AUSTRALIAN PRODUCT INFORMATION – PREPKIT ORANGE™ (CITRIC ACID, MACROGOL 3350, MAGNESIUM CARBONATE HYDRATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, SODIUM PICOSULFATE, SODIUM SULFATE)

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

GLYCOPREP ORANGE® sachet
Macrogol 3350
Potassium chloride
Sodium chloride
Sodium sulfate

PICOPREP ORANGE® sachet
Citric acid
Magnesium carbonate hydrate
Sodium picosulfate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

PREPKIT ORANGE™ is a medicine kit containing one (1) GLYCOPREP ORANGE® 70 g sachet and two (2) PICOPREP ORANGE® 20 g sachets.

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.

Each GLYCOPREP ORANGE® 70 g sachet contains macrogol 3350 (polyethylene glycol) 52.9 g, potassium chloride 740 mg, sodium chloride 2.6 g, and sodium sulfate 5.6 g, as active ingredients. Total sodium content in the 70 g sachet is 2.86 g.

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

3 PHARMACEUTICAL FORM

PREPKIT ORANGE™ is a medicine kit containing one (1) GLYCOPREP ORANGE® 70 g sachet and two (2) PICOPREP ORANGE® 20 g sachets.

GLYCOPREP ORANGE® sachet: Powder for solution. For oral use.
GLYCOPREP ORANGE® contains 70 g of a white to creamy yellow powder which when dissolved in water produces 1 litre of solution with a mild citric acid taste.

PICOPREP ORANGE® sachet: Powder for solution. For oral use.
PICOPREP ORANGE® contains 20 g of a 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

PREPKIT 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

Seven days prior to the procedure

It is recommended to advise the patient to stop all iron containing medications seven days before the procedure as they may affect stool colour and therefore visibility during the procedure.

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 PREPKIT ORANGE™ each hour until bedtime to maintain adequate 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 solutions

The solutions can be prepared prior to taking the dose or prepared in advance and refrigerated if desired. If you prefer to have the solutions refrigerated prior to ingestion, please prepare the solutions in advance and refrigerate as per the instructions below.

PICOPREP ORANGE®

Two (2) x 20 g PICOPREP ORANGE® sachets are provided. Dissolve the contents of each 20 g sachet separately, by slowly adding the powder in approximately 250 mL of water at room (ambient) temperature 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 reconstituted solution should be ingested within 24 hours of reconstitution.

GLYCOPREP ORANGE®

Dissolve the contents of the GLYCOPREP ORANGE® 70 g sachet in one (1) litre of water at room (ambient) temperature using a suitable food grade container. The solution will appear cloudy upon reconstitution. If desired, the solution may be refrigerated after reconstitution. The reconstituted solution should be ingested within 24 hours of reconstitution.

Recommended dosing

Below is the tabulated instruction for use for both single day regimen and split dose regimen
The dosing regimen may be adjusted by a Healthcare Professional as required.

This course of treatment can be taken either as divided (split-dose) or single doses and the timing is dependent on when the clinical procedure is scheduled.

If the procedure is scheduled for the afternoon, it is recommended that the Split-Dose regimen be used.

A split-dose regimen of Picoprep Orange administered over two days provides optimal bowel cleansing compared to a single-day day-before Picoprep Orange regimen, for both morning and afternoon procedures".

Table 1- Dosing instruction for single day regimen and split dose regimen

Single Day Regimen	**Split-dose Regimen (evening before and day of the procedure)**
Day Before Procedure *First Dose: PICOPREP ORANGE® sachet (taken at 3 pm)* The solution should be 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 (see **APPENDIX I**).	***Day Before Procedure*** *First Dose: PICOPREP ORANGE® sachet (taken at 6 pm)* The solution should be 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 (see **APPENDIX I**).
Second Dose: GLYCOPREP ORANGE® sachet (taken at 6 pm) One (1) to two (2) 250 mL glasses of the prepared solution should be taken every 15-20 minutes. This should be followed by adequate glasses of water or Recommended Clear Fluids (see **APPENDIX I**). If nausea is experienced, the rate of intake of GLYCOPREP ORANGE® solution should be reduced.	*Second Dose: GLYCOPREP ORANGE® sachet (taken at 9 pm)* One (1) to two (2) 250 mL glasses of the prepared solution should be taken every 15-20 minutes. This should be followed by adequate glasses of water or Recommended Clear Fluids (see **APPENDIX I**). If nausea is experienced, the rate of intake of GLYCOPREP ORANGE® solution should be reduced.
Third Dose: PICOPREP ORANGE® sachet (taken at 9 pm) The solution should be 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 (see **APPENDIX I**).	***Day Of Procedure*** *Third Dose: PICOPREP ORANGE® sachet taken approx. 2 to 5 hours prior to procedure)* The solution should be 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 (see **APPENDIX I**).

For nasogastric intubation

Administration via nasogastric intubation should be done with careful observation to ensure proper hydration. Infuse 1.2-1.8 Lof the prepared solution each hour, as per oral administration, at a rate of 20 to 30 mL/minute.

4.3 Contraindications

PREPKIT ORANGE™ should not be used by patients with clinically significant renal impairment, gastrointestinal obstruction, gastric retention, bowel perforation (frank or suspected), bowel inflammation, toxic megacolon, toxic colitis, ileus, those with a stoma, children below 9 years of age or whose body weight is less than 20 kg, severe dehydration or hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Identified precautions

PREPKIT ORANGE™ should be administered with caution in debilitated patients or patients with severe ulcerative colitis, heart conditions or diabetes.

