WARNING

Life-threatening dehydration and/or electrolyte disturbances may occur in "at risk" groups. See Contraindications and Precautions.

1 PRODUCT NAME

PicoPrep® powder 15.5 g sachet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The active ingredients are:

- sodium picosulfate has a chemical formula of $C_{18}H_{13}NNa_2O_8S_2,H_2O$, a MW of 499.4 and a CAS No. 10040-45-6 (anhydrous)
- magnesium oxide - heavy, has a chemical formula of MgO, a MW of 40.3 and a CAS No. 1309-48-4;
- citric acid which has a chemical formula of $C_6H_8O_7$, a MW of 192.1 and a CAS No. 77-92-9.

Each sachet contains sodium picosulfate 10 mg, magnesium oxide 3.5 g, citric acid anhydrous 12.0 g and aspartame 36 mg.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Powder for oral solution.

PicoPrep® powder for oral solution is a white crystalline powder packed in sachets each containing 15.546 g. When dissolved in water it produces a solution with a mild citric acid taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

PicoPrep® is indicated for bowel emptying and cleansing by means of total gastrointestinal tract perfusion in preparation for gastrointestinal examination (such as colonoscopy, barium enema x-ray examination), prior to intravenous pyelograms (IVP) or surgery.

4.2 Dose and method of administration

Information for Patients

The first bowel motion should occur approximately 2 to 3 hours after commencing dose. Onset may be sooner in individual patients. This action cleanses the bowel before examination. It should be prepared and taken according to the directions on the box or in the Dosage and Administration section.

No food or drink should be taken for at least six (6) hours before the examination.

It is important that the patient follow the recommended dosing schedule and take adequate fluids to ensure hydration.

Preparation of Solution

Dissolve the contents of one sachet in one full glass of warm water (approximately 250 mLs). This may be chilled in a refrigerator for use if preferred.

Approved Clear Fluids

Water, clear salty fluids (eg: strained chicken noodle soup), clear broth/bouillon, clear fruit juices, plain jelly, black tea or coffee (no milk), sports drinks, Gastrolyte™, clear fruit cordials (clear lemon / lime), (no red or purple colourings). (A good combination of these clear fluids, including 2-3 cups of strained chicken noodle soup, will give you a variation in fluid intake).

Barley sugar may also be sucked if required.

Diabetics may require an alteration to this program depending on their condition.

PicoPrep® produces a watery stool or bowel motion which empties and cleanses the bowel before examination or surgery. It should be prepared and taken according to the following directions unless otherwise directed:

Two days prior to the examination stop eating brown bread, red meat, cereals, vegetables, yellow cheese or anything with seed in it. You may eat boiled or poached eggs, cottage cheese, white bread, low fat plain yoghurt, steamed white fish, boiled chicken, well cooked peeled pumpkin and potato. You may have clear jelly, skim milk and drink plenty of Approved Clear Fluids.

On the day before the examination, no solid foods or milk products are allowed. Drink only Approved Clear Fluids (see above).

Usual Dosage

1. On the day prior to the examination drink Approved Clear Fluids only.

2. Commencing on the day before examination (approx.3pm), dissolve the entire contents of one sachet of PicoPrep® in a glass of warm water. If preferred chill in refrigerator before drinking. Drink the contents of the glass followed by a glass of water. Continue drinking Approved Clear Fluids at least a glass per hour the more the better to ensure adequate body hydration.

3. In the evening of the same day (at approx. 9pm) repeat the above with another sachet of PicoPrep®. ie: dissolve in a glass of warm water, chill if preferred, then drink contents followed by a glass of water. Continue drinking Approved Clear Fluids, at least a glass per hour until six (6) hours prior to the examination.

   No food or drink should be taken for six (6) hours prior to the examination.

If a third sachet is required:

For some patient, this may be required to ensure complete bowel emptying.

1. On the day prior to the examination drink Approved Clear Fluids only.

2. Commencing on the day before examination (**at approx.1pm**), dissolve the entire contents of one sachet of PicoPrep® in a glass of warm water. If preferred chill in refrigerator before drinking. Drink the contents of the glass followed by a glass of water. Continue drinking Approved Clear Fluids at least a glass per hour the more the better to ensure adequate body hydration.

3. In the evening of the same day (**at approx. 5pm**) repeat the above with another sachet of PicoPrep®. ie: dissolve in a glass of warm water, chill if preferred, then drink contents followed by a glass of water. Continue drinking Approved Clear Fluids, at least a glass per hour the more the better to ensure adequate body hydration.

4. In the evening of the same day (**at approx. 9pm**) repeat the above with another sachet of PicoPrep®. ie: dissolve in a glass of warm water, chill if preferred, and drink the contents followed by a glass of water. Continue drinking Approved Clear Fluids, at least a glass per hour until six (6) hours prior to the examination.

