Glycoprep Orange®

Consumer Medicine Information (CMI) summary

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

1. Why am I using Glycoprep Orange?

Glycoprep Orange contains the active ingredients macrogol 3350 (polyethylene glycol), potassium chloride, sodium chloride and sodium sulfate. Glycoprep Orange 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 1. Why am I using Glycoprep Orange? in the full CMI.

2. What should I know before I use Glycoprep Orange?

Do not use if you have ever had an allergic reaction to Glycoprep Orange 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 Orange? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Glycoprep Orange 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 Orange?

- Mix the entire contents of each 70 g 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 4. How do I use Glycoprep Orange? in the full CMI.

5. What should I know while using Glycoprep Orange?

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

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

6. Are there any side effects?

All medicines can have side effects. Glycoprep Orange 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 6. Are there any side effects? in the full CMI.

Glycoprep Orange®

Active ingredient(s): Macrogol 3350 (polyethylene glycol), potassium chloride, sodium chloride and sodium sulfate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Glycoprep Orange. 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 Orange.

Where to find information in this leaflet:

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

1. Why am I using Glycoprep Orange?

Glycoprep Orange contains the active ingredients macrogol 3350 (polyethylene glycol), potassium chloride, sodium chloride and sodium sulfate. Glycoprep Orange 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.

Glycoprep Orange 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 Orange 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 Orange or another purpose.

2. What should I know before I use Glycoprep Orange?

Warnings

Do not use Glycoprep Orange if:

- you are allergic to macrogol 3350 (polyethylene glycol), potassium chloride, sodium chloride and sodium sulfate, or 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, prescriber or pharmacist immediately or go to the Emergency department at the nearest hospital
 - Always check the ingredients to make sure you can use this medicine
- 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 (ulcers in the large bowel), kidney disease, impaired kidney function, difficulty swallowing, diabetes, electrolyte disturbances (such as high magnesium levels or low sodium levels), a heart condition or stoma (a surgical opening from the large bowel through the lower abdomen or stomach to the outside).
- take any medicines for any other condition

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</u>. Are there any side effects?

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 Orange is not generally recommended for use in pregnant women unless the benefits outweigh the risk to the unborn baby. Your doctor, prescriber or pharmacist will discuss the benefits and possible risks with you.

Use in children

 Glycoprep Orange is not recommended in children as the safety and effectiveness in children has not been established.

Use in renal impairment

 If you have kidney disease or impaired kidney function, you may require additional monitoring.
 Please speak to your doctor, prescriber or pharmacist before using Glycoprep Orange.

Use in elderly

 This medication can cause dehydration and electrolyte depletion. If you are elderly, it is important to ensure you are taking adequate fluids whilst taking Glycoprep Orange. Please speak to your doctor, prescriber or pharmacist before using Glycoprep Orange.

Use in diabetic patients

 Tell your doctor, prescriber or pharmacist if you are diabetic. Glycoprep Orange administration may potentially interact with medicines for diabetics. The liquid diet recommended with this medication may affect your blood glucose levels and adjustment to 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.

Some medicines may interfere with Glycoprep Orange and affect how it works.

- Laxatives or other bowel cleansing preparations
- Medicines for heart conditions
- Medicines for diabetes
- Glycoprep Orange may reduce the effect of medicines used to treat infections (antibiotics)
- Other medicines that may affect electrolyte balance
- Glycoprep Orange may reduce the effect of birth control

medicines (oral contraceptive pills) particularly for low-dose contraceptive pills

Iron supplements

Glycoprep Orange may affect any medication, taken orally, one (1) hour before and after taking Glycoprep Orange

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

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 Orange.

4. How do I use Glycoprep Orange?

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.

- Usually, a total of 210 g of Glycoprep Orange will be required for the procedure. Three lots of the 70 g sachets will need to be prepared and used as required.
- 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.

Do not have any food after the first dose of Glycoprep Orange. You must only consume the Recommended Clear Fluids while taking Glycoprep Orange 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 Orange

- Glycoprep Orange should be used as per the instructions provided to you by your doctor, prescriber or pharmacist.
- You can take this treatment as a single day regimen (day before) or a split dose regimen (over 2 days). 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 Procedure

3 Litres (3 x 70g Sachets) Glycoprep Orange taken at 7pm: One (1) to two (2) 250 mL glasses of the prepared solution should be orally ingested every 15-20 minutes. No food should be taken for 2 hours prior to commencing dosing.

Only clear fluids are allowed during the interval between commencing Glycoprep Orange and 2 hours prior to the procedure.

Split-dose Regimen (evening before and day of the procedure)

Day before procedure

<u>First Dose:</u> 2 litres GLYCOPREP ORANGE® (taken at 7 pm). One (1) to two (2) 250 mL glasses of the prepared solution should be taken every 15-20 minutes. This should be followed by adequate glasses of water or Recommended Clear Fluids.

Day Of Procedure

<u>Second Dose:</u> 1 litre GLYCOPREP ORANGE® (taken approx. 2 to 5 hours prior to procedure).

One (1) to two (2) 250 mL glasses of the prepared solution should be taken every 15-20 minutes. This should be followed by adequate glasses of water or Recommended Clear Fluids.

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

How to prepare Glycoprep Orange

- Mix the entire contents of each 70 g sachet in 1 litre of water at room (ambient) temperature using a suitable food grade container.
- 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.

If you use too much Glycoprep Orange

If you think that you have used too much Glycoprep Orange, 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 Orange?

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 Orange
- It is most important that you take adequate fluids whilst using Glycoprep Orange

REMEMBER you need to be close to toilet facilities whilst you are taking Glycoprep Orange

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

Glycoprep Orange 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 Orange.

Tell your doctor, prescriber or pharmacist if, for any reason, you have not taken Glycoprep Orange exactly as prescribed.

Things you should not do

- Do not give Glycoprep Orange 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 Orange affects you.

Glycoprep Orange may cause dizziness in some people.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Do not drink alcoholic beverages whilst taking Glycoprep Orange. Alcohol may add to the dehydrating effect of Glycoprep Orange.

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.

When to discard your medicine

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

Getting rid of any unwanted medicine

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?

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 Nausea Vomiting Abdominal fullness Bloating Abdominal Cramps Anal Irritation Dermatological Skin reactions	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.
Other • Runny nose • Headache • Dizziness	

Serious/rare side effects	What to do
Allergic reactions, hypersensitivity	Call your doctor straight away, or go straight to the Emergency
Severe life-threatening dehydration	Department at your nearest hospital if you notice any of these
Electrolyte disturbance	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 the side effects are severe, you may need urgent medical attention. If you get any side effects, do not stop taking Glycoprep Orange 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 Orange contains

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

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

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

What Glycoprep Orange looks like

Glycoprep Orange is a sachet containing 70 g of a white to creamy yellow powder with an odour characteristic of oranges. It is packed in an outer carton.

(AUST R 370152).

Who distributes Glycoprep Orange

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.