

GLYCOPREP-O KIT™

New Zealand Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine

This leaflet answers some of the common questions people ask about GLYCOPREP-O KIT. It does not contain all the available information. It does not take the place of talking to your doctor, prescriber or pharmacist.

Ask your doctor, prescriber or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor, prescriber or pharmacist will have weighed the risks of you taking GLYCOPREP-O KIT against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine kit is used for

This medicine kit belongs to a group of medicines called Bowel Preparations.

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 components are GLYCOPREP ORANGE sachet, magnesium citrate sachet and bisacodyl tablets.

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.

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.

This results in watery stool or bowel motions which

removes the bowel contents and ensures the bowel is clean before the examination or procedure.

The bowel needs to be clean before the examination or procedure.

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.

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.

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

Before you use this medicine kit

When you must not use it

Do not take this kit if you have, or have had, any of the following medical conditions:

- Kidney failure or disease

- Appendicitis (an inflammation of the appendix)
 - Gastrointestinal obstruction (a blockage in the stomach or bowel)
 - Gastric retention (the stomach retains food and fluids)
 - Bowel perforation (a hole in the stomach, small intestine or large intestine)
 - Toxic colitis (a poisonous and inflamed large bowel)
 - Toxic megacolon (a poisonous and enlarged large bowel)
 - Ileus (a condition where the bowel does not work properly)
 - Severe dehydration (the symptoms of severe dehydration may include lethargy, excessive thirst, dizziness upon standing, rapid pulse, and not passing urine for protracted periods).
 - A body weight less than 20 kg
 - You have 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.**
- 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.

If you are not sure when you should start taking GLYCOPREP-O KIT, talk to your doctor, prescriber or pharmacist.

Before you start to take it

You must talk to your doctor, prescriber or pharmacist about using GLYCOPREP-O KIT if:

- you are allergic to any medicines, foods, dyes or preservatives;
- you are elderly;
- you have or have had any other health problems or medical conditions, including:
- any stomach or bowel problems including ulcerative colitis (ulcers in the large bowel)
- kidney disease
- impaired kidney function (the kidneys not working properly)
- difficulty in swallowing or food coming back after eating
- diabetes
- electrolyte disturbances (such as high magnesium levels or low sodium levels)
- a heart condition
- stoma (a surgical opening from the large bowel through the lower abdomen or stomach to the outside), inflammatory bowel disease

If you have any of the above, you should discuss your condition with your doctor, prescriber or pharmacist before taking

GLYCOPREP-O KIT. Your doctor, prescriber or pharmacist may not want you to take GLYCOPREP-O KIT or may want you to take special precautions or take it in another way.

Tell your doctor, prescriber or pharmacist if you are pregnant, intend to become pregnant, intend to breastfeed, or are breast-feeding.

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

GLYCOPREP-O KIT is not recommended in children aged below 18 years as the safety and effectiveness in children has not been established.

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

Taking other medicines

Tell your doctor, prescriber or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interact with GLYCOPREP-O KIT. These include:

- 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 infect (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 pill
- Iron supplements
- Oral medication taken within one hour of the commencing Glycoprep-O kit, may be flushed from the gastrointestinal tract and not absorbed.

GLYCOPREP-O KIT may affect any medication, taken orally, one (1) hour before and after taking GLYCOPREP-O KIT.

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

How to take this medicine kit

Follow all directions given to you by your

doctor, prescriber or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the carton or in this leaflet, contact your doctor, prescriber or pharmacist for help.

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.

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.

Do not drink alcoholic beverages.

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

How much to take

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

Your doctor, prescriber or pharmacist will have informed you of the dose that you should take and when to take it.

How to prepare this medicine kit

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 Sachet

Mix the entire contents of the GLYCOPREP ORANGE sachet in 1 litre of water at 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.

Bisacodyl BP 5 mg Tablets

Swallow the bisacodyl

tablets whole. Do not crush or chew the tablets.

When to take this medicine kit

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

Your doctor, prescriber or pharmacist will have informed you of the dose that you should take and when to take it.

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.

Second Dose: 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.

Third Dose: 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)

First Dose: 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.

Second Dose: 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.

Third dose: 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.

e 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 recommended 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.

If you forget to take it

It is important for you to take **GLYCOPREP-O KIT** exactly as prescribed. If you forget to take a dose, contact your doctor, prescriber or pharmacist as soon as possible as the time of the examination may need to be changed.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 764 766 in New Zealand) for advice or go to the Accident and Emergency department (Casualty) at your nearest hospital if you think you may have taken too much of a medicine, even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these services handy.

If you are not sure what to do, contact your doctor, prescriber or pharmacist.

While you are using this medicine kit

Things you must do

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.

Ask your doctor, prescriber or pharmacist to answer any questions you may have.

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**.

Tell all doctors, prescribers or pharmacists who are treating you that you are going to take **GLYCOPREP-O KIT**.

Tell your doctor, prescriber or pharmacist if, for any reason, you have not taken **GLYCOPREP-O KIT** exactly as prescribed.

Things you must not do

Do not give **GLYCOPREP-O KIT** to anyone else, even if they have the same condition as you.

Do not take any additional bowel preparation or laxative products unless otherwise stated by your doctor, prescriber or pharmacist.

Things to be careful of

Because of the watery bowel motion caused by **GLYCOPREP-O KIT** you should not plan any other activities until after the examination.

It is most important that you take adequate fluids whilst using **GLYCOPREP-O KIT**.

Possible 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. **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.

Ask your doctor, prescriber or pharmacist to answer any questions you may have.

Tell your doctor, prescriber or pharmacist if you notice any of the following and they worry you:

- Nausea (feeling sick)
- Vomiting
- Stomach pain
- Stomach bloating
- Anal irritation
- Skin reactions
- Runny nose
- Headache
- Dizziness

Do not be alarmed by this list of possible side effects. You may not experience any side effects.

Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects:

Serious/rare side effects:

- Allergic reactions
- Severe life-threatening dehydration
- Electrolyte disturbances

If the effects are severe, you may need medical treatment.

However, these side effects usually disappear when treatment with GLYCOPREP-O KIT is finished.

If you get any side effects, do not stop taking GLYCOPREP-O KIT without first talking to your doctor, prescriber or pharmacist.

Other side effects not listed may also occur in some patients. Tell your doctor, prescriber or pharmacist if you notice anything unusual that is making you feel unwell.

Storage and disposal

Storage

Keep GLYCOPREP-O KIT in a cool dry place where the temperature stays below 25°C.

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.

Do not store GLYCOPREP-O KIT or any other medicine in the bathroom or near a sink.

Do not leave it on a windowsill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Disposal

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

Product description

What it looks like

A medicine kit containing:

- three (3) round yellow Bisacodyl BP 5 mg 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

Ingredients

Each Bisacodyl BP 5 mg Tablet contains bisacodyl 5 mg, as the active ingredient. It also contains lactose monohydrate, 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 and antifoam AF emulsion Q7-2587 (PI

1515).

Each Magnesium Citrate 21.5 g sachet contains magnesium carbonate hydrate 7.2 g and citric acid 14.3 g, as the active ingredients, which together forms magnesium citrate in solution.

Each GLYCOPREP ORANGE 70 g sachet contains macrogol 3350 (polyethylene glycol) 52.9 g, potassium chloride 740 mg, sodium chloride 2.6 g and sodium sulfate 5.6 g, as active ingredients. Total sodium content in 70 g sachet is 2.86 g. It also contains ascorbic acid, silicon dioxide, natural orange flavour and natural Stevia sweetener.

Contains sugars, lactose and sucrose.

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

Sponsor

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