AUSTRALIAN PRODUCT INFORMATION – GLYCOPREP-O KIT™ (MACROGOL 3350, POTASSIUM CHLORIDE, SODIUM CHLORIDE, SODIUM SULFATE, BISACODYL, MAGNESIUM CARBONATE HYDRATE, CITRIC ACID)

1 NAME OF MEDICINE

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

Magnesium citrate sachet
Magnesium carbonate hydrate
Citric acid

Bisacodyl 5 mg Tablets
Bisacodyl

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

GLYCOPREP-O KIT™ is a medicine kit containing:

- Three (3) yellow Bisacodyl 5 mg Tablets. Each Bisacodyl tablet contains bisacodyl 5 mg, as the active ingredient.
- One (1) Magnesium Citrate 21.5 g sachet. Each sachet contains magnesium carbonate hydrate 7.2 g and citric acid 14.3 g, as the active ingredients.
- Three (3) 70 g sachets of GLYCOPREP ORANGE®. 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

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

Magnesium citrate sachet: Powder for solution. For oral use.
Magnesium citrate is a white crystalline powder which when dissolved in water produces 250 mL of cloudy solution with a mild citric taste.

Bisacodyl 5 mg Tablets: Enteric-coated tablets. For oral use.
Bisacodyl is a round yellow enteric-coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

GLYCOPREP-O KIT™ 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 examinations), prior to intravenous pyelograms (IVP) or colorectal surgery.

4.2 Dose and method of administration

The Bisacodyl 5 mg Tablets should be taken whole and not crushed or chewed.

Seven days prior to the procedure
It is recommended to advise the patient to stop taking all iron containing medication 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 GLYCOPREP-O KIT™, 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.

Magnesium Citrate sachet:
Dissolve the contents of the 21.5 g Magnesium Citrate sachet, by slowly adding the powder in approximately 250 mL of warm water (not boiling) using a suitable food grade container. The solution may appear cloudy, 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.

GLYCOPREP ORANGE® sachet:
The course of treatment requires three litres of GLYCOPREP ORANGE® reconstituted solution, i.e. 3 x 70 g of GLYCOPREP ORANGE® sachets.

Dissolve separately the contents of each 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 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 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.

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.

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)**
Day Before Procedure *First Dose: Bisacodyl Tablets (taken at 2 pm)* Take the three (3) Bisacodyl Tablets with one full glass (approx. 250 mL) of water. This should be followed by adequate glasses of water or Recommended Clear Fluids (see **APPENDIX I**), at least one (1) glass every hour after that.	*Day Before Procedure* *First Dose: Bisacodyl Tablets (taken at 2 pm)* Take the three (3) Bisacodyl Tablets with one full glass (approx. 250 mL) of water. This should be followed by adequate glasses of water or Recommended Clear Fluids (see **APPENDIX I**),, at least one (1) glass every hour after that.
Second Dose: Magnesium Citrate sachet (taken at 5 pm) The solution should be ingested slowly but completely. This should be followed by adequate glasses of water or Recommended Clear Fluids (see **APPENDIX I**), at least one (1) glass every hour after that.	*Second Dose: Magnesium Citrate sachet (taken at 5 pm)* The solution should be ingested slowly but completely. This should be followed by adequate glasses of water or Recommended Clear Fluids (see **APPENDIX I**) , at least one (1) glass every hour after that
Third Dose: GLYCOPREP ORANGE® sachet (taken at 7 pm) The full 3 litres of the reconstituted GLYCOPREP ORANGE® solution should be ingested in order to complete the treatment course. One (1) to two (2) glasses of the prepared solution should be orally ingested every 15-20 minutes until completed. 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: 2 litres GLYCOPREP ORANGE® (taken at 7 pm)* Only take 2 litres of GLYCOPREP ORANGE® at this time. Ingest one (1) to two (2) glasses of the prepared solution orally every 15-20 minutes until completed. 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. Prepare the final one (1) litre solution of GLYCOPREP ORANGE® and refrigerate if desired.
	Day Of Procedure *Fourth Dose: 1 litre GLYCOPREP ORANGE® (taken approx. 2 to 5 hours prior to procedure)* Prior to the procedure ingest the final one (1) litre of GLYCOPREP ORANGE® solution in the same way as before. It is recommenced that patients cease taking any fluids two (2) hours prior to the procedure. 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
GLYCOPREP ORANGE® 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-O KIT™ should not be used by patients with clinically significant renal impairment, acute abdominal conditions such as appendicitis, gastrointestinal obstruction, gastric retention, bowel perforation (frank or suspected), toxic megacolon, toxic colitis, ileus, body weight less than 20 kg, severe dehydration or hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use
Identified precautions
GLYCOPREP-O KIT™ should be administered with caution in debilitated patients or patients with inflammatory bowel disease (IBD), those with a stoma, severe ulcerative colitis, heart conditions, pre-existing electrolyte disturbances, congestive heart failure or diabetes.

GLYCOPREP-O KIT™ should be administered with caution and under careful observation to patients with an impaired gag reflex, who are semi-conscious, who are prone to regurgitation or aspiration.

GLYCOPREP-O KIT™ is likely to cause transient hypovolaemia, hence adequate fluid intake or replacement should be ensured (see Section 4.2 Dose and method of administration).

