

Package leaflet: Information for the user

PICOLAX® 10 mg/ 3.5 g/ 12 g Powder for Oral Solution Sodium Picosulfate, Magnesium Oxide, Citric Acid

Read all of this leaflet carefully before you start using 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

1. What Picolax is and what it is used for
2. What you need to know before you take Picolax
3. How to take Picolax
4. Possible side effects
5. How to store Picolax
6. Contents of the pack and other information

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 for clearance of the bowel prior to examination by radiography, endoscopy or surgery.

2. What you need to know before you take Picolax

Do not take Picolax if you:

- are allergic (hypersensitive) to sodium picosulfate 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 appendicitis
- have been told by a doctor that you have congestive cardiac failure (the heart is unable to pump blood efficiently around the body).
- have an active inflammatory bowel disease such as Crohn's 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 movements)
 - toxic colitis (damage to 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.

Do not give Picolax to an unconscious patient, or to a patient with an impaired swallowing reflex.

Warnings and precautions:

Talk to your doctor or pharmacist before using Picolax if you:

- have recently had abdominal surgery
- have heart disease or kidney problems
- have inflammatory bowel disease such as ulcerative colitis or Crohn's disease

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 any of these apply to you, or if you are not sure, contact your doctor before taking Picolax.

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, anti-diabetics, iron, penicillamine or anti-epileptics.
- 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 planning 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 and lactose

Each sachet contains 5 mmol (or 195 mg) potassium. You should discuss this with your doctor or pharmacist 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 this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Picolax powder should be dissolved in a cup of cold water (approximately 150 ml). 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 the elderly) and children 9 and over

The usual dose is one sachet in the morning and one sachet in the afternoon on the day before your procedure.

The first sachet should be taken before 8am followed by at least five 250 ml drinks of clear liquids spread over several hours and the second sachet 6 to 8 hours later, followed by at least three 250 ml drinks of clear liquids spread over several hours. You may drink clear liquids until 2 hours before your procedure.

Children (under 9 years)

Timings as above

From 1 and below 2 years: ¼ sachet morning, ¼ sachet afternoon

From 2 and below 4 years: ½ sachet morning, ½ sachet afternoon

From 4 and below 9 years: 1 sachet morning, ½ sachet afternoon

9 years and above: adult dose

You should expect frequent, loose bowel movements 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 throughout the treatment with Picolax until the bowel movements have ceased. In general, you should try to drink clear liquids when you are thirsty.

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 the hospital procedure 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 or pharmacist 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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Contact your doctor immediately in the case of:

- **allergic reaction (rash, itching, swelling of the throat and difficulty breathing)**
- **change in consciousness, such as loss or reduced level of consciousness, feeling dizzy, confused, disoriented or lightheaded**
- **severe prolonged abdominal pain**
- **severe vomiting**

The known side effects of Picolax are described below.

Common: may affect up to 1 in 10 people

- Headache
- Vomiting
- Nausea
- Abdominal pain

Uncommon: may affect up to 1 in 100 people

- Allergic reaction (rash, hives, redness of skin, itching, swelling of throat and /or trouble breathing)
- Confusion/disorientation
- Dizziness
- Fainting
- Change in consciousness ('loss of or reduced level of consciousness')
- Fits/seizures
- 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: may affect up to 1 in 1,000 people

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Website: www.hpra.ie. 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 the sight and reach of children.

Do not store above 25°C. Store in the original packaging in order to protect from moisture.

Single use only. Discard any unused contents.

Do not use Picolax after the expiry date which is stated on the sachet and on the outer carton after EXP. 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 are 10 mg sodium picosulfate, 3.5 g magnesium oxide and 12 g citric acid.

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

What Picolax looks like and contents of the pack

Your medicine is called Picolax. Picolax is a white crystalline powder for oral solution. It is presented as a pack containing 2 sachets. The pair of sachets is divided by a tear-off perforation.

Marketing Authorisation Holder

Ferring Ireland Limited, United Drug House, Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland.

Manufacturers

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

This leaflet was last revised in July 2020.

**SUGGESTED TREATMENT PLAN
THE DAY BEFORE YOUR EXAMINATION**

If you have special dietary requirements, please inform the medical personnel in charge so that a suitable dietary plan can be suggested for you.

DRINK PLENTY OF CLEAR LIQUIDS THROUGHOUT THE TREATMENT WITH PICOLAX. TRY TO DRINK CLEAR LIQUIDS WHEN YOU ARE THIRSTY.

CLEAR FLUIDS 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.

BE PREPARED FOR FREQUENT, LOOSE BOWEL MOVEMENTS AT ANY TIME AFTER TAKING A DOSE.

BEFORE BREAKFAST (not later than 8.00 am)

Take the first sachet of PICOLAX as described above.

BREAKFAST (8.00 to 9.00 am)

Breakfast, if taken, should be limited to a boiled or poached egg and/or white bread. A scraping of butter or margarine is allowed, but no jam or marmalade.

LUNCH (12.00 to 1.30 pm)

A small portion of steamed, poached or grilled white fish or chicken may be taken with a very small portion of boiled potato OR white bread.

Clear jelly may be taken for dessert.

2 HOURS AFTER LUNCH (not later than 4.00 pm)

Take the second sachet of PICOLAX mixed in water (as described above).

SUPPER (7.00 pm to 9.00 pm)

NO SOLID FOOD IS ALLOWED

Clear soup or a meat extract drink may be taken followed by clear jelly for dessert.

**NO FURTHER FOOD IS ALLOWED UNTIL AFTER THE EXAMINATION.
CONTINUE TO TAKE FLUIDS UNTIL THE BOWEL MOVEMENTS HAVE
CEASED.**

DRINK AS MUCH AS IS REQUIRED TO SATISFY THIRST

The suggested treatment plan is suitable for most patients. In some circumstances, your doctor may choose to modify the dose instructions. It is important that you follow the instructions on the suggested treatment plan or any other instructions specifically given by the hospital.

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