

Patient leaflet in accordance with the Pharmacies' Regulations (Preparations) - 1986

The dispensing of this medicine requires a doctor's prescription

Pico-Salax Orange, Powder for preparation of an oral solution

Pico-Salax Cranberry, Powder for preparation of an oral solution

This medicine package contains two sachets of powder and a measuring spoon.

The active ingredients of one sachet:

sodium picosulfate, 10 mg
magnesium oxide, light 3.5 g
citric acid 12 g

Inactive ingredients and allergens - See section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Additional Information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, refer to your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Pico-Salax is used to clean the bowel prior to an x-ray examination, endoscopy, or surgery.

Therapeutic group: laxative, cathartic.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredients or to any of the other ingredients that this medicine contains (see section 6).
- You are currently suffering from nausea and vomiting.
- You have a condition called gastric retention (reduced ability of the stomach to empty).
- You have ulcers in your digestive tract (in your stomach or bowel).
- You have or are suspected of having a blockage or perforation of your digestive tract.
- You have a condition requiring abdominal surgery, such as acute appendicitis.
- You have a condition called ileus (intestinal blockage or lack of normal bowel movements), toxic colitis (damage to the intestinal wall), or toxic megacolon (acute expansion of the colon).
- You have a serious kidney problem.
- You have an active inflammatory bowel disease such as Crohn's disease or ulcerative colitis.
- You have been told by your doctor that you have high levels of magnesium in your blood.
- You feel extremely thirsty or you may be severely dehydrated.
- You have been told by your doctor that you have damaged muscles that are leaking their contents to your blood.
- You have been told by your doctor that you have congestive heart failure (the heart is unable to pump blood efficiently around the body).

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

Special warnings about using this medicine:

Before treatment with Pico-Salax Orange or Pico-Salax Cranberry, tell your doctor if:

- You have heart disease or a kidney function disorder.
- You have inflammatory bowel disease such as ulcerative colitis or Crohn's disease.
- You have recently had surgery in your digestive tract.
- You are about to use Pico-Salax before intestinal surgery.

Make sure you drink sufficient fluids and electrolytes during treatment. This is particularly important if you are younger than 18 years, elderly or physically weak. If your procedure is performed early in the morning, you may need to take the second dose of the medicine during the night, and possible sleep disturbance may occur.

The period of bowel cleansing should not exceed 24 hours, because longer preparation may increase the risk of water and mineral imbalance in the body.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and nutritional supplements, tell your doctor or pharmacist. In particular tell the doctor or pharmacist if:

- You are using bulk-forming laxatives such as bran.
- Pico-Salax affects the way oral medicines are absorbed so their effect might change. If you are taking oral prescription medicines, particularly if you are prescribed with them regularly, such as contraceptive pills, antidiabetics, antibiotics, iron, penicillamine or antiepileptics, take these medicines at least two hours before and not less than 6 hours after administration of Pico-Salax.
- If you are taking prescription medicines which may affect your water and/or electrolyte balance such as diuretics, steroids, nonsteroidal anti-inflammatory drugs (NSAIDs), lithium, digoxin, antidepressants, carbamazepine and antipsychotics.

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant, or are trying to become pregnant or if you are breastfeeding, consult your doctor or pharmacist before using this medicine.

Driving and using machines

Pico-Salax has no effect on the ability to drive or use machines; however, make sure to have access to a toilet at all times after taking each dose, until its effect wears off.

Important information about some of this medicine's ingredients

- Each sachet of Pico-Salax contains 195 mg of potassium. Consult your doctor if you have kidney problems, or if you have been told to keep a controlled-potassium diet.
- Orange-flavored Pico-Salax Orange contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, including lactose, please consult your doctor before taking this medicine.
- **This medicine contains less than 23 mg of sodium per sachet and is therefore considered sodium free.**

3. How to use this medicine?

Always use the medicine according to your doctor's instructions. Check with the doctor or pharmacist if you are not sure regarding the dosage and manner of treatment with the medicine. Only your doctor will determine your dose and how you should take this medicine.

Do not exceed the recommended dose.

How to prepare the medicine

Adults: Mix the content of the sachet into a partially filled cup containing about 150 ml of cold water. Stir for 2-3 minutes and drink the solution. Sometimes the solution may get warm. If this happens, wait until it cools down sufficiently to drink it.

Children:

To measure a dose with the measuring spoon:

- Fill the spoon with powder from the sachet
 - Pass the flat back of a knife across the top of the spoon
 - The powder left in the measuring spoon is one spoonful (4 g of powder)
- Pure the powder in a cup of water that contains:
- About 50 ml of water for one spoonful of powder
 - About 100 ml of water for two spoonfuls of powder
- Stir the content in the cup for 2-3 minutes.
 - Give you child the solution to drink.
 - Sometimes the solution may warm up while you mix it. If this happens, wait until the solution cools down
 - Throw away the remaining powder from the sachet.

