AUSTRALIAN PRODUCT INFORMATION – PICOPREP ORANGE® (CITRIC ACID, MAGNESIUM CARBONATE HYDRATE, SODIUM PICOSULFATE)

WARNING

Life-threatening dehydration and/or electrolyte disturbances may occur in "at risk" groups. See section 4.3 Contraindications and 4.4 Special warnings and precautions for use.

1 NAME OF MEDICINE

Citric acid
Magnesium carbonate hydrate
Sodium picosulfate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each PICOPREP ORANGE sachet contains sodium picosulfate 10.3 mg, magnesium carbonate hydrate 7.4 g and citric acid 12.2 g, as the active ingredients.

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

3 PHARMACEUTICAL FORM

Powder for solution. For oral use.

PICOPREP ORANGE contains 20 g of white to creamy yellow powder which when dissolved in water produces 250 mL of solution with a mild citric acid taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

PICOPREP ORANGE 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 colorectal surgery, in adults and children 9 years of age and over.

4.2 Dose and method of administration

Prior to the procedure

During the day patients should drink at least one glass (approx. 250 mL) of Recommended Clear Fluids (see **APPENDIX I**), in addition to the water taken with PICOPREP ORANGE, each hour until bedtime to maintain hydration. It is recommended that patients follow a modified diet, such as a low-fibre diet, up until they take the medication. Upon taking the medication, the patient may only have Recommended Clear Fluids. It is recommended that patients cease taking any fluids two (2) hours prior to the procedure.

Preparation of the solution

Dissolve the contents of one (1) sachet, by slowly adding the powder in approximately 250 mL of warm water (not boiling) using a large suitable food grade container. The solution will appear cloudy, may become hot and produce effervescence upon reconstitution. Stir gently until the effervescence ceases. The solution may be refrigerated after reconstitution. The solution should be ingested within 24 hours of reconstitution.

Recommended dosing regimen
Below is an example of a dosing regimen. The dosing regimen may be adjusted by a Healthcare Professional as required.

First Dose: PICOPREP ORANGE sachet (taken at 3:00 PM)
The solution should be orally ingested slowly but completely. This should be followed by one (1) glass of water and at least one (1) 250 mL glass every hour of water or Recommended Clear Fluids.

Second Dose: PICOPREP ORANGE sachet (taken at 9:00 PM)
The solution should be orally ingested slowly but completely. This should be followed by one (1) glass of water and at least one (1) 250 mL glass every hour of water or Recommended Clear Fluids.

If the patient requires a third sachet:

First Dose: PICOPREP ORANGE sachet (taken at 1:00 PM)
The solution should be orally ingested slowly but completely. This should be followed by one (1) glass of water and at least one (1) 250 mL glass every hour of water or Recommended Clear Fluids.

Second Dose: PICOPREP ORANGE sachet (taken at 5:00 PM)
The solution should be orally ingested slowly but completely. This should be followed by one (1) glass of water and at least one (1) 250 mL glass every hour of water or Recommended Clear Fluids.

Third Dose: PICOPREP ORANGE sachet (taken at 9:00 PM)
The solution should be orally ingested slowly but completely. This should be followed by one (1) glass of water and at least one (1) 250 mL glass every hour of water or Recommended Clear Fluids.

For nasogastric intubation
Administration via nasogastric intubation should be done with careful observation to ensure proper hydration. Infuse 250 mL of the prepared solution each hour, as per oral administration, at a rate of 20 to 30 mL/minute.

4.3 Contraindications
PICOPREP ORANGE should not be used by patients with clinically significant renal impairment, gastrointestinal obstruction, gastric retention, bowel perforation (frank or suspected), toxic megacolon, toxic colitis, ileus, those with a stoma or hypersensitivity to any of the ingredients.

PICOPREP ORANGE should not be used in children below 9 years of age.

4.4 Special warnings and precautions for use
Identified precautions
PICOPREP ORANGE should be administered with caution in debilitated patients or patients with severe ulcerative colitis, pre-existing electrolyte disturbances, heart conditions, dehydration, congestive heart failure or diabetes.

PICOPREP ORANGE should be administered with caution and careful observation to patients with impaired gag reflex, who are unconscious or semi-unconscious, who are prone to regurgitation or aspiration and particularly those with nasogastric intubation Administration

via nasogastric intubation should be done with careful observation to ensure proper hydration.

PICOPREP ORANGE is likely to cause transient hypovolaemia, hence adequate fluid intake or replacement should be ensured (see Section 4.2 Dose and method of administration).

PICOPREP ORANGE should be administered with caution in patients with congestive heart failure and pre-existing electrolyte disturbances. These patients should be monitored.

PICOPREP ORANGE should be administered with caution to patients using calcium channel blockers, diuretics or other medications that may affect electrolyte serum levels and exacerbate volume depletion. These patients should be monitored.

PICOPREP ORANGE 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.

Use in hepatic impairment
No data available.

Use in renal impairment
PICOPREP ORANGE should not be used in patients with clinically significant renal impairment (see Section 4.3). Patients with kidney disease or impaired kidney function should be monitored.

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
PICOPREP ORANGE is contraindicated in children below 9 years (see Section 4.3 Contraindications).

Effects on laboratory tests
No data available.

4.5 Interaction with other medicines and other forms of interactions

Oral medication, especially those medicines with a sustained release, short half-life or a narrow therapeutic window, taken within one hour of the commencing PICOPREP ORANGE may be flushed from the gastrointestinal tract and not absorbed.

