NEW ZEALAND DATA SHEET

1 PRODUCT NAME
GLYCOPREP ORANGE® powder 70 g sachet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
The active ingredients are:

- macrogol 3350 has a chemical formula of $HOCH_2[CH_2OCH_2]m.\ CH_2OH$ (where 'm' equals 45 to 70).
- sodium chloride has a chemical formula of NaCl, a MW of 58.44 and a CAS No. 7647-14-5.
- potassium chloride has a chemical formula of KCl, a MW of 74.6 and a CAS No. 7447-40-7.
- sodium sulfate has a chemical formula of Na_2SO_4, a MW of 142.0 and a CAS No. 7757-82-6.

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 therefore three (3) lots of 70 g sachets will 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 temperature (ambient) 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)**
Day Before Procedure *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. 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.	*Day Before Procedure* *First Dose: 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.
	Day Of Procedure *Second Dose: 1 litre GLYCOPREP ORANGE® (taken approx. 2-5 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.

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.

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.

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 aged below 18 years 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 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 data available.

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 data available.

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 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 authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

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 advice on the management of overdose, please contact the National Poisons Centre on 0800 POISON (0800 764 766).

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Alimentary Tract and Metabolism, Drugs for Constipation, Osmotically acting laxatives

ATC code: A06AD65

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
Approved Shelf Life as packaged for sale
2 years

6.4 Special precautions for storage
Store at or 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 (aluminium foil) 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

*Not all pack sizes may be marketed.

6.6 Special precautions for disposal
No special requirements for disposal. Any unused medicine or waste material should be disposed of in accordance with local requirements.

7 MEDICINE SCHEDULE (POISONS STANDARD)
Restricted Medicine

8 SPONSOR
Fresenius Kabi New Zealand Ltd,
c/o GNZCC,
HSBC Tower, Level 14, 188 Quay Street,
Auckland 1010,
New Zealand.

9 DATE OF FIRST APPROVAL

22 July 2021

10 DATE OF REVISION OF THE TEXT

9 April 2026

Summary table of changes

Section	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.