

PICOSTIVE POWDER FOR ORAL SOLUTION

Sodium Picosulfate 10.0mg, Citric acid 12.0g, Magnesium Oxide 3.5g

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What is PICOSTIVE used for

PICOSTIVE is used to clean the bowel prior to X-ray examination or endoscopy. It is also used to clean the bowel prior to surgery when judged clinically necessary.

How PICOSTIVE works

The active components of PICOSTIVE are sodium picosulfate and magnesium citrate. Sodium picosulfate is a locally acting stimulant cathartic, which after bacterial cleavage in the colon forms the active laxative compound, bis-(p-hydroxyphenyl)-pyridyl-2-methane (BHPM), which has a dual-action with stimulation of the mucosa of both the large intestine and of the rectum. Magnesium citrate acts as an osmotic laxative by retaining moisture in the colon. The combined action of the two substances is of a 'washing out' effect combined with peristaltic stimulation to clear the bowel. The product is not intended for use as a routine laxative.

Before you use PICOSTIVE

- When you must not use it

- DO NOT take PICOSTIVE if you:
- Are allergic to active substance or any of the excipients of PICOSTIVE.
 - Have heart failure, gastric retention, stomach ulcer
 - Acute colonic distension, Complication of inflammatory bowel disease, painful obstruction of ileum,
 - Severe Nausea and vomiting
 - Acute surgical abdominal conditions
 - Known or suspected gastro-intestinal obstruction or perforation
 - Severe dehydration
 - Condition of dissolution of skeletal muscle

-abnormally elevated magnesium level in blood
 -Active inflammatory bowel disease
 -In-patients with severely reduced renal function, accumulation of magnesium in plasma may occur. Another preparation should be used in such cases.

- Before you start to use it

Check with your doctor before taking PICOSTIVE if you
 -pregnant or breastfeeding or planning to become pregnant.

Take special care with PICOSTIVE if:

-have recent gastro-intestinal surgery, renal impairment, heart disease or inflammatory bowel disease.

Because a clinically relevant benefit of bowel cleansing prior to elective, open colorectal surgery could not be proven, bowel cleansers should only be administered before bowel surgery if clearly needed. The risks of the treatment should be carefully weighed against possible benefits and needs depending on surgical procedures performed.

An insufficient or excessive oral intake of water and electrolytes could create clinically significant, deficiencies, particularly in less fit patients.

Drinking only water to replace the fluid losses may lead to electrolyte imbalance which may in severe cases lead to complications such as seizures and coma. In rare cases, PICOSTIVE can cause severe or life-threatening electrolyte problems or impaired renal function in fragile or debilitated patients.

- Taking other medications

Please tell you doctor or pharmacist if you are taking/using or have recently taken/used, any other medication, including medicines obtained without a prescription.

The absorption of other orally administered medicines (e.g. anti-epileptics, contraceptives, anti-diabetics, antibiotics) may therefore

be modified during the treatment period. Tetracycline and fluoroquinolone antibiotics, iron, digoxin, chlorpromazine and penicillamine, should be taken at least 2 hours before and not less than 6 hours after administration of PICOSTIVE to avoid chelation with magnesium.

The efficacy of PICOSTIVE is lowered by bulk-forming laxatives.

Care should be taken with patients already receiving drugs which may be associated with hypokalaemia (such as diuretics or corticosteroids, or drugs where hypokalaemia is a particular risk i.e. cardiac glycosides). Caution is also advised when PICOSTIVE is used in patients on NSAIDs or drugs known to induce SIADH e.g. tricyclic antidepressants, selective serotonin re-uptake inhibitors, antipsychotic drugs and carbamazepine as these drugs may increase the risk of water retention and/or electrolyte imbalance.

How to use PICOSTIVE

- How much to use

Always use PICOSTIVE exactly as your doctor has told you. You should check with your doctor if you are not sure.

PICOSTIVE, supplied as a powder, must be reconstituted with cold water right before its use. There are two dosing regimens, each requires two separate dosing times:

- The preferred method is the "Split-Dose" method and consists of two separate doses: the first dose during the evening before the procedure and the second dose the next day, during the morning prior to the procedure.
- The alternative method is the "Day Before" method and consists of two separate doses: the first dose during the afternoon or early evening before the procedure and the second dose 6 hours later during

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the evening before the procedure.

Directions for reconstitution for adult dosing:

- Reconstitute the PICOSTIVE powder right before each administration. Do not prepare the solution in advance.
- Fill a cup with cold water (approximately 150 ml) and pour in the contents of one packet of PICOSTIVE powder.
- Stir for 2 to 3 minutes. The reconstituted PICOSTIVE solution may become slightly warm as the powder dissolves.

