

PROGLUTROL G2 SUSTAINED RELEASE TABLET

Glimepiride /Metformin (2mg/500mg)

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What Proglutrol G2 is used for

Proglutrol G2 is used as an adjunct to diet and exercise in non-insulin dependent diabetes mellitus (NDDM) (Type 2) patients who are unable to achieve sufficient glycaemic control with monotherapy of Metformin & Glimepiride alone or who are already treated with combination of Metformin & Glimepiride as separate tablets.

How Proglutrol G2 works

Glimepiride reduces blood glucose levels by:

- Correcting both defective insulin secretion and peripheral insulin resistance.
 - It interacts with specific receptors at the plasma membrane of the insulin releasing pancreatic beta- cells
 - This results in opening of calcium channels & increase in intracellular calcium.
 - Thus insulin level is increased.
- Metformin lowers high blood glucose levels by:
- improving your body's sensitivity to insulin and restoring the way it normally uses glucose
 - reducing the amount of glucose your liver makes
 - delaying the amount of glucose your intestine absorbs

Before you use Proglutrol G2

When you must not take it

Do not take Proglutrol G2 if you are allergic to:

- medicines containing Metformin (such as Diaformin, Glucophage) or

any other biguanide Glimepiride (Such as Amaryl).

- any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take Proglutrol G2 if you have any of the following medical conditions:

- Type 1 diabetes mellitus that is well controlled by insulin alone
- Type 2 diabetes that is already well controlled by diet alone
- serious complications with your diabetes or diabetic ketoacidosis (a symptom of uncontrolled diabetes, in which substances called ketone bodies accumulate in the blood - you may notice this as an unusual fruity odour on your breath)
- kidney failure or severe kidney disease
- shock from severe injury or blood loss
- severe liver disease
- acute alcohol intoxication, chronic alcohol dependence
- certain heart or blood circulation problems, including a recent heart attack or heart failure (when the heart fails to pump blood effectively)
- blood clots in the lungs (symptoms include coughing, shortness of breath, chest pain and a fast heart rate), severe breathing difficulties
- a severe infection or gangrene.

Do not take Proglutrol G2 if you need to have major surgery or an examination such as an X-ray or a scan requiring an injection of iodinated contrast (dye).

You must stop taking Proglutrol G2 for a certain period of time before and after the examination or the surgery. Your doctor will decide whether you need any other treatment for this time. It is important that you follow your doctor's instructions precisely.

Do not take this medicine if you are pregnant or plan to become pregnant.

Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will replace Proglutrol G2 with insulin while you are pregnant.

Do not take Proglutrol G2 if you are breastfeeding. Your doctor will discuss the options available to you.

Do not take this medicine after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking Proglutrol G2, ask your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives. Before starting Proglutrol G2 your doctor will ask you to have a blood test to check your kidney function.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- liver problems
- heart or blood vessel problems including heart failure.

Tell your doctor if you drink alcohol.

Alcohol can affect the control of your diabetes. Drinking excessive amounts of alcohol while you are being treated with Proglutrol G2 may also lead to serious side effects.

Your doctor may suggest you stop drinking or reduce the amount of alcohol you drink.

If you have not told your doctor about any of the above, tell him/her before you start taking Proglutrol G2.

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Taking other medicines

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

Some medicines and Proglutrol G2 may interfere with each other. These include:

