

PRODUCT INFORMATION

WARNING

Caution should be exercised with “at risk” patients and electrolyte depletion may occur
- **see Contraindications and Precautions**
PHENYLKETONURICS ARE WARNED THAT THIS PRODUCT CONTAINS PHENYLALANINE

NAME OF THE MEDICINE

GLYCOPREP-C KIT

Gastrointestinal Lavage Preparation

Glycoprep-C Sachet Powder for Solution

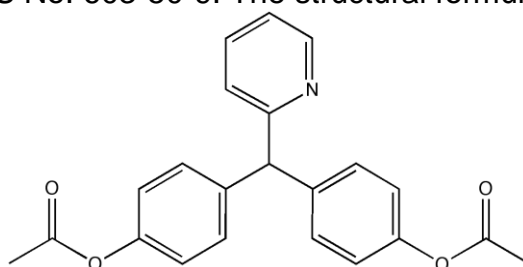
Active ingredients

- Macrogol 3350 has a chemical formula of $\text{HOCH}_2 [\text{CH}_2\text{OCH}_2]_m \text{CH}_2\text{OH}$ (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 anhydrous has a chemical formula of Na_2SO_4 , a MW of 142.0 and a CAS No. 7757-82-6

Bisacodyl

A white or almost white crystalline powder.

Bisacodyl is practically insoluble in water, soluble in acetone, sparingly soluble in ethanol (96 per cent). It dissolves in dilute mineral acids. The chemical name is 4,4'-(Pyridin-2-ylmethylene) diphenyl diacetate. It has a chemical formula of $\text{C}_{22}\text{H}_{19}\text{NO}_4$, a MW of 361.4 and CAS No. 603-50-9. The structural formula is:



Magnesium Citrate Sachet Powder for Solution

A white crystalline powder.

Magnesium citrate has a chemical formula of $\text{C}_6\text{H}_6\text{MgO}_7$ and a MW of 214.41. Magnesium citrate is made *in situ* from magnesium carbonate - heavy and citric acid anhydrous when dissolved in water:

- Magnesium Carbonate is a white powder practically insoluble in water. It dissolves in dilute acids with strong effervescence. Molecular formula is MgCO_3 with a MW of 84.31 and CAS No. 546-93-0.
- Citric Acid Anhydrous is a white crystalline powder, colourless crystals or granules, very soluble in water and freely soluble in alcohol. It has a chemical formula of $\text{C}_6\text{H}_8\text{O}_7$, a MW of 192.1 and CAS No. 77-92-9.

DESCRIPTION

Glycoprep-C Kit is a composite pack containing:

- Three yellow bisacodyl 5mg tablets. The excipients are calcium carbonate, silica-colloidal anhydrous, gelatin, lactose, macrogol 6000, magnesium stearate, methacrylic acid copolymer, cellulose microcrystalline, povidone, talc- purified, quinoline yellow, sodium starch glycolate A, starch, sucrose and antifoam AF emulsion QF 2587 (PI 1515).
- One 21.5g sachet of effervescent white crystalline powder composed of magnesium carbonate - heavy 7.5g and citric acid - anhydrous 14g, which together form a magnesium citrate solution when dissolved in water.
- One 210g sachet of Glycoprep-C, a white crystalline powder. Each sachet contains macrogol 3350 (polyethylene glycol) 158.7g, sodium chloride 7.8g, potassium chloride 2.2g and sodium sulfate anhydrous 16.9g. The excipients are ascorbic acid, citric acid anhydrous, aspartame and lemon flavour QL58817.

PHARMACOLOGY

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).

Pharmacokinetics

Following oral administration, bisacodyl is converted to the active desacetyl metabolite bis(p-hydroxyphenyl)pyridyl-2-methane by intestinal and bacterial enzymes. Absorption from the gastrointestinal tract is minimal with enteric coated tablets or suppositories. The small amount absorbed is excreted in the urine as a glucuronide. Bisacodyl is mainly excreted in the faeces. When taken on an empty stomach, bisacodyl tablets will have an effect within 6 to 8 hours. When taken with food the effect of the tablets is exhibited within 10 to 12 hours.