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

GLYCOPREP-O KIT™ 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-O KIT™ may cause bloating, distension or abdominal pain. 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 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
The safety and efficacy in children has 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 the commencing GLYCOPREP-O KIT™, 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-O KIT™ 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-O KIT™ 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-O KIT™ 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-O KIT™ can cause fetal harm or affect reproductive capacity. GLYCOPREP-O KIT™ 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, 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 rhinorrhea attributed to macrogol which is contained in GLYCOPREP-O KIT™.

Prolonged use of GLYCOPREP-O KIT™ may result in dehydration and electrolyte disturbances in "at risk" groups (see Section 4.3 and 4.4).

Hypersensitivity reactions including angioedema and anaphylactoid reactions have been reported rarely.

Healthcare professionals are asked to inform patients that sleep disturbance may be experienced with both a single-dayregimen 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 an 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

Bisacodyl

Bisacodyl is a stimulant laxative acting mainly in the large intestine. It acts locally in the gastrointestinal tract, stimulating the sensory nerve endings in the colonic mucosa to produce parasympathetic reflexes resulting in increased peristaltic contractions of the colon. Local axonic reflexes as well as segmental reflexes are initiated in the region of contact and contribute to the widespread peristaltic activity producing evacuation. For this reason, bisacodyl may be used in patients with ganglionic blockage or spinal cord damage (e.g. paraplegia, poliomyelitis).

When taken on an empty stomach, bisacodyl tablets will have an effect within six (6) to eight (8) hours. When taken with food the effect of the tablets is exhibited within ten (10) to twelve (12) hours.

Magnesium Citrate

Magnesium citrate is an osmotic laxative. and acts by increasing the intestinal osmotic pressure thereby promoting retention of fluid within the bowel. Magnesium citrate draws water from the tissues into the small intestine. This stimulates the normal forward movement of the intestines (peristalsis), resulting in bowel movement within three (3) to six (6) hours.

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 loss of electrolyte or water.

Clinical trials

No data available.

5.2 Pharmacokinetic properties

Absorption

Bisacodyl: Absorption from the gastrointestinal tract is minimal with enteric coated tablets or suppositories.

Magnesium citrate: Magnesium citrate is not significantly absorbed.

GLYCOPREP ORANGE®: Macrogol 3350 is not significantly absorbed.

Distribution
No data available.

Metabolism
Bisacodyl: Following oral administration, bisacodyl is converted to the active desacetyl metabolite bis(p-hydroxyphenyl)pyridyl-2-methane by intestinal and bacterial enzymes.

Excretion
Bisacodyl: The small amount absorbed is excreted in the urine as a glucuronide. Bisacodyl is mainly excreted in the faeces.

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

GLYCOPREP ORANGE® sachet
Ascorbic Acid
Silicon Dioxide
Natural Orange Flavour FACB076 (Proprietary Ingredient 106181)
Sweetesse Stevia™ 97 (Natural Sweetener/Steviol glycosides Ingredient 107000)

Bisacodyl 5 mg Tablets

Excipients	Quantity per Tablet (mg)
Antifoam AF Emulsion Q7-2587 (PI 1515)	0.011
Calcium carbonate	3.726
Colloidal anhydrous silica	0.1
Gelatin	0.766
Lactose monohydrate	26.3
Macrogol 6000	0.616
Magnesium stearate	0.4
Maize starch	1.5
Methacrylic acid copolymer	4.513
Microcrystalline cellulose	15.0
Povidone	1.675
Purified talc	10.976
Quinoline yellow	0.02
Sodium starch glycollate type A	4.0
Sucrose	35.396

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 below 25°C. Store in a dry place. 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
GLYCOPREP-O KIT™ is presented as a medicine kit packed in an outer carton containing:

- one (1) blister pack of three (3) round yellow enteric-coated Bisacodyl 5 mg Tablets
- one (1) Magnesium Citrate 21.5 g sachet containing 21.5 g of a white crystalline powder
- three (3) GLYCOPREP ORANGE® 70 g sachet containing 70 g of a white to creamy yellow powder with an odour characteristic of oranges

The Australian registration number is AUST R 370154.

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

Potassium chloride
KCl
Molecular weight: 74.6 g/mol

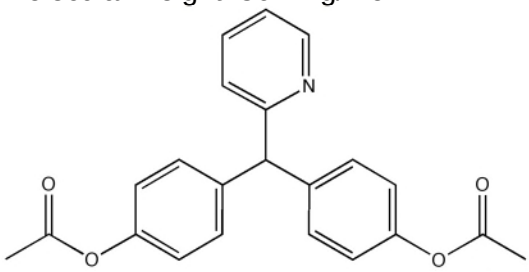
Sodium chloride
NaCl
Molecular weight: 58.44 g/mol

Sodium sulfate
Na_2SO_4
Molecular weight: 142.0 g/mol

Magnesium carbonate hydrate
$MgCO_3$
Molecular weight: 84.31 g/mol

Citric acid
$C_6H_8O_7$
Molecular weight: 192.1 g/mol

Bisacodyl
$C_{22}H_{19}NO_4$
Molecular weight: 361.4 g/mol



CAS number

Active Substance	**CAS number**
Macrogol 3350	9002-90-8
Potassium chloride	7447-40-7
Sodium chloride	7647-14-5
Sodium sulfate	7757-82-6
Bisacodyl	603-50-9
Magnesium carbonate hydrate	546-93-0
Citric acid	77-92-9

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