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 increasing the activity of the intestine.

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
- have had diarrhoea with fever, tenderness or swelling, colicky pain and vomiting
- are very thirsty or may be severely dehydrated
- have had a condition called ileus (intestinal blockage or failure of the large bowel)
- 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 pregnant or are trying to get pregnant.

Talk to your doctor or pharmacist before taking Picolax®:

- if you have 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 younger than 18 years, elderly or physically weak.

You should make sure that you have access to a toilet at all times following each dose, until the effervescent tablets have dissolved.

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 water (approximately 150 ml) for swallowing. Stir for 2-3 minutes and then drink the solution immediately. If you have not completed the bowel emptying process and one sachet has not dissolved, you might need to take the second dose during night and possible sleep disturbance may occur.

Other medicines and Picolax®

If you are taking, have recently taken or might take any of these medicines, it is especially important to tell your doctor if you are taking:

- prescribed oral medication, especially if it is regularly prescribed.

Their effects may be modified e.g. contraceptives, antibiotics, anti-diabetics, iron, pericoline or anti-epileptics. These medicines should be taken at least 2 hours before and not less than 6 hours after administration of Picolax®.

Picolax® contains potassium and lactose

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.

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 water (approximately 150 ml) for swallowing. Stir for 2-3 minutes and then drink the solution immediately. If you have not completed the bowel emptying process and one sachet has not dissolved, you might need to take the second dose during night and possible sleep disturbance may occur.

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 spread over several hours and the second sachet taken, should be 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.

Adults (including elderly) and children 9 and over

From 9 and above 11 years: first dose is 2 spoonfuls, second dose is 1 spoonful.

From 2 and below 4 years: first dose is 1 spoonful, second dose is 2 spoonfuls.

From 4 and below 9 years: first dose is 1 sachet taken as described above, second dose is 2 spoonfuls.

Children (under 9 years)

Picolax® is not recommended for use 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 above, second dose is 2 spoonfuls.

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.

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If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor 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 may also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard.

Reporting side effects 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 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 picosulphate, 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 3 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 4.75 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, 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
Picolax® 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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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 55 ml of water if you are measuring the amount 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 throughout the treatment with Picolax® until the bowel movements have ceased. In general, you should try to drink clear liquids when you are thirsty.

A bowel movement may happen. However, if your bowel movements become troublesome or give you concern, you should contact your doctor.