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. 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

Picolax® is a powder that contains sodium picosulfate, a laxative that works by increasing the activity of the intestine. Picolax® also contains magnesium oxide and citric acid, 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 clinically 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 a condition called:
  - ileus (intestinal blockage or failure of contents to your blood)
  - toxic megacolon (expansion of the large bowel)
  - toxic colitis (damage to the intestinal wall)
  - ileus (intestinal blockage or failure of contents to your blood)
- 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 bowel
- 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, tiredness or swelling, colicky pain and fever.

Warnings and precautions

Talk to your doctor or pharmacist before taking Picolax® if you:

- 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 water and/or electrolytes during the course of the treatment. This is particularly important if you are younger than 18 years, pregnant, elderly or physically weak.

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

Other medicines and Picolax®

Tell your doctor if you are taking, have taken recently or might take any of the following medicines. It is especially important to tell your doctor if you are taking:

- built-up laxatives e.g. bran
- prescribed oral medication, especially if regularly prescribed as their effects may be modified e.g. contraceptives, antibiotics, anti-cancer, anti-epileptics or anti-anti-psychotics.

Pregnancy, breast-feeding and fertility

If you are breast-feeding or planning to become pregnant, you may be pregnant or are trying to 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 or use machines. However, you should make sure that you have access to a toilet at all times following each dose, at least 2 hours after taking it.

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 if you have been put on a controlled potassium diet.

This medicine also contains lactose. If you have diabetes or 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 or pharmacist if you are unsure.

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 6 hours before your procedure. If you have been advised to take a second sachet, this should be taken at least 2 hours before your procedure.

The first sachet should be followed by at least five 250 ml drinks of clear liquids (not only water) spread over several hours and the second sachet, 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) 2 hours before your procedure. Do not drink only water.

Children (under 9 years)

For the timing of dosing in children, refer to the table given for adults above.

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 8 years: first dose is 1 sachet taken as described under ‘adults’, second dose is 2 spoonfuls 9 years and above: adult dose.
Other known side effects of Picolax
- Vomiting (common)
- Abdominal pain (common)
- Seizures (uncommon)
- Dizziness/light-headedness (uncommon)
- Confusion/disorientation (uncommon)
- Change in consciousness, such as loss of speech, vision, or awareness
- Rash, hives, itching, swelling of the throat, and/or difficulty breathing
- Allergic reaction including such as rash, hives, itching, swelling of the throat, and/or difficulty breathing

If you experience any of the following side effects as these might be severe:
- Allergic reaction including such as rash, hives, itching, swelling of the throat, and/or difficulty breathing
- Seizures, confusion/disorientation
- Dizziness/light-headedness
- Seizures
- Abdominal pain
- Vomiting

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 (‘hypotonic diarrhoea’)
  - 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 on the 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 1 g of powder (47.5 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

Picoquick®

Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Portugal, Slovakia, Sweden, Spain, Switzerland, United Kingdom

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