Standard dosage in the absence of other instruction from the doctor:

Adults (including elderly) and children above the age of 9:

It is recommended to take the first sachet 10 to 18 hours before the procedure and the second sachet 4 to 6 hours before the procedure. After taking the first sachet, drink at least 5 full glasses (about 250 ml per glass) of clear liquids (not only water). It is important not to drink only water and not to drink all the liquids simultaneously, but to spread the drinks over several hours. After taking the second sachet, drink at least 3 full glasses (about 250 ml per glass) of clear liquids (not only water). It is important not to drink only water and not to drink all the liquids simultaneously, but to spread the drinks over several hours.

Clear liquids include a variety of clear fruit juices, soft drinks, clear soups, tea, coffee (without milk, soy or cream). **Do not drink only water!**

You may drink clear liquids up to two hours before the procedure

Dosage for children (below the age of 9):

For times of medication intake in children, read the instructions for adult dosage above.

Measuring spoon is supplied in the medicine package.

Age of 1 to 2 years: First dose: one full measuring spoon (equivalent to 1/4 sachet). Second dose: one full measuring spoon (equivalent to 1/4 sachet).

Age 2-4 years: First dose: two full measuring spoons (equivalent to 1/2 sachet). Second dose: two full measuring spoons (equivalent to 1/2 sachet).

Age 4-9 years: First dose: one sachet (prepare as explained in the "Adults" section). Second dose: two full measuring spoons (equivalent to 1/2 sachet).

Age 9 and up: see adult dosage.

How can you contribute to the success of the treatment?

Complete the course of treatment as recommended by your doctor.

Prepare yourself for frequent and loose bowel movements any time after taking a dose of Pico-Salax. Please make sure you have access to a toilet at all times after taking each dose, until the effect wears off.

You should drink a lot of clear liquids (not only water) during treatment with Pico-Salax until your bowel movements stop. In general, try to drink a full cup (about 250 ml per glass) of a clear liquid (not only water) every time you feel thirsty.

Clear liquids include a variety of clear fruit juices, soft drinks, clear soups, tea, coffee (without milk, soy or cream) and water. **Do not drink only water!**

The success of the procedure you are about to undergo at the hospital depends on your bowel being as clear as possible. If you do not achieve adequate emptying of your bowel you may need to repeat the procedure. Be careful to follow your doctor's instructions about nutrition. Pico-Salax should not be used as a routine laxative.

If you have accidentally taken a higher dose or if a child has accidentally swallowed some of the medicine, go immediately to a doctor or a nearby hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the regular time and consult your doctor.

Do not take medicines in the dark! Check the label and dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding the use of this medicine, consult your doctor or pharmacist.

4. Side effects

Like all medicines, taking Pico-Salax may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Contact your doctor immediately in the event if the following side effects, which may be serious:

- Allergic reactions, including rash, redness of the skin, urticaria, itching, swelling of the throat and/or difficulty breathing (uncommon)
- Change in state of consciousness, such as loss of consciousness or stupor (uncommon)
- Confusion/disorientation (uncommon)
- Fainting (uncommon)
- Dizziness (uncommon)
- Seizures (uncommon)
- Abdominal pain (common)
- Vomiting (common)

Additional side effects

Common side effects (affect 1-10 in 100 users)

- Headaches
- Nausea
- Hypermagnesemia (elevated levels of magnesium in the blood)

Uncommon side effects (affect 1-10 in 1000 users)

- Low levels of potassium in the blood (hypokalemia)
- As part of the medicine's mechanism of action, there may be increased bowel movements or diarrhea, however, if your bowel movements become troublesome or cause you concern, you should contact your doctor.

Rare side effects (affect 1-10 in 10,000 users)

- Low levels of blood sodium (hyponatremia)
- Intestinal ulcers
- Uncontrollable emptying of bowel content
- Anal pain

If a side effect appears, if any of the side effects worsens or if you experience any side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health (MoH) by following the link 'Reporting Side Effects of Medication' on the MoH home page (www.health.gov.il) which links to an online form for reporting side effects, or by following the link below:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Storage conditions

- Do not store at a temperature above 25°C. Store in the original package.

6. Additional information

In addition to the active ingredients, this medicine also contains:

Pico-Salax Orange:

potassium hydrogen carbonate, saccharin sodium, natural spray dried orange flavor which contains arabic gum, lactose, ascorbic acid, butylated hydroxyanisole.

Pico-Salax Cranberry:

potassium bicarbonate, saccharin sodium, cranberry flavor S/D.

What does the medicine look like and what are the contents of the package:

Pico-Salax is a powder for preparing an oral solution. Each package contains two sachets with powder and a measuring spoon. A full measuring spoon contains 4 g of powder.

Name and address of the registration holder: Ferring Pharmaceuticals Ltd., 8 Hashita Street, Industrial Park, Caesarea 3088900.

Name and address of the manufacturer: Ferring GmbH, Germany.

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Medicine registration number in the National Medicines Registry of the Ministry of Health:

Pico-Salax Orange: 144-04-32928

Pico-Salax Cranberry: 157-91-35155