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# PICOLAX

## Powder for oral solution

### 1. NAME OF THE MEDICINAL PRODUCT

PICOLAX powder for oral solution

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains the following active ingredients:

Sodium picosulfate	10.0mg
Magnesium oxide, light	3.5g
Citric acid, anhydrous	12.0g

Each sachet also contains:

Potassium hydrogen carbonate 0.5g [equivalent to 5 mmol (195 mg) potassium]

Lactose (as a component of the flavour)

For full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Powder for oral solution in sachet.

White crystalline powder.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

To clean the bowel prior to X-ray examination or endoscopy.

To clean the bowel prior to surgery when judged clinically necessary (see section 4.4 regarding open colorectal surgery)

#### 4.2 Posology and method of administration

Route of administration: Oral

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A low residue diet is recommended on the day prior to the hospital procedure. To avoid dehydration during treatment with PICOLAX it is recommended to drink approximately 250ml per hour, of water or other clear fluid while the washout effect persists.

*Directions for reconstitution:*

Reconstitute the contents of one sachet in a cup of water (approximately 150ml). 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 becomes hot, wait until it cools sufficiently to drink.

*Adults (including the elderly):*

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

*Children:*

1 - 2 years: ¼ sachet morning, ¼ sachet afternoon

2 - 4 years: ½ sachet morning, ½ sachet afternoon

4 - 9 years: 1 sachet morning, ½ sachet afternoon

9 and above: adult dose

#### **4.3 Contraindications**

- Hypersensitivity to any of the ingredients of the product
- Congestive cardiac failure
- Gastric retention
- Gastro-intestinal ulceration
- Toxic colitis
- Toxic megacolon
- Ileus
- Nausea and vomiting
- Acute surgical abdominal conditions such as acute appendicitis
- Known or suspected gastro-intestinal obstruction or perforation.
- Severe dehydration
- Rhabdomyolysis
- Hypermagnesemia
- 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.

#### **4.4 Special warnings and special precautions for use**

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.

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Recent gastro-intestinal surgery. Care should also be taken in patients with renal impairment, heart disease or inflammatory bowel disease.

Use with caution in patients on drugs that might affect water and/or electrolyte balance e.g. diuretics, corticosteroids, lithium (see 4.5).

PICOLAX may modify the absorption of regularly prescribed oral medication and should be used with caution e.g. there have been isolated reports of seizures in patients on antiepileptics, with previously controlled epilepsy (see 4.5 and 4.8).

An inadequate oral intake of water and electrolytes could create clinically significant deficiencies, particularly in less fit patients. In this regard children, the elderly, debilitated individuals and patients at risk of hypokalaemia may need particular attention. Prompt corrective action should be taken to restore fluid/electrolyte balance in patients with signs or symptoms of hyponatraemia.

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

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

This medicine contains lactose as a component of the flavour. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Picolax should not be used as a routine laxative.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

As a purgative, PICOLAX increases the gastrointestinal transit rate. The absorption of other orally administered medicines (e.g. anti-epileptics, contraceptives, anti-diabetics, antibiotics) may therefore be modified during the treatment period (see 4.4). 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 PICOLAX to avoid chelation with magnesium.

The efficacy of PICOLAX 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 PICOLAX 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.

#### **4.6 Pregnancy and lactation**

For PICOLAX no clinical data on exposed pregnancy are available. Studies in animals have shown reproductive toxicity (see section 5.3). As picosulfate is a stimulant laxative, for safety measure, it is preferable to avoid the use of PICOLAX during pregnancy.

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There is no experience with the use of PICOLAX in nursing mothers. However, due to the pharmacokinetic properties of the active ingredients, treatment with PICOLAX may be considered for females who are breastfeeding.

#### 4.7 Effects on ability to drive and use machines

Not applicable.

#### 4.8 Undesirable effects

<b>MedDRA Organ Class</b>	<b><u>Common (&gt;1/100 to ≤1/10)</u></b>	<b><u>Uncommon ((≥1/1000 to ≤1/100)</u></b>	<b><u>Not known (cannot be estimated from the available data)</u></b>
Immune system disorder		Anaphylactic reaction, hypersensitivity	
Metabolism and nutrition disorders		Hyponatraemia and hypokalaemia	
Nervous system disorders	Headache	Epilepsy, grand mal convulsion, conculsions, confusional state	
Gastrointestinal disorders	Nausea and proctalgia	Vomiting, abdominal pain, aphthoid ileal ulcers*	Diarrhoea, faecal incontinence
Skin and subcutaneous tissue disorders		Rash (including erythematous and maculo-papular rash, urticaria, purpura)	

\*Isolated cases of mild reversible aphthoid ileal ulcers have been reported.

☒ The frequencies of the side effects are based on post-marketing experience.

Diarrhoea and faecal incontinence are the primary clinical effect of PICOPREP. Isolated cases of severe diarrhoea have been reported post-marketing.

Hyponatraemia has been reported with or without associated convulsions. In epileptic patients, there have been isolated reports of seizure/grand mal convulsion without associated hyponatraemia. There have been isolated reports of anaphylactoid reaction.

#### 4.9 Overdose

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Overdosage would lead to profuse diarrhoea. Treatment is by general supportive measures and maintenance of fluid intake.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Contact Laxatives

ATC code: A06A B58

The active components of PICOLAX 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.

### **5.2 Pharmacokinetic properties**

Both active components are locally active in the colon, and neither are absorbed in any detectable amounts.

### **5.3 Preclinical safety data**

Prenatal developmental studies in rats and rabbits did not reveal any teratogenic potential after oral dosing of sodium picosulfate, but embryotoxicity has been observed in rats at 1000 and 10000 mg/kg/day and in rabbits at 1000 mg/kg/day. The corresponding safety margins were 3000 to 30000 times the anticipated human dose. In rats, daily doses of 10 mg/kg during late gestation (fetal development) and lactation reduced body weights and survival of the offspring. Male and female rat fertility was not affected by oral doses of sodium picosulfate up to 100 mg/kg.

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## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Potassium hydrogen carbonate

Sodium saccharin

Natural, spray dried orange flavour which contains acacia gum, lactose, ascorbic acid, butylated hydroxyanisole.

### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf life**

3 years

Once the sachet has been opened, use immediately and discard any unused powder or solution.

### **6.4 Special precautions for storage**

Do not store above 25°C. Store in the original package in order to protect from moisture.

### **6.5 Nature and contents of container**

Sachet:

4 layers: paper-low density polyethylene-aluminium-thermofusible resin

Each pack contains a pair of sachets that can be separated by tearing apart the perforated strip.

Weight of sachet contents: 16.1g

### **6.6 Instructions for use, handling and disposal**

None

## **7. MANUFACTURER**

Ferring GmbH, Germany

## **8. LICENSE HOLDER**

Ferring Pharmaceuticals Ltd

8, Hashita Street, Industrial Park Caesarea 38900

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