Magnesium Citrate

Magnesium citrate is an osmotic laxative. Magnesium Citrate is not significantly absorbed 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 3 to 6 hours.

Glycoprep-C

A mixture of macrogol 3350 with electrolytes is used as an osmotic laxative to empty the bowel. Macrogol 3350 is not significantly absorbed and acts as an osmotic agent to induce 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 electrolyte or water loss.

INDICATIONS

Glycoprep-C Kit is indicated for bowel cleansing in conjunction with intravenous pyelograms (IVP), abdominal x-ray examinations, surgery and colonoscopy.

CONTRAINDICATIONS

Glycoprep-C Kit should not be used by patients with:

- clinically significant renal impairment
- severe dehydration
- acute abdominal conditions such as appendicitis, gastrointestinal obstruction, gastric retention, bowel perforation (frank or suspected), toxic megacolon, paralytic ileus, toxic colitis
- body weight is less than 20kg
- hypersensitivity to any of the ingredients
- Phenylketonuria – Glycoprep-C contains aspartame

PRECAUTIONS

Use with caution in patients with heart conditions, severe ulcerative colitis, inflammatory bowel disease (IBD), marked bloody diarrhoea, impaired renal function, pre-existing electrolyte disturbances, congestive heart failure, diabetes, those with a stoma and debilitated or elderly patients.

Patients with impaired gag reflex, who are semi-conscious, are prone to regurgitation or aspiration should be carefully observed during the administration of Glycoprep-C Kit.

Glycoprep-C Kit is likely to cause transient hypovolaemia, hence adequate fluid intake or replacement should be ensured (see *Dosage and Administration*).

Patients with congestive heart failure should be monitored; as should patients using calcium channel blockers, diuretics or other medications that may affect electrolyte levels.

Patients with kidney disease or impaired renal function should also be monitored, as should those with pre-existing electrolyte disturbances.

There have been reports of skin reactions and rhinorrhea attributed to macrogol which is contained in Glycoprep-C Kit.

Glycoprep-C Kit may cause bloating, distension or abdominal pain. If this develops, the rate of administration should be slowed or temporarily ceased until the symptoms abate.

Nephrocalcinosis and renal impairment may occur following the use of this medicine.

Phenylketonurics are warned that this product contains phenylalanine.

Effects on Fertility

No fertility studies have been conducted.

Use in Pregnancy

It is not known whether Glycoprep-C Kit can cause foetal harm or affect reproductive capacity. Glycoprep-C Kit should only be used if the benefits clearly outweigh the risks.

Use in Lactation

No lactation studies have been conducted.

Paediatric Use

The safety and efficacy of Glycoprep-C Kit in children has not been established.

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.

Genotoxicity

No genotoxic studies have been conducted.

Carcinogenicity

No carcinogenic studies have been conducted.

INTERACTIONS WITH OTHER MEDICINES

Oral medication taken within one hour of the commencement of the administration of Glycoprep-C Kit, 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-C.

The low dose contraceptive pill will not work when taken with Glycoprep-C 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-C

Seven days prior to procedure stop taking all iron containing medication. Continue with other regular medications.

Glycoprep-C 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-C 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.

ADVERSE EFFECTS

Nausea, abdominal fullness and bloating are the most common adverse reactions. Abdominal cramps, vomiting and anal irritation occur less frequently.

These adverse effects are usually transient and subside rapidly.

Use can result in diarrhoea with excessive loss of water and electrolytes particularly in at risk patients, and/or where fluid intake is inadequate. Hypersensitivity reactions including angioedema and anaphylactoid reactions have been reported rarely.

