PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PICOLAX® Powder for oral solution

Sodium picosulphate, magnesium oxide, light, citric acid, anhydrous

Contains sweetener (sodium saccharin 60 mg per sachet)

Contains sugar (lactose component of the flavouring)

Read all of this leaflet carefully before you start taking PICOLAX®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- PICOLAX® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 to remove the bowel contents and cleanse it prior to examination by radiography (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 a condition called gastric retention (reduced ability of the stomach to empty)
- suffer gastro-intestinal ulceration (gastric or intestinal ulcers)
- have gastro-intestinal blockage or perforation
- have a serious abdominal condition such as appendicitis
- have been told that you have congestive heart failure (the heart is unable to pump blood efficiently around the body)
- have been 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 been told by your doctor that you have too much magnesium in your blood
- have active inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- have a stoma
- have undiagnosed rectal bleeding
- are a diabetic
- have high blood pressure
- have severe problems with your kidneys

- are allergic to oral saline laxatives and dehydration
- 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 bowel may be impaired or prevented. Symptoms include such as nausea, vomiting, diarrhoea, abdominal pain, tenderness or swelling, colicky pain and fever.

Warnings and precautions

Talk to your doctor or pharmacist before using PICOLAX® if you:

- suffer from heart or kidney disease
- suffer from inflammatory bowel disease such as ulcerative colitis or Crohn's disease
- have recently had gastro-intestinal surgery
- have a history of seizures
- have an impaired gag reflex

Children and adolescents

PICOLAX® should not be given to children younger than 2 years of age.

Other medicines and PICOLAX®

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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

- Bulk forming laxatives (medicines that create a bulky, more liquid-like stool 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, penicillin or anti-epileptics. 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, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machines

PICOLAX® may less frequently cause dizziness, light-headedness or confusion. Do not drive or operate any machinery until you know how PICOLAX® will affect your ability to drive or concentrate.

It is not always possible to predict to what extent PICOLAX® may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which PICOLAX® affects you.

PICOLAX® contains potassium and lactose (part of the flavouring)

PICOLAX® contains 5 mmol (or 195 mg) potassium per sachet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this PICOLAX®.

3. How to take PICOLAX®

Do not share medicines prescribed for you with any other person.

Always take PICOLAX® exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will inform you of the dose that you should take.

ADULTS (including the elderly):

The first PICOLAX® sachet (see method of Administration section below for reconstitution guidance) is taken the night before the procedure, and the second is taken the next day, in the morning prior to the procedure.

On the day before the procedure – 1 sachet:

- The first reconstituted sachet is taken in the late afternoon / evening (e.g., 5:00 to 9:00 PM), followed by at least 5 x 250 ml drinks of clear liquids (not only water), spread over several hours.

On the day of the procedure – 1 sachet:

- The second reconstituted sachet is taken in the morning (5-9 hours before the procedure), followed by at least 3 x 250 ml drinks of clear liquids (not only water), spread over several hours. Clear liquids (not only water) may be consumed until 2 hours before the time of the procedure.

Paediatric population

Children from 2 up to 9 years:

The first dose reconstituted in water as directed (see section below for reconstitution guidance), should be taken before 8 AM on the day before the procedure. Second dose to be taken 6 to 8 hours later.

From 2 up to 4 years: ½ sachet in the morning and ½ sachet in the afternoon.

From 4 up to 9 years: 1 sachet morning and ½ sachet in the afternoon.

Maintaining hydration in children is very important. Guidelines for treating dehydration in children should be followed to ensure adequate hydration during treatment with PICOLAX.

Children from age 9 and above:

The same dose, scheduling of dose and liquid intake as for adults should be applied.

A low residue diet is recommended on the day prior to the procedure. A clear liquid diet is recommended on the day of the procedure.

Clear liquids should include a variety of soft drinks, clear soup, tea, coffee (without milk, soy or cream), fruit juice without pulp, and water. Liquid intake should not be restricted to only drinking water.

Directions for reconstitution in adults (including elderly):

Reconstitute a fresh sachet immediately prior to each dose. Reconstitute the contents of one sachet in a cup of cold water (approximately 150 ml). Stir for 2- 3 minutes, the solution should now become an off-white, cloudy liquid with a faint odour of orange. Drink the solution. If it has become warm, wait until it cools sufficiently to drink.

Directions for reconstitution in children:

Reconstitute a fresh sachet immediately prior to each dose. Reconstitute the required amount of powder in a cup containing approximately 100 ml cold water per ½ sachet. Stir for 2-3 minutes, the solution should now become an off-white, cloudy liquid with a faint odour of orange. Drink the solution. If it has become warm, wait until it cools sufficiently to drink. Discard the remaining contents of the sachet.

For directions on reconstitution of the full sachet for children from 4 up to 9 years, refer to the instructions given for adults.

Your doctor will tell you how long your treatment with PICOLAX® will last. If you have the impression that the effect of PICOLAX® is too strong or too weak, tell your doctor or pharmacist.

If you take more PICOLAX® than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison center.

If you forget to take PICOLAX®

Please consult your doctor, nurse or pharmacist for advice.

4. Possible side effects

PICOLAX® can have side effects.

Not all side effects reported for PICOLAX® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PICOLAX®, please consult your healthcare provider for advice.

If any of the following happens, stop taking PICOLAX® and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to PICOLAX®. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- unusual tiredness or weakness, confusion, irregular heartbeat, muscle cramps (These may be signs of electrolyte imbalance e.g., hypokalaemia).
- vomiting, confusion, fatigue and irritability (These may be signs of electrolyte imbalance e.g., hyponatraemia).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- vomiting, nausea, stomach pain, feeling full and bloated
- headache

Less frequent side effects

- stomach cramps
- diarrhoea
- increased thirst
- griping
- ulcers of the bowel
- anal pain
- inability to control bowel movements, causing stool (faeces) to leak unexpectedly from the rectum through the anus
- feeling confused and disorientated
- sensation of feeling faint without actually fainting
- fits

- feeling dizzy, loss of consciousness
- skin rashes e.g. hives, purple spots due to small blood vessels leaking blood into the skin, redness of the skin, small raised skin bumps

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of PICOLAX®.

5. How to store PICOLAX®

Store at or below 25 °C. Protect from light.

Store in the original package.

The reconstituted solution must be used immediately after chilling in the refrigerator.

KEEP OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the label / carton.

Return any unused medicine to the pharmacy or your healthcare professional who will dispose of the medicine on your behalf.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PICOLAX® contains

The active ingredients are sodium picosulphate (10,0 mg), magnesium oxide light (3,5 g) and anhydrous citric acid (12,0 g) per sachet.

The other ingredients in the sachet 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

White crystalline powder with a faint odour of orange.

Reconstituted solution is off-white, cloudy liquid with a faint odour of orange.

Picolax® powder for oral solution is supplied in white sachets. Double sachets divided by tear-off perforation are packed in cartons of 2 x 25 sachets or an original patient pack containing 2 sachets. The sachet is made from a four layer foil of paper-polyethylene aluminium-thermofusible resin (Surlyn).

Certain presentations described here, may not all be available on the market.

Holder of Certificate of Registration

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