# **Consumer Medicine Information (CMI) summary**

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

**WARNING**: Important safety information is provided in a boxed warning in the <u>full CMI</u>. Read before using this medicine. [Include if applicable]

# 1. Why am I using Glycoprep-O Kit?

Glycoprep-O Kit contains the active ingredients macrogol 3350 (polyethylene glycol), potassium chloride, sodium chloride, sodium sulfate, magnesium carbonate hydrate, citric acid and bisacodyl. Glycoprep-O Kit is used to remove the bowel contents and cleanse it prior to gastrointestinal examination (such as colonoscopy, barium enema x-ray examination), prior to intravenous pyelograms (IVP) or colorectal surgery.

For more information, see Section <u>1. Why am I using Glycoprep-O Kit?</u> in the full CMI.

# 2. What should I know before I use Glycoprep-O Kit?

Do not use if you have ever had an allergic reaction to Glycoprep-O Kit or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant, intend to breastfeed or are breastfeeding.

For more information, see Section 2. What should I know before I use Glycoprep-O Kit? in the full CMI.

# 3. What if I am taking other medicines?

Some medicines may interfere with Glycoprep-O Kit and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

# 4. How do I use Glycoprep-O Kit?

- Swallow the Bisacodyl tablets whole. Do not crush or chew the tablets.
- Slowly mix the contents of the Magnesium Citrate sachet in 250 mL of warm water using a suitable food grade container.
- Mix the entire contents of the 70 g Glycoprep Orange sachet in 1 litre of water at room (ambient) temperature using a suitable food grade container.
- It is important to follow the instructions your doctor, prescriber or pharmacist has provided to you.

More instructions can be found in Section <u>4. How do I use Glycoprep-O Kit?</u> in the full CMI.

# 5. What should I know while using Glycoprep-O Kit?

Things you should do	<ul> <li>Remind any doctor, dentist or pharmacist you visit that you are using Glycoprep-O Kit.</li> <li>Drink plenty of recommended clear fluids whilst taking Glycoprep-O Kit</li> <li>Be close to toilet facilities whilst taking Glycoprep-O Kit</li> <li>Tell your doctor, prescriber or Pharmacist if you are pregnant, or intend to become pregnant or breastfeeding</li> </ul>
Things you should not do	<ul> <li>Do not give Glycoprep-O Kit to anyone else</li> <li>Do not take additional bowel preparation or laxative products unless stated by your doctor, prescriber or Pharmacist.</li> </ul>
Looking after your medicine	<ul> <li>Keep Glycoprep-O Kit in a cool dry place where the temperature stays below 25°C</li> <li>Once reconstituted, you may refrigerate for up to 24 hours.</li> </ul>

For more information, see Section 5. What should I know while using Glycoprep-O Kit? in the full CMI.

# 6. Are there any side effects?

All medicines can have side effects. Glycoprep-O Kit may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

# Glycoprep-O Kit™

**Active ingredient(s):** Macrogol 3350 (polyethylene glycol), potassium chloride, sodium chloride, sodium sulfate, magnesium carbonate hydrate, citric acid and bisacodyl

# **Consumer Medicine Information (CMI)**

This leaflet provides important information about using Glycoprep-O Kit. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Glycoprep-O Kit.

# Where to find information in this leaflet:

- 1. Why am I using Glycoprep-O Kit?
- 2. What should I know before I use Glycoprep-O Kit?
- 3. What if I am taking other medicines?
- 4. How do I use Glycoprep-O Kit?
- 5. What should I know while using Glycoprep-O Kit?
- 6. Are there any side effects?
- 7. Product details

# 1. Why am I using Glycoprep-O Kit?

**Glycoprep-O Kit contains the active ingredients macrogol** 3350 (polyethylene glycol), potassium chloride, sodium chloride, sodium sulfate, magnesium carbonate hydrate, citric acid and bisacodyl. It is a medicine kit containing Glycoprep Orange 70 g sachets, Magnesium Citrate sachet and Bisacodyl 5mg Tablets. Glycoprep-O Kit is classified as a bowel preparation. Glycoprep Orange contains macrogol, which acts as a laxative in the intestine. Macrogol works by causing excess water to remain in your stool and stimulates bowel movements. This results in watery stool or bowel motions which removes the bowel contents and ensures the bowel is clean before the examination or procedure. Magnesium citrate also works by causing excess water to remain in your stool and stimulates bowel movements. Bisacodyl works by being broken down by intestinal bacteria and then acting on the lining in your intestine to stimulate bowel movements.