DOSAGE AND ADMINISTRATION

Information for Patients

Glycoprep-C Kit produces watery stools or bowel motions some 2 to 3 hours after the first administration. This action cleanses the bowel before the procedure. Patients should be warned that Glycoprep-C Kit will cause frequent loose bowel motions and there may also be a number of bowel actions during the night. Patients should ensure bathroom facilities are within easy access.

Glycoprep-C Kit should be prepared and taken according to the directions on the carton or as per the below dosage instruction.

The bisacodyl tablets should be taken whole and not crushed or chewed.

Glycoprep-C Kit contains aspartame. Patients suffering from phenylketonuria need to be advised accordingly.

It is important the patient follows the recommended dosing schedule and ensures an adequate intake of fluids.

Usual Dosage (Adult). Not recommended in children.

Glycoprep-C Kit should be prepared and taken according to the directions unless otherwise directed by your doctor.

Preparation for the procedure begins seven (7) days before the procedure.

Directions

Recommended Clear Fluids

Recommended clear fluids which may be consumed whilst taking Glycoprep-C Kit include water, strained fruit juice without the pulp (apple, white grape, pineapple, pear), clear broth, tea or coffee without milk or cream, clear sugar-free cordials such as lemon or lime (no red or purple colourings), plain sugar-free jelly and clear ice blocks. Do not drink carbonated beverages. Do not drink alcoholic beverages.

7 days prior to procedure

Stop taking all iron containing medication. Continue with other regular medications.

2 days prior to procedure

1. Stop eating brown bread, red meat, cereals, vegetables and fruit. Do not have anything with seeds in it. Do not have any hard cheese.
2. You may eat eggs, steamed white fish, boiled chicken, cottage cheese, low fat plain yoghurt, white bread, white pasta, white rice, clear jelly, skim milk and well cooked pumpkin or peeled potato.

1 day prior to procedure

1. NO FOOD or MILK products allowed.
2. Drink only recommended clear fluids.
3. During the day drink at least one glass (approx. 250mL) of clear fluids each hour to maintain hydration. Continue drinking recommended clear fluids until bedtime.
4. Prepare the Magnesium Citrate solution by dissolving the contents of the sachet in one glassful of hot water (approx. 250mL) and refrigerate prior to use.
5. Prepare the Glycoprep-C solution by dissolving the contents of the 210g sachet in three (3) litres of water and refrigerate prior to use.
6. At approximately 2pm take the three (3) Bisacodyl tablets with one full glass (approx. 250mL) of water.
7. At approximately 5pm drink the Magnesium Citrate solution which was previously prepared.
8. At approximately 7pm commence drinking the Glycoprep-C solution which was previously prepared. Drink approximately 1 to 2 glasses every 15 to 20 minutes until completed. Drink the mixture slowly but completely. If you become nauseated, reduce the rate of intake.
9. Continue drinking adequate glasses of recommended clear fluids until bedtime.

On the day of procedure

1. NO FOOD to be taken.
2. NO DRINK should be taken for six (6) hours prior to the procedure.

OVERDOSAGE

Overdose is unlikely as the carton contains only enough medication for one treatment. However in the event of an 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 information on the management of overdose, contact the Poison Information Centre on 13 11 26 (Australia).

PRESENTATION AND STORAGE CONDITIONS

Glycoprep-C Kit is a carton containing:

- one blister pack of three yellow bisacodyl 5mg tablets
- one sachet containing 21.5g of a dry white effervescent crystalline powder labelled Magnesium Citrate

- one sachet of Glycoprep-C containing 210g of white crystalline powder

Store in a dry place. Store below 25°C.

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NAME AND ADDRESS OF THE SPONSOR

Fresenius Kabi Australia Pty Limited
Level 2, 2 Woodland Way
Mount Kuring-gai
NSW 2080
Tel: 1300 732 001

POISON SCHEDULE OF THE MEDICINE

S3 – Pharmacist Only Medicine

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS: 10 October 1991

DATE OF MOST RECENT AMENDMENT: 25 February 2016