

# PICOSALAX

Sodium picosulfate 10mg, magnesium oxide 3.5g, citric acid 12.0g

## **Presentation**

Sachets containing 16.1g of powder for oral solution.

*Active ingredients:* sodium picosulfate 10mg with magnesium citrate formed in solution from magnesium oxide 3.5g and citric acid 12.0g.

## **Uses**

### **Actions**

The active components of PICOSALAX are sodium picosulfate, which stimulates bowel movements following metabolism by colonic bacteria, and magnesium citrate which acts as an osmotic laxative by increasing intestinal osmotic pressure thereby promoting retention of fluid within the bowel. The combined action of these components results in evacuation of the bowel contents.

### **Pharmacokinetics**

Sodium picosulfate itself is pharmacologically inactive but is metabolised to an active metabolite, desacetylbisacodyl (bis(*p*-hydroxyphenyl)pyridyl-2-methane), which influences the chemoreceptors in the mucosa to increase intestinal motility. Desacetylbisacodyl is the same active metabolite formed following ingestion of bisacodyl, is insoluble in water and is minimally absorbed from the gastro-intestinal tract.

### **Indications**

For clearance of the bowel prior to examination by radiography, endoscopy or surgery.

## **Dosage and Administration**

### **Dosage**

*Adults and children 9 years of age and over*

Two sachets are normally taken 6 to 8 hours apart the day before the examination according to the treatment plan below or, alternatively, as directed by the doctor.

### **Directions for Reconstitution**

Mix the contents of ONE sachet in 120mL (approximately half a cup) of water. Stir for 2 to 3 minutes and drink the mixture. If it becomes hot, wait until it cools sufficiently to drink.

1<sup>st</sup> dose – 1 sachet before breakfast (not later than 8am) on the day prior to examination.

2<sup>nd</sup> dose – 1 sachet 2 hours after lunch (not later than 4 pm) on the day prior to examination.

A low residue diet is recommended for 2 days prior to examination. The patient should maintain a liberal intake of clear fluids throughout the treatment. A suggested diet plan is given in the Patient Information Leaflet.

Patients should be warned to expect frequent, loose bowel movements. Some authorities recommend a high fluid intake but no food at all during the 24 hours prior to examination.

PICOSALAX should not be used in children under 9 years of age (see **Precautions**).

## **Contraindications**

PICOSALAX is contraindicated in patients with gastrointestinal obstruction, gastric retention, gastro-intestinal ulceration, bowel perforation, toxic colitis, toxic megacolon, ileus, those with a stoma, nausea and vomiting, acute surgical abdominal conditions such as acute appendicitis, congestive cardiac failure.

Hypersensitivity to any of the ingredients.

In patients with severely reduced renal function, accumulation of magnesium in plasma may occur. Another preparation should be used in such cases.

PICOSALAX should not be used in patients with undiagnosed abdominal symptoms.

PICOSALAX should not be used in children under 9 years of age.

### **Warnings and Precautions**

#### **Precautions**

***Life-threatening dehydration and/or electrolyte disturbances may occur in 'at risk' groups (see 'Contraindications').***

Use with caution following recent gastro-intestinal surgery, in patients with inflammatory bowel disease and those with suspected bowel obstruction. Those patients with kidney disease, impaired renal function or congestive heart failure should be monitored, as should those with pre-existing electrolyte disturbances.

Patients using diuretics or other medications (such as corticosteroids, lithium) that may affect water and/or electrolyte balance should also be monitored (See **Interactions**).

In all patients, adequate fluid intake should be maintained (See **Dosage**). An inadequate oral intake of water and electrolytes could create clinically significant deficiencies, particularly in less fit patients. In this regard, 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.

PICOSALAX 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 anti-epileptics, with previously controlled epilepsy (see **Interactions and Adverse Effects**).

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

PICOSALAX is not intended for use as a routine laxative.

#### **Use in children**

PICOSALAX should not be used in children under 9 years of age.

#### **Use in pregnancy**

Whilst animal reproduction studies with sodium picosulfate have revealed no evidence of a harmful action on the foetus, clinical experience of the use of PICOSALAX during pregnancy is limited and caution should be observed, particularly during the first trimester.

#### **Use in lactation**

Neither sodium picosulfate nor magnesium citrate has been shown to be excreted in breast milk.

### **Adverse Effects**

Isolated cases of allergic reactions have been reported including anaphylaxis. Vomiting, and/or severe diarrhoea have also been reported and may lead to hyponatraemia and convulsions in the absence of adequate salt replacement.

The following adverse reactions have been reported with PICOSALAX:

- Hyponatraemia
- Epilepsy
- Convulsions
- Confusion state
- Headache
- Vomiting
- Diarrhoea
- Abdominal pain
- Nausea
- Anal pain

- Rashes
- Drug interaction

Gastrointestinal adverse reactions such as nausea, abdominal pain, vomiting and anal pain are usually transient.

Hyponatraemia has been reported with or without associated convulsions (see **Warnings and Precautions**). In epileptic patients, there have been isolated reports of seizure/grand mal convulsion without associated hyponatraemia. There have been isolated reports of anaphylactoid reaction. Isolated cases of mild reversible aphthoid ileal ulcers have been reported.

#### **Interactions**

As a purgative, PICOSALAX increases 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 **Warnings and Precautions**).

Broad spectrum antibiotics may decrease the effect of PICOSALAX by interfering with the colonic bacteria needed to break down sodium picosulfate to form its active substance.

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 PICOSALAX is used in patients on NSAIDs or drugs known to induce SIADH (Syndrome of Inappropriate Antidiuretic Hormone secretion) 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.

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

#### **Overdosage**

Overdosage would lead to profuse diarrhoea with dehydration and fluid/electrolyte imbalance. Treatment is by general supportive measures and maintenance of fluid intake.

#### **Pharmaceutical Precautions**

Store below 30°C. The contents of the sachet are not for immediate use but must be reconstituted in water before administration.

#### **List of Excipients**

*Inactive:* potassium bicarbonate, saccharin sodium, orange flavour.

#### **Shelf Life**

2 years.

#### **Medicine Classification**

Pharmacist Only Medicine

#### **Package Quantities**

2 sachets each containing 16.1g of powder.

#### **Further Information**

*Sodium picosulfate.* Molecular formula  $C_{18}H_{13}NNa_2O_8S_2$ , MW 481.4, CAS: 10040-45-6

*Magnesium oxide.* Molecular formula:  $MgO$ , MW: 40.3, CAS: 1309-48-4

*Citric acid.* Molecular formula:  $C_6H_8O_7$ , MW: 192.1, CAS: 77-92-9

#### **Name and Address**

Pharmaco (NZ) Ltd  
P O Box 4079  
Auckland 1140

**Date of Preparation**

16 October 2007

(SmPC Picolax-131.01 29/2/08)

PI 9 Aug 2006