

GLYCOPREP ORANGE®

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine

This leaflet answers some common questions about GLYCOPREP ORANGE. 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 ORANGE 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 is used for

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

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 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.

The bowel needs to be clean before your doctor can examine it properly.

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.

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 for another purpose.

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.

Before you use this medicine

When you must not take it

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

- 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
- A body weight less than 20 kg
- You are hypersensitive to or have had an allergic reaction 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, prescriber or pharmacist immediately or go to the Accident and 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

ORANGE, contact your doctor, prescriber or pharmacist.

Before you start to take it

You must talk to your doctor, prescriber or pharmacist about using GLYCOPREP ORANGE 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 severe 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
 - a heart condition
 - stoma (a surgical opening from the large bowel through the lower abdomen or stomach to the outside).

If you have any of the above, you should discuss your condition with your doctor, prescriber or pharmacist before taking GLYCOPREP ORANGE. Your doctor, prescriber or pharmacist may not want you to take GLYCOPREP ORANGE 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 or are breast-feeding.

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.

GLYCOPREP ORANGE is not recommended in children 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 ORANGE. These include:

- Laxatives or other bowel cleansing preparations
- Medicines for heart conditions
- Medicines for diabetes
- Antibiotics
- Other medicines that may affect electrolyte balance
- Oral contraceptive pills (“the pill”)
- 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.

If you have not told your doctor, prescriber or pharmacist about any of the above, tell them before you start taking GLYCOPREP ORANGE.

How to take this medicine

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, sachet or in this leaflet, contact your doctor, prescriber or pharmacist for help.

GLYCOPREP ORANGE 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 ORANGE.

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.

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 to you by your doctor, prescriber or pharmacist and ensure 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.

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.

How to prepare this medicine

Mix the entire contents of each 70 g sachet in 1 litre of water at room temperature using a suitable food grade container. Stir gently. 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.

When to take this medicine

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.

Commence drinking the prepared GLYCOPREP ORANGE solution as directed by your doctor. Drink approximately one or two 250 mL glasses of the prepared solution every 15-20 minutes until completed. Drink the mixture slowly but completely. If you become nauseated, reduce the rate of intake. Continue drinking Recommended Clear Fluids at least a glass per hour until bedtime.

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 ORANGE.

Bowel movements may continue for several hours after the last dose of GLYCOPREP ORANGE has been taken.

If you forget to take it

It is important for you to take GLYCOPREP ORANGE 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 GLYCOPREP ORANGE, 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

Things you must do

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.

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 ORANGE.

Tell all doctors, prescribers or pharmacists who are treating you that you are going to take GLYCOPREP ORANGE.

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

Things you must 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.

Things to be careful of

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

It is most important that you take adequate fluids whilst using GLYCOPREP ORANGE.

Possible side effects

Tell your doctor, prescriber or pharmacist as soon as possible if you do not feel well while you are taking GLYCOPREP ORANGE.

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.

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

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

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

However, these side effects usually disappear when treatment with GLYCOPREP ORANGE is finished.

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

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

Storage and disposal

Storage

Keep GLYCOPREP ORANGE 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 ORANGE or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill 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 ORANGE 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 sachet containing 70 g of a white to creamy yellow powder with an odour characteristic of oranges. It is packed in an outer carton.

Ingredients

Each sachet contains macrogol 3350, sodium sulfate, sodium chloride and potassium chloride, as the active ingredients. It also contains ascorbic acid, silicon dioxide, natural orange flavour and natural Stevia sweetener.

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

Sponsor

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

Australian Registration Number

AUST R 370152

This leaflet was prepared in June 2021.