

AUSTRALIAN PRODUCT INFORMATION – GLYCOPREP ORANGE® (MACROGOL 3350, POTASSIUM CHLORIDE, SODIUM CHLORIDE, SODIUM SULFATE)

1 NAME OF MEDICINE

Macrogol 3350
Potassium chloride
Sodium chloride
Sodium sulfate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 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 70 g sachet is 2.86 g.

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

3 PHARMACEUTICAL FORM

Powder for solution. For oral use.

GLYCOPREP ORANGE® contains 70 g of white to creamy yellow powder which when dissolved in water produces 1 litre of cloudy solution with a mild citric acid taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

GLYCOPREP 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.

4.2 Dose and method of administration

A course of treatment consists of three litres of GLYCOPREP ORANGE®. A total of 210 g (3 x 70 g sachets) of GLYCOPREP ORANGE® will be required for the procedure and need to be prepared and used as required.

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

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 day 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.

Table 1- Instruction for use for single day regimen and split dose regimen

Single Day Regimen	Split-dose Regimen (evening before and day of the procedure)
<p><u>Day Before Procedure</u></p> <p>3 litres (3 x 70 g sachets) GLYCOPREP ORANGE® (taken at 7 pm) One (1) to two (2) 250 mL glasses of the prepared solution should be orally ingested every 15-20 minutes. The recommended dosing intake rate is from 1.2 litres to 1.8 litres per hour. If nausea is experienced, the rate of intake of GLYCOPREP ORANGE® solution should be reduced.</p> <p>No food should be taken for 2 hours prior to commencing dosing. Only clear fluids are allowed during the interval between commencing the GLYCOPREP ORANGE® preparation and 2 hours prior to the procedure.</p>	<p><u>Day Before Procedure</u></p> <p><u>First Dose:</u> 2 litres GLYCOPREP ORANGE® (taken at 7 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</p>
	<p><u>Day Of Procedure</u></p> <p>Second Dose: 1 litre GLYCOPREP ORANGE® (taken approx. 2 to 5 hours prior to procedure) 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.</p>

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

For nasogastric intubation

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

4.3 Contraindications

GLYCOPREP ORANGE® should not be used by patients with hypersensitivity to any of the ingredients, gastrointestinal obstruction, gastric retention, bowel perforation (frank or suspected), toxic colitis, toxic megacolon, ileus, severe dehydration or whose body weight is less than 20 kg.

4.4 Special warnings and precautions for use

Identified precautions

GLYCOPREP ORANGE® should be administered with caution in patients with severe ulcerative colitis, those with a stoma, pre-existing electrolyte disturbances, dehydration, undiagnosed abdominal pain, congestive heart failure or diabetics.

GLYCOPREP ORANGE® should be administered with caution and under careful observation to patients with impaired gag reflex, who are semi-unconscious, who are prone to regurgitation or aspiration, and particularly those with nasogastric intubation. If administered via nasogastric intubation, proper hydration should be ensured.

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

GLYCOPREP 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.

GLYCOPREP 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 renal function may need to 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

The safety and efficacy in children have not been established.

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 GLYCOPREP ORANGE®, to one hour after completing its administration may be flushed from the gastrointestinal tract and not absorbed.

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

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

GLYCOPREP 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.

GLYCOPREP 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 GLYCOPREP ORANGE® can cause fetal harm or affect reproductive capacity. GLYCOPREP ORANGE® should only be used if the benefits clearly outweigh the risks.

Use in lactation

No lactation studies have been conducted.

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, dehydration, 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.

Hypersensitivity and anaphylactic reactions are rare adverse reactions.

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

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 overdose, dehydration may occur. 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

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

Clinical trials

No data available.

5.2 Pharmacokinetic properties

Absorption

Macrogol 3350 is not significantly absorbed.

Distribution

No data available.

Metabolism

No data available.

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

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 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 70 g of a white to creamy yellow powder with an odour characteristic of oranges packed in an outer carton.

Pack Sizes*:

3 x 70 g sachets

12 x 70 g sachets

The Australian registration number is AUST R 370152.

*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

Macrogol 3350

$\text{H}(\text{OCH}_2\text{CH}_2)_n\text{OH}$ (where 'n' equals 45 to 70).

Molecular weight: varies

Potassium chloride

KCl

Molecular weight: 74.6 g/mol

Sodium chloride

NaCl

Molecular weight: 58.44 g/mol

Sodium sulfate

Na_2SO_4

Molecular weight: 142.0 g/mol

CAS number

Active Substance

Macrogol 3350

Potassium chloride

Sodium chloride

Sodium sulfate

CAS number

9002-90-8

7447-40-7

7647-14-5

7757-82-6

7 MEDICINE SCHEDULE (POISONS STANDARD)

Australia: S3 – Pharmacist Only Medicine

8 SPONSOR

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Mount Kuring-gai, NSW 2080
Australia

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.
4.8	Adverse effects section updated to include headache, dizziness, dehydration, 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.