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

First Dose: Bisacodyl Tablets (taken at 11:00 AM)
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 5:00 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 8:00 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.

**For nasogastric intubation**
GLYCOPREP ORANGE® 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
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)
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.

**Reporting suspected adverse effects**

**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

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<td>Colloidal anhydrous silica</td>
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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(OCH₂CH₂)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
Na₂SO₄
Molecular weight: 142.0 g/mol

Magnesium carbonate hydrate
MgCO₃
Molecular weight: 84.31 g/mol

Citric acid
C₆H₈O₇
Molecular weight: 192.1 g/mol
Bisacodyl  
C\textsubscript{22}H\textsubscript{19}NO\textsubscript{4}  
Molecular weight: 361.4 g/mol

CAS number

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<td>Sodium sulfate</td>
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<td>Magnesium carbonate hydrate</td>
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<td>Citric acid</td>
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7 MEDICINE SCHEDULE (POISONS STANDARD)  
Australia: S3 – Pharmacist Only Medicine  
New Zealand: Restricted Medicine

8 SPONSOR  
Fresenius Kabi Australia Pty Ltd  
Level 2, 2 Woodland Way  
Mount Kuring-gai, NSW 2080  
Australia

9 DATE OF FIRST APPROVAL  
24 June 2021.

10 DATE OF REVISION OF THE TEXT  
Not applicable.

Summary table of changes

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<th>Summary of new information</th>
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<td>All</td>
<td>Reformat PI as per new TGA PI form</td>
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</table>
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.