1 PRODUCT NAME

Glycoprep® powder 200g 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_2SO4, a MW of 142.0 and a CAS No. 7757-82-6.
- sodium bicarbonate has a chemical formula of $NaHCO_3$, a MW of 84.0 and a CAS No. 144-55-8.

Each 200 g sachet contains macrogol 3350 (polyethylene glycol) 856.92 mg/g, sodium chloride 22 mg/g, potassium chloride 11.25 mg/g, sodium sulfate (anhydrous) 84.51 mg/g and sodium bicarbonate 25.32 mg/g.

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

3 PHARMACEUTICAL FORM

Powder, oral.

Glycoprep® powder for solution is a white crystalline powder packed in a sachet containing 200 g. When dissolved in water it produces a solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Glycoprep® is indicated for bowel emptying and cleansing by means of total gastrointestinal tract perfusion in preparation for gastrointestinal procedure (such as colonoscopy, barium enema x-ray examination), prior to intravenous pyelograms (IVP) or colonic surgery.

4.2 Dose and method of administration

For Oral Use.

Glycoprep® is usually taken the day before the procedure. This may be varied if considered appropriate by the doctor.
Guidance for clinicians/doctors: Glycoprep® can be taken in the evening prior to the procedure (if a morning procedure) or on the morning of the procedure (if an afternoon procedure).

<u>On the day before the procedure</u>
Patients should fast until after the procedure. Patients should only drink recommended clear sugar free fluids. During the day, patients should drink at least one glass (approx. 250 mL) of fluids each hour to maintain hydration. Solid foods or milk products should not be taken.

** Recommended clear sugar free fluids: water, soups (e.g. strained chicken noodle soup), broth/bouillon, fruit juices (apple, pear, white grape), black tea or coffee (no milk), electrolyte

replacing drinks, cordials (lemon / lime), plain jelly (no red or purple colourings). Barley sugar may be sucked if required.
The patient should not drink carbonated or alcoholic beverages.

Glycoprep® produces a watery diarrhoea which empties and cleanses the bowel before procedure or surgery. It should be prepared and taken according to the directions. The onset of diarrhoea is about 1 hour and should be complete in 4 hours.

Preparation of Solution
The contents of the sachet should be dissolved in 3 litres of water using a suitable food grade container. The solution may be chilled if desired.

Usual Dosage
Glycoprep® is usually taken orally but may be given by nasogastric tube to patients who are unwilling or unable to drink it.

The patient should fast for 2 hours before starting to take Glycoprep® and only take recommended clear sugar free fluids until after the procedure.

One or two 250 mL glasses of the prepared solution should be taken 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® solution should be reduced. Lavage is complete when the faecal discharge is clear.

No food should be taken for 2 hours prior to commencing dosing. Only recommended clear sugar free fluids are allowed during the interval between commencing the Glycoprep® preparation and 6 hours prior to the procedure.

For Nasogastric Intubation
Infuse the prepared solution at a rate of 20 to 30 mL/minute.
It is important that the patient follow the recommended dosing schedule.

Note: Individual responses to laxatives may vary. The preparation may cause multiple bowel movements and usually induces frequent loose bowel movements within 2 to 3 hours of taking the first dose. Patients should be advised to remain within easy reach of toilet facilities and not plan to go out.

4.3 Contraindications
Glycoprep® 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
Use with caution in patients with severe ulcerative colitis, those with a stoma, impaired renal function, pre-existing electrolyte disturbances, dehydration, undiagnosed stomach pain, congestive heart failure, diabetics and in the elderly.

Patients with impaired gag reflex; who are semi-conscious; who are prone to regurgitation or aspiration; and particularly those with nasogastric intubation; should be carefully observed during the administration of Glycoprep®.

Patients with congestive heart failure; pre-existing electrolyte disturbances; kidney disease or impaired renal function; using calcium channel blockers; diuretics or other medications which may affect electrolyte levels may need to be monitored.

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

Glycoprep® 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 abate.

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 taken within one hour of the commencement of the administration of Glycoprep®, to one hour after completing its administration, may be flushed from the gastrointestinal tract and not absorbed.

Sustained release preparations, or medicines with a short half-life or a narrow therapeutic window may need to be taken more than one hour before or after administration of Glycoprep®.

The low-dose contraceptive pill will not work when taken with Glycoprep® 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 in conjunction due to the macrogol content of Glycoprep®.

4.6 Fertility, pregnancy and lactation

Effects on fertility
No data available.

Use in pregnancy (Category - none)
It is not known whether Glycoprep® can cause foetal harm or affect reproductive capacity. Glycoprep® should only be used if clearly needed.

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

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.

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 overdosage, dehydration may ensue. 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 is not significantly absorbed and acts as an osmotic agent to induce a watery diarrhoea usually within 1 hour after commencing treatment and which normally removes the bowel contents by about 4 hours after commencing treatment.

The water and included electrolytes are iso-osmotic with normal intestinal contents and help to reduce or prevent electrolytes or water loss.

Clinical trials

No data available.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

Genotoxicity

No studies have been performed.

Carcinogenicity

No studies have been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Refer to section 4.2 Dose and method of administration.

6.3 Shelf life

Approved Shelf Life as packaged for sale

3 years

6.4 Special precautions for storage

Store in a cool dry place below 30°C.

6.5 Nature and contents of container

Sachet (aluminium foil) containing 200 g of dry powder

Pack sizes

Sachet 1 x 200 g

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

Restricted Medicine

8 SPONSOR

Fresenius Kabi New Zealand Limited
60 Pavilion Drive
Airport Oaks, Auckland 2022
New Zealand
Freecall: 0800 144 892

9 DATE OF FIRST APPROVAL

10 October 1991

10 DATE OF REVISION OF THE TEXT

01 April 2019

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	Reformat PI as per new Medsafe template