The low-dose contraceptive pill will not work when taken with PICOPREP ORANGE as it needs as much time as possible in the gastrointestinal tract for absorption.

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

PICOPREP ORANGE administration may potentially interact with medicines for heart conditions such as calcium channel blockers, diuretics or other medications that may affect electrolyte levels and other bowel cleansing preparations or laxatives.

PICOPREP ORANGE administration may potentially interact with medicines for diabetes and diabetic patients may require adjustment of their diabetic medication, as the recommended liquid diet may affect blood glucose levels.

4.6 Fertility, pregnancy and lactation

Effects on fertility

No fertility studies have been conducted.

Use in pregnancy (Category - none)

It is not known whether PICOPREP ORANGE can cause fetal harm or affect reproductive capacity. PICOPREP ORANGE should only be used if the benefits clearly outweigh the risks.

Use in lactation

PICOPREP ORANGE 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 Adverse effects (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.

Life threatening dehydration and/or electrolyte disturbances may occur in "at risk" groups (see Section 4.3 and 4.4).

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at https://www.tga.gov.au/reporting-problems.

4.9 Overdose

In the event of overdose, dehydration may occur. The 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 information on the management of overdose, contact the Poison Information Centre on 131126 (Australia) or National Poisons Centre on 0800 764 766 (New Zealand).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

Sodium picosulfate is a stimulant laxative which, when metabolised to its active metabolite, acts directly on the colonic mucosa to stimulate colonic peristalsis. The citric acid reacts with the magnesium carbonate to form magnesium citrate, an osmotic laxative. This induces a watery stool or bowel motion, usually within three (3) hours, which normally removes the bowel contents.

Clinical trials

No data available.

5.2 Pharmacokinetic properties

Absorption
Sodium picosulfate is not absorbed systemically.

Distribution
No data available.

Metabolism
Sodium picosulfate is hydrolyzed by the colonic bacterial enzyme, sulfatase, to form the active compound bis(p-hydroxy-phenyl)-pyridyl-2-methane.

Excretion
No data available.

5.3 Preclinical safety data

Genotoxicity
No genotoxic studies have been conducted.

Carcinogenicity
No carcinogenic studies have been conducted.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Natural Orange Flavour FACB076 (Proprietary Ingredient 106181)
Sweetesse Stevia™ 97 (Natural Sweetener/Steviol glycosides Ingredient 107000)

6.2 Incompatibilities

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 Shelf life

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 Special precautions for storage

Store in a cool dry place below 25°C. To reduce microbiological hazard, use as soon as practicable after reconstitution. If storage is necessary, hold at 2-8°C for not more than 24 hours or 6 hours at room temperature.

6.5 Nature and contents of container

Aluminium foil sachet containing 20 g of white to creamy yellow powder with an odour characteristic of oranges and packed in an outer carton.

Pack Sizes*:
2 x 20 g sachets
3 x 20 g sachets
50 x 20 g sachets

The Australian registration number is AUST R 363537.
*Not all pack sizes may be marketed.

6.6 Special precautions for disposal

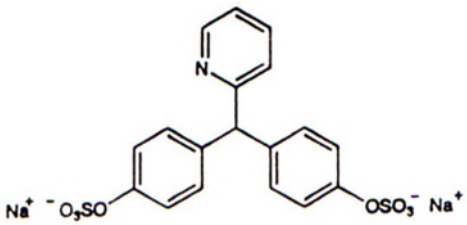
In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 Physicochemical properties

Chemical structure

Sodium picosulfate

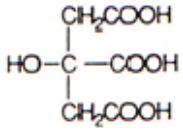
$C_{18}H_{13}NNa_2O_8S_2.•H_2O$



Molecular weight: 499.4 g/mol

Citric acid

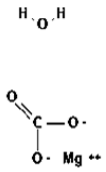
$C_6H_8O_7$



Molecular weight: 192.1 g/mol

Magnesium carbonate hydrate

$MgCO_3•H_2O$



Molecular weight: 102.3 g/mol

CAS number

Active Substance	**CAS number**
Sodium picosulfate	10040-45-6
Citric acid	77-92-9
Magnesium carbonate hydrate	23389-33-5

7 MEDICINE SCHEDULE (POISONS STANDARD)

Australia: S3 – Pharmacist Only Medicine

New Zealand: Restricted Medicine

8 SPONSOR

Fresenius Kabi Australia Pty Ltd
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Mount Kuring-gai, NSW 2080
Australia

9 DATE OF FIRST APPROVAL

28 April 2021

10 DATE OF REVISION OF THE TEXT

Not applicable

Summary table of changes

Section Changed	Summary of new information
All	Reformat PI as per new TGA PI form

APPENDIX I

Recommended Clear Fluids:

- water
- fat-free clear soups (e.g. strained chicken noodle soup)
- broth/bouillon, pulp-free fruit juices (e.g. apple, pear, grape)
- black tea or coffee (no milk)
- electrolyte replacing drinks
- commercial high-energy, fat-free, milk-free nutritional supplements
- carbonated beverages
- clear fruit cordials (e.g. lemon, lime, etc.)
- plain jelly
- sorbet
- plain boiled sweets
- gums and jubes

Sugar, salt, and sweetener can be used. No red or purple colouring. Barley sugar may be sucked if required.