NEW ZEALAND DATA SHEET

PICOSALAX® powder for oral solution

Sodium picosulfate 10 mg, magnesium oxide 3.5g, citric acid 12 g

1 PRODUCT NAME

PICOSALAX powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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 12g.

Excipient(s) with known effect: Saccharin sodium, lactose

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder for oral solution.

White crystalline powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Dose and method of administration

Instructions for timing of dose and dietary and fluid restrictions vary greatly between centres and may over-ride the recommendations given below. Clinical studies with PICOSALAX have shown the following regimens to be effective.

Adults (including the elderly) and children aged 9 years of age and older:

(if the procedure is scheduled for the afternoon, it is recommended that the Split-Dose regimen be used):

Split-dose Regimen (evening-before and day of the procedure)

The first PICOSALAX sachet 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 evening (e.g. 5:00 to 9:00 pm), followed by at least five 250mL drinks of clear liquids, 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 three 250mL drinks of clear liquids, spread over several hours
- Clear liquids may be consumed until 2 hours before the time of the procedure.

or

Day-Before Regimen (evening-before the procedure only)

The first PICOSALAX sachet is taken in the afternoon or early evening and the second is taken approximately 6 hours later, the night before the procedure.

On the day before the procedure - 2 sachets:

- The first reconstituted sachet is taken in the afternoon or early evening (e.g. 4:00 to 6:00pm), followed by at least five 250mL drinks of clear liquids, spread over several hours
- The second reconstituted sachet is taken in the late evening (e.g. 10:00pm to 12:00am), followed by at least three 250mL drinks of clear liquids, spread over several hours
- Clear liquids may be consumed until 2 hours before the time of the procedure.

Directions for Reconstitution

Immediately before use, mix the contents of one sachet in approximately 150mL (⅔ of a cup) of water. Stir for 2-3 minutes, the solution should now become an off-white, cloudy liquid with a faint odour of orange. If it becomes warm wait until it cools sufficiently to drink. Drink the solution. Do not prepare the solution in advance.

Further Information

Patients should be warned to expect frequent, loose bowel movements. To avoid dehydration it is recommended to drink a sufficient amount of clear liquids whilst the effects of PICOSALAX persist. Apart from the liquid intake together with the treatment regimen (PICOSALAX + additional liquids), a normal, thirst driven intake of clear liquids is recommended. Clear liquids may include water, clear soup, fruit juice without pulp, soft drinks, tea and/or coffee without milk (including soy and cream). Patients should be advised NOT to drink just water alone but to also drink a balanced electrolyte solution; drinking only water to replace fluid losses may lead to electrolyte imbalance, particularly hypokalaemia or hyponatraemia and possibly seizures (see section 4.4). Patients should be instructed to consume only clear fluids (no solid food or milk) on the day before the procedure up until 2 hours before the time of the procedure.

4.3 Contraindications

PICOSALAX is contraindicated in patients with:

- congestive heart failure,
- clinically significant renal impairment,
- known or suspected gastrointestinal obstruction or perforation,
- gastric retention,
- gastro-intestinal ulceration,
- toxic colitis,
- toxic megacolon,
- ileus,
- those with a stoma,
- nausea and vomiting,
- acute surgical abdominal conditions such as acute appendicitis,
- severe dehydration,

- rhabdomyolysis,
- hypermagnesemia,
- active inflammatory bowel disease or
- hypersensitivity to any of the ingredients as listed in section 6.1.

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.

4.4 Special warnings and precautions for use

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

Use with caution in patients with recent gastro-intestinal surgery, renal impairment, heart disease or inflammatory bowel disease. Those patients with kidney disease, or impaired renal function should be monitored, as should those with pre-existing electrolyte disturbances. Diabetics may need adjustment of their medication and careful monitoring of their blood glucose.

Patients using diuretics or other medications (such as corticosteroids, lithium) that may affect water and/or electrolyte balance should also be monitored (see section 4.5).

In all patients, adequate fluid intake should be maintained. An insufficient or excessive oral intake of water and electrolytes could create clinically significant deficiencies, particularly in less fit patients. In this regard, patients with low bodyweight, children, the elderly, debilitated individuals and patients at risk of hypokalaemia or hyponatremia may need particular attention. Prompt corrective action should be taken to restore fluid/electrolyte balance in patients with signs or symptoms of hypokalaemia or hyponatraemia. 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, PICOSALAX can cause severe or life-threatening electrolyte problems or impaired renal function in fragile or debilitated patients. Nephrocalcinosis and renal impairment may occur following use of oral sodium phosphate products in 'at risk' or inappropriate patient groups.
The period of bowel cleansing should not exceed 24 hours because longer preparation may increase the risk of water and electrolyte imbalance (see section 4.2).