Directions for reconstitution for children under 9 years old dosing:

- Reconstitute the PICOSTIVE powder right before each administration. Do not prepare the solution in advance.
- Fill a cup with cold water (approximately 200 ml) and pour in the contents of one packet of PICOSTIVE powder.
- Stir for 2 to 3 minutes. Take $\frac{1}{4}$ or $\frac{1}{2}$ of the solution according to the dosing regimen. The reconstituted PICOSTIVE solution may become slightly warm as the powder dissolves.

A low residue diet is recommended on the day prior to the hospital procedure. A clear liquid diet is recommended on the day of the procedure. To avoid dehydration, it is important to follow the liquid intake recommendation as advocated together with the PICOSTIVE dosing whilst the effects of PICOSTIVE persist. Apart from the liquid intake together with the treatment regimen (PICOSTIVE + additional liquids), a normal, thirst driven intake of clear liquids is recommended. 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.

Additional fluids must be consumed after every dose in both regimens up until 2 hours before the time of the procedure. Instruct patients that if

they experience severe bloating, distention, or abdominal pain following the first dose, delay the second dose until their symptoms resolve.

Adults: Split-Dose Dosing Regimen (Preferred Method)

The Split-Dose regimen is the preferred dosing method. Instruct patients to take two separate doses in conjunction with fluids, as follows:

- Take the first dose during the evening before the procedure (e.g., 5:00 to 9:00 PM) followed by five 250 ml drinks (upper line on the dosing cup) of clear liquids before bed. Consume clear liquids within 5 hours.
- Take second dose, the next day approximately 5 hours before the procedure followed by at least three 250 ml drinks of clear liquids before the procedure. Consume clear liquids within 5 hours up until 2 hours before the time of the procedure.

Day-Before Dosing Regimen (Alternative Method)

The Day-Before regimen is the alternative dosing method for patients for whom the Split-Dosing is inappropriate. Instruct patients to take two separate doses in conjunction with fluids, as follows:

- Take the first dose in the afternoon or early evening (e.g., 4:00 to 6:00 PM) before the procedure followed by five 250 ml drinks (upper line on the dosing cup) of clear liquids before the next dose. Consume clear liquids within 5 hours.
- Take the second dose approximately 6 hours later in the late evening (e.g., 10:00 PM to 12:00 AM), the night before the procedure followed by three 250 ml drinks of clear liquids before bed. Consume clear liquids within 5 hours.

Children:

The first dose reconstituted in water as directed, taken before 8 am on the day before the procedure. Second dose 6 to 8 hours later.

1 - 2 years: $\frac{1}{4}$ sachet morning, $\frac{1}{4}$ sachet afternoon

2 - 4 years: $\frac{1}{2}$ sachet morning, $\frac{1}{2}$ sachet afternoon
4 - 9 years: 1 sachet morning, $\frac{1}{2}$ sachet afternoon
9 and above: adult dose

-When to use it

Always use PICOSTIVE exactly as your doctor has told you. If you are not sure, check with your doctor.

-How long to use it

You should use PICOSTIVE following what your doctor tells you to.

-If you forget to use it

Use it as soon as you remember, unless it is nearly time for your next dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

If you take more PICOSTIVE than you should: Seek treatment immediately.

While you are using it

-Things you must do

Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists treating you that you are taking PICOSTIVE.

-Things you must not do

Do not take any new medicines without consulting your doctor. Do not give PICOSTIVE to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

If PICOSTIVE make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, PICOSTIVE can cause side-effects although not everybody gets them.

Consult your doctor at once if you experience:

-Common ($\geq 1/100$ to $\leq 1/10$): nausea, abdominal pain, hypermagnesaemia, headache and vomiting.

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Tell your doctor if you notice any of the side-effects listed or notice any other effects not listed.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of PICOSTIVE

-Storage

Store below 30°C.

-Disposal

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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

Your medicine is called PICOSTIVE. It is white, odourless powder packed in sachet for oral solution. It is supplied in pack of 2 sachets.

Reconstituted solution: The reconstituted solution is off-white, cloudy liquid after 2-3 minutes of stirring and becomes a clear solution within 20 minutes in approximately 150 mL.

-Ingredients

Active Ingredients

10.0 mg sodium picosulfate
3.5 g magnesium oxide heavy
12.0 g anhydrous citric acid

Inactive ingredients

Lactose anhydrous, polyvinyl pyrrolidone (E1201), potassium carbonate (E501) and sucralose (E955).

-MAL number

MAL

Manufacturer

Ind-Swift Laboratories Limited
Off NH-21, Village Jawaharpur,
Tehsil Derabassi, District S.A.S
Nagar (Mohali) Punjab 140507,
India

Product Registration Holder

Medispec (M) Sdn Bhd
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Taman Mayang,
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Malaysia

Date of revision

12/05/2026

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