 10 but more than 1 in 100 patients):

- Headache
- Nausea

Uncommon (affects less than 1 in 100 but more than 1 in 1,000 patients):

- Low levels of potassium in the blood ('hypokalaemia')
- As the primary clinical effect, very regular, loose bowel movements, or diarrhoea may happen. However, if your bowel movements become troublesome or give you concern, you should contact your doctor.

Rare (affects less than 1 in 1,000 but more than 1 in 10,000 patients):

- Low levels of sodium in the blood ('hyponatraemia')
- Ulcers of the bowel
- Involuntary/accidental loss of bowel contents ('anal incontinence')
- Anal pain

If any of the side effects gets serious contact your doctor or nurse. If you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Picolax®

Keep this medicine out of sight and reach of children.

Store in the original packaging in order to protect from moisture.

Single use only. Discard any unused contents.

Do not use this medicine after the expiry date which is stated on the carton and sachet. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Picolax® contains

The active substances of 1 sachet are 10 mg sodium picosulfate, 3.5 g magnesium oxide light and 12 g anhydrous citric acid.

The other ingredients are potassium hydrogen carbonate, saccharin sodium and natural, spray-dried orange flavour which includes acacia gum, lactose, ascorbic acid, butylated hydroxyanisole.

What Picolax® looks like and contents of the pack

Your medicine is called Picolax®. It is a powder for oral solution. It is supplied in packs of 2 sachets, 100 sachets (50 packs, each containing 2 sachets), or 300 sachets (150 packs, each containing 2 sachets).

A measuring spoon is included in the pack, in order to ensure correct dosing for children. The spoon is used to measure 4 g of powder (4.75 ml). You should only use the spoon if you are dosing a child under 9 years.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Ferring Pharmaceuticals Limited, Drayton Hall, Church Road, West Drayton, UB7 7PS, UK.

Manufacturers

Ferring GmbH, Wittland 11, D-24109 Kiel, Germany

This medicinal product is authorised in the Member States of EEA under the following names

Picolax®
United Kingdom

Picoprep®
Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Portugal, Romania, Slovak Republic, Spain, Sweden

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