#### Glycoprep-O Kit is used to remove the bowel contents and cleanse it prior to gastrointestinal examination (such as colonoscopy, barium enema x-ray examination), prior to intravenous pyelograms (IVP) or colorectal surgery.

Glycoprep-O Kit produces watery stools or bowel motions within 1 to 4 hours after the first dose and may cause frequent loose bowel motions depending on your individual response.

# Ask your doctor, prescriber or pharmacist if you have any questions about why this medicine has been prescribed for you or how you are to take it.

You should discuss with your doctor, prescriber or pharmacist what is going to happen before you have the examination or procedure. Your doctor, prescriber or pharmacist however, may prescribe Glycoprep-O Kit for another purpose.

# 2. What should I know before I use Glycoprep-O Kit?

#### Warnings

#### Do not use Glycoprep-O Kit if:

- you have had an allergy to any of the ingredients listed at the end of this leaflet.
  - Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.
  - If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Emergency department at the nearest hospital.
- you have kidney failure or disease
- you have appendicitis (an inflammation of the appendix)
- you have gastrointestinal obstruction (a blockage in the stomach or bowel)
- you have gastric retention (the stomach retains food and fluids)
- you have bowel perforation (a hole in the stomach, small intestine or large intestine)
- you have toxic colitis (a poisonous and inflamed large bowel)
- you have toxic megacolon (a poisonous and enlarged large bowel)
- you have ileus (a condition where the bowel does not work properly)
- you have severe dehydration (the symptoms of severe dehydration may include lethargy, excessive thirst, dizziness upon standing, rapid pulse, and not passing urine for protracted periods).
- you have a body weight less than 20 kg
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn, shows signs of tampering or it does not look quite right

#### Check with your doctor or pharmacist if you:

 have any other medical conditions such as stomach or bowel problems including ulcerative colitis, kidney disease, impaired kidney function, difficulty swallowing or food coming back after eating, diabetes, electrolyte disturbances (such as high magnesium levels or low sodium levels), a heart condition, stoma or inflammatory bowel disease.

- take any medicines for any other condition
- are elderly
- are allergic to any medicines, foods, dyes or preservatives

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects?</u>

# Pregnancy and breastfeeding

- Check with your doctor or pharmacist if you are pregnant or intend to become pregnant
- Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

Glycoprep-O Kit is not generally recommended for use in pregnant women unless the benefits outweighs the risk to the unborn baby. Your doctor will discuss the benefits and possible risks with you

# Use in children

 Glycoprep-O Kit is not recommended for use in children as the safety and effectiveness in children has not been established.

# Use in renal impairment

• Patients with kidney disease or impaired renal function may need to be monitored.

# Use in elderly

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

# Use in diabetic patients

Tell your doctor, prescriber or pharmacist if you are diabetic.

• The liquid diet recommended with this medication may affect your blood glucose levels and adjustment of your diabetic medication may be required.

# 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. Glycoprep-O Kit may affect any medication, taken orally, one (1) hour before and after taking Glycoprep-O Kit.

# Some medicines may interfere with Glycoprep-O Kit and affect how it works.

- Laxatives or other bowel cleansing preparations
- Medicines for heart conditions
- Medicines for diabetes
- Glycoprep-O kit may reduce the effect of medicines used to treat infections (Antibiotics)

- Other medicines that may affect electrolyte balance
- Glycoprep-O kit may reduce the effect of birth control medicines (Oral contraceptive pills or "the pill"), particularly for low-dose contraceptive pills
- Iron supplements
- Oral medication taken within one hour of the commencing Glycoprep-O kit, may be flushed from the gastrointestinal tract and not absorbed.

