

# NEW ZEALAND DATA SHEET

**WARNING:**

Life threatening dehydration and / or electrolyte disturbances may occur in “at risk” groups. See Contraindications and Precautions.

## 1 PRODUCT NAME

Prepkit-C® (Combination pack)

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The active ingredients in **Glycoprep-C® Sachet Powder for Solution** are:

- macrogol 3350 has a chemical formula of HOCH<sub>2</sub> [CH<sub>2</sub>OCH<sub>2</sub>]<sub>m</sub>. CH<sub>2</sub>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 has a chemical formula of Na<sub>2</sub>SO<sub>4</sub>, a MW of 142.0 and a CAS No. 7757-82-6.

The active ingredients in **PicoPrep® Sachet Powder for Solution** are:

- sodium picosulfate has a chemical formula of C<sub>18</sub>H<sub>13</sub>NNa<sub>2</sub>O<sub>8</sub>S<sub>2</sub>.H<sub>2</sub>O, a MW of 499.4 and a CAS No. 10040-45-6 (anhydrous)
- magnesium oxide - heavy, has a chemical formula of MgO, a MW of 40.3 and a CAS No. 1309-48-4;
- citric acid which has a chemical formula of C<sub>6</sub>H<sub>8</sub>O<sub>7</sub>, a MW of 192.1 and a CAS No. 77-92-9.

Each Glycoprep-C® 70 g sachet contains macrogol 3350 (polyethylene glycol) 52.9 g, sodium chloride 2.6 g, potassium chloride 740 mg, sodium sulfate (anhydrous) 5.6 g and ascorbic acid 6.0 g. This solution also contains citric acid (anhydrous), aspartame and flavouring. Total sodium content 2.83 g.

Each PicoPrep® sachet contains sodium picosulfate 10 mg, magnesium oxide 3.5 g, citric acid anhydrous 12.0 g and aspartame 36 mg.

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

## 3 PHARMACEUTICAL FORM

Powder for oral solution.

Prepkit-C® is a combination kit containing one sachet of Glycoprep-C® 70 g powder for solution to produce one litre of solution and two sachets of PicoPrep® 15.5 g powder for solution. They both contain dry white crystalline powders which, when dissolved in water, produce solutions with a lemon like taste.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Prepkit-C® 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.

### Information for Patients

**PrepKit-C®** produces watery diarrhoea about an hour after the first administration. This action cleanses the bowel before examination. It should be prepared and taken according to the directions (see below).

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

### Preparation of Solutions

**PicoPrep®**: Dissolve the contents of the 15.5g sachet in one full glass of warm water (approximately 250 mL). Please note that the solution may become hot. If preferred, chill before use in a refrigerator prior to use.

**Glycoprep-C®**: Dissolve the contents of the 70g sachet in one (1) litre of water using a suitable food grade container. Chill before use if preferred. The full litre of solution should be taken.

Usual Dosage – **unless otherwise directed by your doctor.**

**PrepKit-C®** produces watery diarrhoea that empties and cleanses the bowel before examination or surgery. It should be prepared and taken according to the directions. The onset of diarrhoea is in about three (3) hours.

### Seven days before the examination

Stop all iron containing medicines but continue with regular medication.

### Two days before the examination

- Stop eating brown bread, cereals, vegetables and fruit.
- Do not have any yellow cheese.
- Eat boiled or poached egg, cottage cheese, low fat plain yoghurt, white bread, steamed white fish, boiled chicken, well cooked peeled pumpkin or well cooked peeled potato. Consume only clear jelly, skim milk and drink plenty of clear approved liquids\*\* (see below).

In the evening, make up the sachet of **Glycoprep-C®** with one litre of water as above. **Do not discard the empty sachet to ensure directions are followed completely.**

### 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 /

## NEW ZEALAND DATA SHEET

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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.

### FIRST DOSE. (3.00 p.m.)

Add the entire contents of one sachet of **PicoPrep®** to a glass of warm water (approximately 250 mL) and stir until dissolved. Chill for half an hour before drinking if preferred. Drink the mixture slowly but completely. This should be followed by adequate glasses of water or approved clear liquids\*\* (see above)- at least a glass per hour- in order to retain hydration throughout the body.