PREPKIT ORANGE™ should be administered with caution and careful observation to patients with an impaired gag reflex, who are unconscious or semi-conscious, 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.

PREPKIT 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).

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

PREPKIT 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.

PREPKIT 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 subside.

Use in hepatic impairment

No data available.

Use in renal impairment

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

PREPKIT ORANGE™ is contraindicated in children below 9 years (see Section 4.3).

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 commencing PREPKIT ORANGE™ may be flushed from the gastrointestinal tract and not absorbed.

The low-dose contraceptive pill will not work when taken with PREPKIT 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.

There is a possible reduction in the effect of bacitracin and benzylpenicillin when used concomitantly, due to the macrogol content of GLYCOPREP ORANGE®.

PREPKIT 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.

PREPKIT 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 reproductive studies have been conducted.

Use in pregnancy (Category - none)

It is not known whether PREPKIT ORANGE™ can cause fetal harm or affect reproductive capacity. PREPKIT 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. No lactation studies have been conducted for GLYCOPREP ORANGE®.

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)

Headache, dizziness, nausea, abdominal fullness and bloating are the most common reactions. Abdominal cramps, vomiting, and anal irritation occur less frequently. These adverse effects are usually transient and subside rapidly.

There have been reports of skin reactions and rhinorrhoea attributed to macrogol which is contained in GLYCOPREP ORANGE®.

Hypersensitivity and anaphylactic reactions are rare adverse reactions.

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

Healthcare professionals are asked to inform patients that sleep disturbance or insomnia may be experienced with both a single-day regimen or a 2-day split-dose regimen.

Advice on mitigating disturbances of sleep may be provided e.g. changing dose timing or even dose-regimen if sleep disturbance is likely or the patient may be particularly anxious about the procedure.

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 overdosage, 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

PICOPREP ORANGE®

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.

GLYCOPREP ORANGE®

Macrogol 3350 acts as an osmotic laxative to induce watery diarrhoea usually within one (1) hour after commencing treatment and which normally removes the bowel contents within four (4) hours of commencing treatment. The water and included electrolytes are iso-osmotic with normal intestinal contents and help to reduce or prevent the loss of electrolytes and water.

Clinical trials

No data available.

5.2 Pharmacokinetic properties

Absorption

PICOPREP ORANGE®

Sodium picosulfate is not absorbed systemically.

GLYCOPREP ORANGE®

Macrogol 3350 is not significantly absorbed.

Distribution

No data available.

Metabolism

PICOPREP ORANGE®

Sodium picosulfate is broken down by colonic bacteria to form the active compound bis(p-hydroxyphenyl)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

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

GLYCOPREP ORANGE®
Ascorbic acid
Silicon dioxide
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 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

PREPKIT ORANGE™ is presented as a medicine kit packed in carton containing:

- one (1) GLYCOPREP ORANGE® aluminium foil sachet containing 70 g of a white to creamy yellow powder with an odour characteristic of oranges.
- two (2) PICOPREP ORANGE® aluminium foil sachets each containing 20 g of a white to creamy yellow powder with an odour characteristic of oranges.

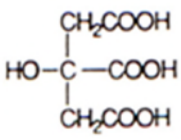
The Australian registration number is AUST R 370153.

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

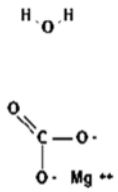
Chemical structure
Citric acid
$C_6H_8O_7$



Molecular weight: 192.1 g/mol

Macrogol 3350
$H(OCH_2CH_2]nOH$ (where 'n' equals 45 to 70).
Molecular weight: varies

Magnesium carbonate hydrate
$MgCO_3 \bullet H_2O$

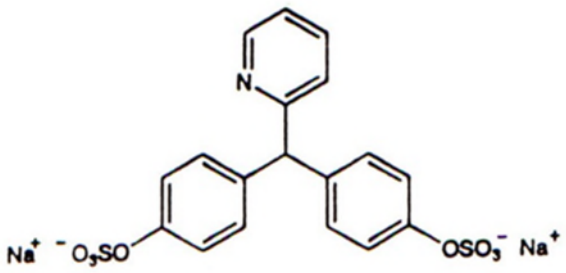


Molecular weight: 102.3 g/mol

Potassium chloride
KCl
Molecular weight: 74.6 g/mol

Sodium chloride
NaCl
Molecular weight: 58.44 g/mol

Sodium picosulfate
$C_{18}H_{13}NNa_2O_8S_2 \bullet H_2O$



Molecular weight: 499.4 g/mol

Sodium sulfate
Na_2SO_4
Molecular weight: 142.0 g/mol
CAS number

Active Substance	**CAS number**
Citric acid	77-92-9
Macrogol 3350	9002-90-8
Magnesium carbonate hydrate	23389-33-5
Potassium chloride	7447-40-7
Sodium chloride	7647-14-5
Sodium picosulfate	10040-45-6
Sodium sulfate	7757-82-6

7 MEDICINE SCHEDULE (POISONS STANDARD)
Australia: S3 – Pharmacist Only Medicine

8 SPONSOR
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9 DATE OF FIRST APPROVAL
24 June 2021

10 DATE OF REVISION OF THE TEXT
6 January 2025

Summary table of changes

Section Changed	Summary of new information
4.2	Added split-dosing details
4.2	Amount of liquid to be infused corrected in Naso-gastric intubation.
4.3	Bowel inflammation added as contraindication
4.8	Adverse effects section updated to include headache, dizziness, and rare adverse reactions. Experience of sleep disturbance and insomnia and advice from healthcare professional has been added.
All	Minor editorial changes

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.