Your doctor, prescriber or pharmacist will have more information on medicines to be careful with or avoid while taking Glycoprep-O kit.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Glycoprep-O Kit. Your doctor, prescriber or pharmacist may have more information on medicines to be careful with while taking Glycoprep-O Kit.

If you have not told your doctor, prescriber or pharmacist about any of the above, tell them before you start taking Glycoprep-O Kit.

# 4. How do I use Glycoprep-O Kit?

# How much to take / use

It is important that you follow the instructions specifically given to you by your doctor, prescriber or pharmacist and ensure that you drink plenty of Recommended Clear Fluids.

- Glycoprep-O Kit contains 3 sachets of Glycoprep Orange, 1 Magnesium Citrate sachet and 3 x Bisacodyl tablets.
- The treatment can be taken as either a single day regimen (day before) or split dose regimen (over 2 days) depending on the time of the clinical procedure
- Your doctor, prescriber or pharmacist will have informed you of the dose that you should take and when to take it and which dosing schedule to follow.

Glycoprep-O Kit will produce numerous bowel motions within a short period of time. Ensure you have toilet facilities within easy access from when you start to take Glycoprep-O Kit.

If you are diabetic, discuss your requirements, and your diet and dosage program with your doctor, prescriber or pharmacist before commencing.

Do not have any food after the first dose of Glycoprep-O Kit. You must only consume the Recommended Clear Fluids while taking Glycoprep-O Kit and until after the procedure.

Recommended Clear Fluids include water, soups (e.g. strained chicken noodle soup), broth/bouillon, pulp-free fruit juices (apple, pear, white grape), black tea or coffee (no milk), electrolyte replacing drinks, nutritional supplements, carbonated beverages, clear cordials (lemon/lime), plain jelly, sorbet, boiled sweets, and gums/jubes. Sugar, salt, and sweetener

can be used. No red or purple colouring. Barley sugar may be sucked if required.

# When to take / use Glycoprep-O Kit

- Glycoprep-O Kit should be used as per the instructions provided to you by your doctor, prescriber or Pharmacist.
- Glycoprep-O Kit can be taken as either a single day regimen (one day) or a split dose regimen (over 2 days).
- The dosing regimen may be adjusted by a Healthcare Professional as required.
- The times given below are only suggestions for a morning procedure; your doctor may tell you different times.
- If the procedure is scheduled for the afternoon, it is recommended that the Split-Dose regimen be used.

#### Single day regimen (day before)

First Dose: Bisacodyl Tablets (taken at 2 pm)

Take the three (3) Bisacodyl 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.

<u>Second Dose:</u> Magnesium Citrate sachet (taken at 5 pm) Prepare the Magnesium Citrate sachet as per the instructions in "**How to prepare Glycoprep-O Kit**" or if prepared earlier and chilled take the mixture out of the refrigerator. 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.

<u>Third Dose:</u> Glycoprep Orange sachets (taken at 7 pm) Prepare the Glycoprep Orange sachet as per the instructions in "**How to prepare Glycoprep-O Kit**" or if prepared earlier and chilled, take the mixture out of the refrigerator. 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 solution should be orally ingested every 15-20 minutes until completed. This should be followed by adequate glasses of water or Recommended Clear Fluids. If nausea is experienced, the rate of intake of Glycoprep Orange solution should be reduced.

To split the dose over a period of two (2) days follow the below recommended guide:

#### Split dose regimen (over 2 days)

<u>First Dose:</u> 3 x Bisacodyl tablets (taken at 2 pm) Take the three (3) Bisacodyl 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.

<u>Second Dose</u>: 1 x Magnesium Citrate Sachet (taken at 5 pm). Prepare the Magnesium Citrate sachet as per the

instructions in "**How to prepare Glycoprep-O Kit**" or if prepared earlier and chilled take the mixture out of the refrigerator. 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.