### SECOND DOSE (6.00 p.m.)

Remove the made up **Glycoprep-C®** from the refrigerator as per instructions above. Try to drink a glass of the prepared solution about every 15 minutes. Total intake time should take approximately one (1) hour in duration. If you start to feel nauseated whilst drinking the preparation, slow down the rate of intake.

### THIRD DOSE (9.00 p.m.)

Add the entire contents of one sachet of **PicoPrep®** to a glass of warm water (approximately 250 mL) and stir until dissolved. Chill for half an hour before drinking if preferred. Drink the mixture slowly but completely. This should be followed by adequate glasses of water or approved clear liquids\*\* (see above)- at least a glass per hour- in order to retain hydration throughout the body.

### 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.

## 4.3 Contraindications

**PrepKit-C®** should not be used by patients with clinically significant renal impairment, gastrointestinal obstruction, gastric retention, bowel perforation (frank or suspected), toxic megacolon, ileus, toxic colitis or whose body weight is less than 20 kg.

## 4.4 Special warnings and precautions for use

Use with caution in patients with ulcerative colitis, impaired renal function, heart conditions, pre-existing electrolyte disturbances, congestive heart failure, diabetes, those with a stoma, patients taking other medicines that may affect electrolyte levels and elderly or debilitated patients.

Adequate hydration is very important for safe and effective use of the product, and that medications such as a diuretic may exacerbate volume depletion associated with bowel cleansing.

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

## NEW ZEALAND DATA SHEET

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Patients with kidney disease or impaired kidney function; using calcium channel blockers, diuretics or other medications that may affect electrolyte may need to be monitored.

Nephrocalcinosis and renal impairment may occur following use of oral sodium phosphate products in “at risk” or inappropriate patient groups.

There have been reports of skin reactions and rhinorrhoea attributed to macrogol which is contained in **Glycoprep-C®**.

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

As **PicoPrep®** contains aspartame, persons suffering from Phenylketonuria need to be advised accordingly.

Both products may cause bloating, distension or abdominal pain. 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 Prepkat-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.

## **4.6 Fertility, pregnancy and lactation**

### Effects on fertility

No reproductive studies have been performed.

### Use in pregnancy (Category - none)

It is not known whether either product can cause foetal harm or affect reproductive capacity. They should only be used if clearly needed.

### Use in lactation

No lactation studies have been performed.

## **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 while 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 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 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

##### *For PicoPrep®*

Sodium picosulfate is broken down by colonic bacteria to form the active compound bis(p-hydroxyphenyl)pyridyl-2-methane which is a contact laxative. The citric acid reacts with the magnesium oxide to form magnesium citrate, an osmotic laxative. This induces a watery stool or bowel motion, usually within 3 hours, which normally removes the bowel contents.

##### *For Glycoprep-C®*

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.

The two products are used sequentially to ensure total removal of intestinal and colonic contents.

#### Clinical trials

No data available.

### 5.2 Pharmacokinetic properties

No data available.

### 5.3 Preclinical safety data

#### Genotoxicity

No genotoxic studies have been performed.

## Carcinogenicity

No carcinogenic studies have been performed.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

#### *Glycoprep-C®*

Ascorbic acid 85.16 mg/g

Aspartame 5.11 mg/g

Citric acid 12.77 mg/g

Lemon flavour QL58817 12.77 mg/g

#### *PicoPrep®*

Aspartame 2.36 mg/g

### 6.2 Incompatibilities

Refer to section 4.2 Dose and method of administration.

### 6.3 Shelf life

Approved Shelf Life as packaged for sale

2 years

### 6.4 Special precautions for storage

Store in a dry place below 25°C.

### 6.5 Nature and contents of container

PrepKit-C® is presented as a combination kit containing:

- one sachet of Glycoprep-C® 70 g
- two PicoPrep® 15.5 g sachets.

### 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

16 December 2010

# NEW ZEALAND DATA SHEET

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## 10 DATE OF REVISION OF THE TEXT

25 June 2019

### SUMMARY TABLE OF CHANGES

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