

1 PRODUCT NAME

GLYCOPREP-O KIT (Combination pack)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

GLYCOPREP-O KIT is a medicine kit containing:

- Three (3) yellow Bisacodyl BP 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.

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

Magnesium carbonate hydrate

MgCO_3

Molecular weight: 84.31 g/mol

Citric acid

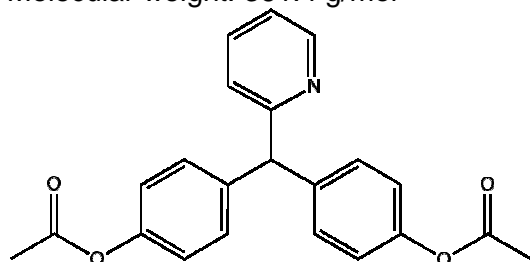
$\text{C}_6\text{H}_8\text{O}_7$

Molecular weight: 192.1 g/mol

Bisacodyl

$\text{C}_{22}\text{H}_{19}\text{NO}_4$

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 |

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 BP 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 BP 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

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 the contents of each 70 g sachet in one (1) litre of water at ambient temperature separately 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 BP 5 mg Tablets (taken at 11:00 AM)

Take the three (3) Bisacodyl BP 5 mg Tablets with one full glass (approx. 250 mL) of water. This should be followed by adequate glasses of water or Recommended Clear Fluids, 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, at least one (1) glass every hour after that.

Third Dose: GLYCOPREP ORANGE® sachets (commencing 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 solutions 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 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 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 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

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 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, 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

Bisacodyl BP 5 mg Tablets

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 BP 5 mg Tablets: 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 BP 5 mg Tablets: Following oral administration, bisacodyl is converted to the active desacetyl metabolite bis(p-hydroxyphenyl)pyridyl-2-methane by intestinal and bacterial enzymes.

Excretion

Bisacodyl BP 5 mg Tablets: 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 BP 5 mg Tablets

| <u>Excipients</u> | <u>Quantity per Tablet (mg)</u> |
|--|---------------------------------|
| 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

Approved Shelf Life as packaged for sale

2 years.

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 BP 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

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

9 DATE OF FIRST APPROVAL

20 January 2022

10 DATE OF REVISION OF THE TEXT

21 January 2022

Summary table of changes

| Section Changed | Summary of new information |
|------------------------|-----------------------------------|
| All | New Data Sheet |

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.