<u>Third dose:</u> 2 litres Glycoprep Orange (taken at 7 pm) Prepare the Glycoprep Orange sachets as per the instructions in "**How to prepare Glycoprep-O Kit**" or if prepared earlier and chilled, take the mixture out of the refrigerator. Only take 2 litres of Glycoprep Orange at this time. Ingest one (1) to two (2) glasses of the prepared solution orally every 15-20 minutes until completed. This should be followed by adequate glasses of water or Recommended Clear Fluids. If nausea is experienced, the rate of intake of Glycoprep Orange solution should be reduced. Prepare the final one (1) litre solution of Glycoprep Orange and refrigerate if desired.

*Fourth Dose:* 1 litre Glycoprep Orange (taken approx. 2 to 5 hours prior to procedure). Prior to the procedure ingest the final one (1) litre of Glycoprep Orange solution in the same way as before. It is recommenced that patients cease taking any fluids two (2) hours prior to the procedure.

No food or drink should be taken for two (2) hours prior to the examination.

# **REMEMBER** you need to be close to toilet facilities whilst you are taking Glycoprep-O Kit.

• Bowel movements may continue for several hours after the last dose of Glycoprep-O Kit has been taken.

# How to prepare Glycoprep-O Kit

#### **Bisacodyl Tablets**

• Swallow the bisacodyl tablets whole. Do not crush or chew the tablets.

#### Magnesium Citrate Sachet

• Slowly mix the entire contents of the Magnesium Citrate sachet in approximately 250 mL of warm water (not boiling). Be aware that the solution will be effervescent (fizz and bubble). Stir gently until the effervescence ceases. The solution will appear cloudy and may be hot. Allow solution to cool before drinking. You also have the option of chilling the prepared Magnesium Citrate mixture in the refrigerator for up to 24 hours prior to drinking.

#### **Glycoprep Orange sachets**

 Mix the entire contents of each Glycoprep Orange sachet in 1 litre of water at room (ambient) temperature using a suitable food grade container. The solution will appear cloudy. You also have the option of chilling the prepared Glycoprep Orange mixture in the refrigerator for up to 24 hours prior to drinking.

# If you use too much Glycoprep-O Kit

If you think that you have used too much Glycoprep-O Kit, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

# You should do this even if there are no signs of discomfort or poisoning.

# 5. What should I know while using Glycoprep-O Kit?

#### Things you should do

- No food or drink should be taken for two (2) hours prior to the examination.
- If you are taking any other medicines, whether they require a prescription or not, talk to your doctor, prescriber or pharmacist before taking Glycoprep-O Kit.
- It is most important that you take adequate fluids whilst using Glycoprep-O Kit.

# REMEMBER you need to be close to toilet facilities whilst you are taking Glycoprep-O Kit

- Bowel movements may continue for several hours after the last dose of Glycoprep-O Kit has been taken.
- Because of the watery bowel motion caused by Glycoprep-O Kit you should not plan any other activities until after the examination.

#### Glycoprep-O Kit can lead to dehydration and electrolyte disturbances. You must ensure that you drink the recommended amount of liquid to replace the fluid that may be lost during bowel emptying.

- Remind any doctor, dentist or pharmacist you visit that you are using Glycoprep-O Kit.
- Tell your doctor, prescriber or pharmacist if, for any reason, you have not taken Glycoprep-O Kit exactly as prescribed.
- Ask your doctor, prescriber or pharmacist to answer any questions you may have.

# Things you should not do

- Do not give Glycoprep-O Kit to anyone else, even if they have the same procedure as you.
- Do not take any additional bowel preparation or laxative products unless otherwise stated by your doctor, prescriber or pharmacist.

# Driving or using machines

#### Be careful before you drive or use any machines or tools until you know how Glycoprep-O Kit affects you.

Glycoprep-O Kit may cause dizziness in some people.