   No food or drink should be taken for six (6) hours prior to the examination.

Note:
Timing of sachets and time without food or drink prior to examination may be varied.

Nasogastric Intubation
Infuse the prepared solution at a rate of 20 to 30 mLs/minute. Adequate steps should be taken to ensure proper hydration by administration of clear fluids through the nasogastric tube at the rate of 250 mLs per hour as for oral use.

4.3 Contraindications
PicoPrep® should not be used by patients with gastrointestinal obstruction, gastric retention, bowel perforation (frank or suspected), toxic colitis, toxic megacolon and ileus and those with a stoma.

PicoPrep® should not be used in children below the age of 9 years.

4.4 Special warnings and precautions for use
Use with caution in patients with severe ulcerative colitis, impaired renal function, pre-existing electrolyte disturbances, congestive heart failure, and in the elderly.

Patients with impaired gag reflex; who are unconscious or semi-unconscious; who are prone to regurgitation or aspiration; should be carefully observed during the administration of PicoPrep®.

Patients with nasogastric intubation must be carefully observed during the administration of PicoPrep®. Proper steps should be taken to ensure hydration by means of gastric tube.

PicoPrep® is likely to cause transient hypovolaemia, hence adequate fluid intake or replacement should be ensured (see section 4.2 Dosage and Method of Administration).

Patients with congestive heart failure should be monitored; as should patients using calcium channel blockers; diuretics or other medications which may affect electrolyte levels.

Patients with kidney disease or impaired renal function should also be monitored as should those with pre-existing electrolyte disturbances.

PicoPrep® may cause bloating, distension or abdominal pain, especially if administered by nasogastric tube. If this develops, the rate of administration should be slowed or temporarily ceased until the symptoms abate.

As PicoPrep® contains aspartame, persons suffering from phenylketoneuria need to be advised.

Use in the elderly
Caution should be exercised in the elderly as dehydration and electrolyte depletion may occur. Elderly patients must receive adequate fluids during administration.

Paediatric use
Only to be used in children aged above 9 years (see 4.3 Contraindications above).

Effects on laboratory tests
No data available.

4.5 Interaction with other medicines and other forms of interactions

Oral medication taken within one hour of the commencement of the administration of PicoPrep® may be flushed from the gastrointestinal tract and not absorbed.

The use of antibiotics may reduce the effectiveness of PicoPrep® since sodium picosulfate is broken down by colonic bacteria to form the active substance.

4.6 Fertility, pregnancy and lactation

Effects on fertility
No data available.

Use in pregnancy (Category - none)
It is not known whether PicoPrep® can cause foetal harm or affect reproductive capacity. PicoPrep® should only be used if clearly needed.

Use in lactation
Sodium Picosulfate is unlikely to be excreted in breast milk as it exerts a local action and is not absorbed systemically.

4.7 Effects on ability to drive and use machines

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 Undesirable effects

Nausea, abdominal fullness and bloating are the most common reactions.

Abdominal cramps, vomiting and anal irritation occur less frequently.

These adverse reactions are usually transient and subside rapidly.

Reporting suspected adverse effects

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 https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

In the event of overdosage, dehydration may ensue. Calcium, potassium, chloride and sodium levels should be carefully monitored and immediate corrective action should be taken to restore electrolyte balance with appropriate fluid replacements.

For advice on the management of overdose, please contact the National Poisons Centre on 0800 POISON (0800 764 766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Alimentary Tract and Metabolism, Drugs for Constipation, Osmotically acting laxatives

ATC code: A06AD65

Mechanism of action

Sodium Picosulfate is broken down by colonic bacteria to form the active substance, the citric acid reacts with the magnesium oxide to form magnesium citrate, an osmotic laxative. This induces a watery stool or bowel motion, usually within 3 hours, which normally removes the bowel contents.

Clinical trials

No data available.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

Genotoxicity

No studies have been performed.

Carcinogenicity

No studies have been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aspartame 2.36 mg/g

6.2 Incompatibilities

Refer to section 4.2 Dose and method of administration.

6.3 Shelf life

Approved Shelf Life as packaged for sale

3 years

6.4 Special precautions for storage
Store in a cool dry place below 30°C.

6.5 Nature and contents of container
Each sachet (aluminium foil) contains 15.546 g of dry white powder.

Pack sizes
Sachets of 2's, 3's and 50's

6.6 Special precautions for disposal
No special requirements for disposal. Any unused medicine or waste material should be disposed of in accordance with local requirements.

7 MEDICINE SCHEDULE
Restricted Medicine

8 SPONSOR
Fresenius Kabi New Zealand Limited
60 Pavilion Drive
Airport Oaks, Auckland 2022
New Zealand
Freecall: 0800 144 892

9 DATE OF FIRST APPROVAL
23 September 1999

10 DATE OF REVISION OF THE TEXT
25 June 2019

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	Reformat PI as per new Medsafe template