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 sections 4.4 and 4.8).

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

PICOSALAX contains lactose as a component of the flavour (approximately 5mg per sachet). Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

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.

4.5 Interaction with other medicines and other forms of interaction

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 decreased during the treatment period (see section 4.4).

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.

Medicines with the potential to chelate with magnesium (e.g. tetracyclines 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 PICOSALAX.

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.

4.6 Fertility, pregnancy and lactation

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.

Breastfeeding

Neither sodium picosulfate nor magnesium citrate has been shown to be excreted in breast milk. As there is no experience with the use of PICOSALAX in nursing mothers, the product should only be used if clearly indicated.

Fertility

Studies with PICOSALAX in animals have shown no impairment of fertility or embryofetal toxicity. In studies with sodium picosulfate alone, embryofetal toxicity has been observed in rats and rabbits at very high doses.

4.7 Effects on ability to drive and use machines

No data.

4.8 Undesirable effects

The most common adverse reactions are vomiting, nausea, abdominal pain and headache. Hyponatraemia is rare, but is the most commonly reported serious adverse reaction.

Adverse reactions from spontaneous reports are presented by frequency category based on incidence in clinical trials when known. Frequency from spontaneous reports for adverse reactions never observed in clinical trials is based on an algorithm as recommended in the European Commission SmPC guideline, 2009, rev 2.

MedDRA Organ Class	**Common (≥1/100 to ≤1/10)**	**Uncommon (≥1/1000 to <1/100)**	**Rare (≥1/10000 to <1/1000)**
Immune system disorders		Anaphylactic reaction, hypersensitivity	
Metabolism and nutrition disorders	Hypermagnesaemia	Hypokalaemia	Hyponatraemia
Nervous system disorders	Headache	Epilepsy, Generalised tonic-clonic seizure[a], Seizure[b], Loss of or depressed level of consciousness Syncope Dizziness Confusional state including disorientation	Presyncope
Gastrointestinal disorders	Vomiting, Nausea, Abdominal pain	Diarrhoea[c],	Ileal ulcers[d], Anal incontinence[e] Proctalgia,
Skin and subcutaneous tissue disorders		Rash (including erythematous and maculo-papular rash, urticaria, purpura)	

[a] Defined as grand mal convulsion in previous MedDRA versions. In epileptic patients, there have been isolated reports of seizure/generalised tonic-clonic seizure without associated hyponatreamia.
[b] Defined as convulsions in previous MedDRA versions.
[c] Isolated cases of severe diarrhoea have been reported post-marketing.
[d] Isolated cases of mild reversible aphthoid ileal ulcers have been reported.
[e] Defined as faecal incontinence in previous MedDRA versions.

Diarrhoea and faecal incontinence are the primary clinical effect of PICOSALAX.

Hyponatraemia has been reported with or without associated convulsions (see section 4.4).

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to https://pophealth.my.site.com/carmreportnz/s/

4.9 Overdose

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

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Contact laxatives

ATC code: A06A B58

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.

5.2 Pharmacokinetic properties

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.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of repeated dose toxicity and genotoxicity.

Due to the very short treatment duration no long-term studies in animals have been performed.

Reproductive studies have shown no potential for impairment of fertility or harm to the foetus for sodium picosulfate and PICOSALAX.

In an animal study on pre- and postnatal development, the NOAEL of PICOSALAX was the mid dose of 750mg/kg BID. The adverse effect that occurred in the 2000mg/kg BID group (approximately 8 times the recommended human dose), was pup mortality, between lactation days 2 to 4 due to maternal toxicity.

Effects in reproductive and developmental toxicity studies in animals with sodium picosulfate alone were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium bicarbonate (equivalent to 5mmol [195mg] potassium),

Saccharin sodium,

Orange flavour (containing lactose monohydrate (equivalent to 4.5mg of lactose)).

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

2 sachets each containing 16.1g of powder for oral solution.

The contents of the sachet are not for immediate use but must be reconstituted in water before administration.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MEDICINE SCHEDULE

Pharmacist Only Medicine

8 SPONSOR

Pharmaco (NZ) Ltd
4 Fisher Crescent
Mt Wellington
Auckland 1060
Telephone: 09 377 3336

9 DATE OF FIRST APPROVAL

26 November 2009

10 DATE OF REVISION OF THE TEXT

11 September 2024

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SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
4.8	Update to adverse event reporting link and adverse event table to include hypermagnesaemia.