# **Drinking alcohol**

#### Tell your doctor or pharmacist if you drink alcohol.

Do not drink alcohol while taking Glycoprep-O kit. Alcohol may add to the dehydrating effect of Glycoprep-O Kit.

# Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly. If you prefer to have your bowel preparation chilled, cover the mixture and place in a refrigerator prior to drinking for no more than 24 hours.

Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 25°C; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

# Getting rid of any unwanted medicine

If your doctor, prescriber or pharmacist tells you to stop taking Glycoprep-O Kit, or it has passed the expiry date, ask your pharmacist what to do with any medicine that is left over.

- If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.
- Do not use this medicine after the expiry date.

# 6. Are there any side effects?

Tell your doctor, prescriber or pharmacist as soon as possible if you do not feel well while you are taking Glycoprep-O Kit.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

# Side effects

Less serious side effects	What to do
Gastrointestinal <ul> <li>Nausea</li> <li>Vomiting</li> <li>Bloating</li> <li>Abdominal Cramps</li> <li>Anal Irritation</li> </ul> Dermatological <ul> <li>Skin Reactions</li> </ul> Other <ul> <li>Runny Nose</li> <li>Headache,</li> <li>Dizziness</li> </ul>	Speak to your doctor or pharmacist if you have any of these side effects and they worry you. Usually, they are transient and will subside once the preparation is finished.

Serious/rare side effects	What to do
<ul> <li>Allergic reactions</li> </ul>	Call your doctor straight
<ul> <li>Severe life-threatening</li> </ul>	away, or go straight to
dehydration	the Emergency
• Electrolyte disturbances	Department at your
	nearest hospital if you
	notice any of these
	serious side effects.

#### Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. If you get any side effects, do not stop taking Glycoprep-O Kit without first talking to your doctor, prescriber or pharmacist

# Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

# 7. Product details

This medicine is available over-the-counter without a doctor's prescription.

# What Glycoprep-O Kit contains:

#### Glycoprep Orange Sachets x3:

Active ingredient (main ingredient)	macrogol 3350 potassium chloride sodium chloride sodium sulfate
Other ingredients	ascorbic acid
(inactive ingredients)	silicon dioxide
	Natural Orange flavour
	Sweetesse Stevia <sup>™</sup> 97
Potential allergens	none

Total sodium content in Glycoprep Orange 70 g sachet is 2.86 g.

#### Magnesium Citrate sachet x1:

Active ingredient	magnesium carbonate hydrate
(main ingredient)	citric acid
Other ingredients	none
(inactive ingredients)	
Potential allergens	none

#### **Bisacodyl Tablets x 3:**

Active ingredient	bisacodyl
(main ingredient)	

Other ingredients	lactose monohydrate
(inactive ingredients)	sucrose
	gelatin
	maize starch
	calcium carbonate
	colloidal anhydrous silica
	magnesium stearate
	macrogol 6000
	quinoline yellow (104)
	methacrylic acid copolymer
	microcrystalline cellulose
	povidone,
	purified talc
	sodium starch glycollate type A
	antifoam AF emulsion Q7-2587 (PI 1515).
Potential allergens	lactose

#### Contains sugars, lactose and sucrose.

This medicine does not contain gluten, tartrazine, any other azo dyes or sulfites.

#### Do not take this medicine if you are allergic to any of these ingredients.

# What Glycoprep-O Kit looks like

A medicine kit containing:

- Three (3) round yellow Bisacodyl 5 mg enteric-• coated tablets in a blister pack
- One (1) 21.5 g Magnesium Citrate sachet containing white crystalline powder and
- Three (3) 70 g Glycoprep Orange sachets containing a white to creamy yellow powder with an odour characteristic of oranges

(AUST R 370154)

# Who distributes Glycoprep-O Kit

Fresenius Kabi Australia Pty Ltd. Level 2, 2 Woodland Way Mount Kuring-Gai NSW 2080 Tel: 1300 732 001

This leaflet was prepared in April 2023.