

## PRODUCT INFORMATION

### GLYCOPREP-C

Electrolyte Gastrointestinal Lavage Preparation

#### DESCRIPTION

Glycoprep-C powder for solution is a white crystalline powder packed in a sachet containing 70g or 210g. When dissolved in water it produces a solution.

#### CHEMICAL CHARACTERISTICS

For the active ingredients these are -

- . 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  $\text{NaCl}$ , a MW of 58.44 and a CAS No. 7647-14-5.
- . potassium chloride has a chemical formula of  $\text{KCl}$ , a MW of 74.6 and a CAS No. 7447-40-7.
- . sodium sulfate has a chemical formula of  $\text{Na}_2\text{SO}_4$ , a MW of 142.0 and a CAS No. 7681-38-1.

Each 70g or 210g sachet contains Macrogol 3350 (polyethylene glycol) 755.69mg/g, Sodium sulfate (anhydrous) 80.62mg/g, sodium chloride 37.33mg/g, Potassium chloride 10.55mg/g, Citric Acid 12.77mg/g, Ascorbic acid 85.16mg/g, Aspartame 5.11mg/g and Lemon flavour 12.77mg/g.

#### PHARMACOLOGY

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.

#### INDICATIONS

Glycoprep-C 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 colonic surgery.

#### CONTRAINDICATIONS

Glycoprep-C should not be used by patients with gastrointestinal obstruction, gastric retention, bowel perforation (frank or suspected), toxic colitis, toxic megacolon, ileus, those with a stoma or whose body weight is less than 20kg.

## **PRECAUTIONS**

Use with caution in patients with severe ulcerative colitis, impaired renal function, pre-existing electrolyte disturbances, congestive heart failure, diabetics and in the elderly.

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

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 rhinorrhoea attributed to macrogol which is contained in Glycoprep-C.

Glycoprep-C 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.

### **Carcinogenesis, Mutagenicity, Impairment of Fertility.**

No carcinogenic or reproductive studies have been performed.

### **Drug Interactions**

Oral medication taken within one hour of the commencement of the administration of Glycoprep-C may be flushed from the gastrointestinal tract and not absorbed.

Because of the macrogol content of Glycoprep-C there is a possible reduction in the effect of bacitracin and benzylpenicillin when used in conjunction.

### **Pregnancy (Category - none)**

It is not known whether Glycoprep-C can cause fetal harm or affect reproductive capacity. Glycoprep-C should only be used if clearly needed.

### **Use in Children**

The safety and efficacy in children has not been established.

### **Elderly**

Caution should be exercised in the elderly as dehydration and electrolyte depletion may occur. Elderly patients must receive adequate fluids during administration.

### **Information for Patients**

Glycoprep-C produces a watery diarrhoea about an hour after the first administration and after four hours should produce a clear discharge. This action cleanses the bowel before examination. It should be prepared and taken according to the directions on the sachet or in the Dosage and Administration section.

The patient should fast for 2 hours before starting to take Glycoprep-C and only take clear fluids until after the examination..

It is important that the patient follow the recommended dosing schedule.

### **ADVERSE REACTIONS**

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.

### **DOSAGE AND ADMINISTRATION**

#### **Preparation of Solution.**

Dissolve the contents of the 70g sachet in one (1) litre of water using a suitable food grade container; or, dissolve the contents of the 210g sachet in three (3) litres of water using a suitable food grade container. These may be chilled if desired.

#### **Usual Dosage**

#### ***Unless otherwise directed by your doctor***

Three litres of solution is to be made up for the 210 g sachet and taken while one litre should be made up for each 70g sachet.

#### For Oral Use.

Glycoprep-C produces a watery diarrhoea which empties and cleanses the bowel before examination or surgery. It should be prepared and taken according to the directions. The onset of diarrhoea is about one (1) hour and should be complete in four (4) hours.

Two average size glasses of the prepared solution (350mLs) every 15 minutes. The recommended dosing intake rate is from 1.2 litres to 1.8 litres per hour. Lavage is complete when the faecal discharge is clear.

No food should be taken for two (2) hours prior to commencing dosing. Only clear drinks or liquids are allowed during the interval between commencing the Glycoprep-C preparation and six (6) hours prior to the examination.

**One day before the examination.**

During the day, drink at least one glass of clear fluid (plus preparation liquids) each hour. Keep drinking approved\*\* clear fluids all day until bedtime. Do not have solid foods or milk products.

\*\* Approved clear fluids or liquids are: Water, Bonox™, clear salty fluids (eg: strained chicken noodle soup), clear broth/bouillon, clear fruit juices (apple, pear & grape), plain jelly, black tea or coffee (no milk), sports drinks, Lucozade™, carbonated beverages, barley sugar, clear fruit cordials (clear lemon / lime), (No red or purple colourings). (A good combination of these clear fluids, including 2-3 cups of strained chicken noodle soup, will give you a variation in fluid intake).

**Note:** Individual responses to laxatives 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. Please remain within easy reach of toilet facilities and do not plan to go out.

**On the day of the examination.**

***For a morning procedure.***

From midnight last night, nothing more to be taken (nil) by mouth until after the examination.

***For an afternoon procedure.***

Drink only approved clear fluids\*\* (see above) for breakfast. Nothing (nil) by mouth 6 hours prior to the procedure.

**For Nasogastric Intubation**

Infuse the prepared solution at a rate of 20 to 30 mLs/minute.

**OVERDOSAGE**

In the event of overdosage, dehydration may ensue. 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.

**PRESENTATION**

Sachet containing 70g of dry powder or 210g of dry powder.

**STORAGE**

Store in a cool dry place below 30°C.

**REGISTRATION**

The Australian registration number is AUST R 20502.

**POISONS SCHEDULE**

Australia: S3- Pharmacist Only Medicine

New Zealand: Restricted Medicine

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