- other medicines used to treat diabetes such as insulin, glitinides (Novonorm), and sulfonylureas (e.g. Amaryl, Daonil, Diamicon, Glimel, Glyade, Melizide, Minidiab)
- iodinated contrast agents (dyes)
- medicines that contain alcohol, such as cough and cold syrups
- corticosteroids such as prednisone (Panafacort, Sone) and cortisone (Cortate)
- medicines used to treat high blood pressure and some heart conditions, such as beta-blockers, metoprolol (e.g. Betaloc, Minax), calcium channel blockers such as nifedipine (e.g. Adalat, Adefin), ACE inhibitors such as captopril (e.g. Capoten, Acenorm), enalapril (e.g. Alphapril, Amprace, Renitec) fosinopril (Monopril), lisinopril (e.g. Lisodur, Prinivil, Zestril), perindopril (Coversyl), quinapril (Accupril, Asig).
- Some medicines used to treat asthma such as salbutamol (Ventolin) or terbutaline (Bricanyl).
- diuretics, also called fluid tablets, such as amiloride (Midamor, Kaluril), bumetanide (Burinex), frusemide (Lasix, Uremide, Urex), hydrochlorothiazide (Dithiazide), spirinolactone (Aldactone, Spiractin). Some medicines may lead to low blood glucose (hypoglycaemia) by increasing the blood glucose-lowering effect of Proglutrol G2. These include: alcohol, other medicines used to treat diabetes anabolic steroids, some antibiotics, some antidepressants, some anti-inflammatory agents, such as ibuprofen and naproxen, some medicines used to treat arthritis and gout. Some blood pressure lowering medicines, such as beta-blockers and ACE inhibitors, some medicines used to treat blood clots, blood vessel problems and irregular heart rhythms, some cholesterol-lowering and weight

reduction medicines, some cancer and organ transplant treatments.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Proglutrol G2.

How to take Proglutrol G2

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

The dose varies from person to person. Your doctor will decide the right dose for you.

The usual starting dose is 1 tablet once daily or as directed by the physician. The maximum recommended daily dose of Metformin in adults is 2000 mg and Glimepiride is 8 mg once daily.

When to take it

Take your medicine everyday.

Take it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Keep taking Proglutrol G2 for as long as your doctor recommends.

Proglutrol G2 will help control diabetes but will not cure it. Most people will need to take Proglutrol G2 for long periods of time. When you start treatment with Proglutrol G2, it can take up to some weeks for your blood glucose levels to be properly controlled.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally. Do not take a double dose to make up for the dose you missed.

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

If you take too much (overdose)

Seek emergency medical attention if you think you have used too much of this medicine.

If you take too much Proglutrol G2, you may feel very tired, sick, vomit, have trouble breathing and have unusual muscle pain, stomach pain or diarrhoea. These may be early signs of a serious condition called lactic acidosis (build up of lactic acid in the blood). Lactic acidosis is a medical emergency and must be treated in hospital. You may also experience the symptoms of low blood glucose (hypoglycaemia).

While you are using Proglutrol G2

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Proglutrol G2. Tell all the other doctors, dentists and pharmacists who are treating you that you are taking this medicine. If you become pregnant while taking this medicine, tell your doctor. Tell your doctor if you plan to have:

- surgery with general anaesthesia
- any x-ray procedures requiring an injection of an iodinated contrast agent (dye).

Your doctor will advise you when to stop taking Proglutrol G2 before you have these procedures and when to start again.

HYPOGLYCAEMIA

Metformin does not normally cause hypoglycaemia (low blood sugar), although you may experience it while taking together with other medicines for diabetes such as insulin, sulfonylureas or glinide.

Make sure that you, your friends, family and work colleagues can recognise the symptoms of

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hypoglycaemia (low blood sugar) and know how to treat them.

Hypoglycaemia can occur suddenly. Initial signs may include:

- weakness, trembling or shaking
- sweating
- lightheadedness, dizziness, headache or lack of concentration
- irritability, tearfulness or crying
- hunger
- numbness around the lips and tongue.

If not treated promptly, these may progress to:

- loss of co-ordination
- slurred speech
- confusion
- fits or loss of consciousness.

If you experience any of the symptoms of hypoglycaemia, you need to raise your blood glucose immediately.

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates such as plain biscuits, fruit or milk. Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

HYPERGLYCAEMIA

If you experience any of the signs of hyperglycaemia (high blood sugar), contact your doctor immediately.

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less Proglutrol G2 than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Tell your doctor if any of the following happen:

- you become ill
- you become dehydrated (for instance due to persistent or severe diarrhoea or recurrent vomiting)
- you are injured
- you have a fever
- you have a serious infection such as influenza, respiratory tract infection or urinary tract infection
- you are having major surgery

• you are having an examination such as an X-ray or a scan requiring an injection of an iodinated contrast agent (dye).

• you become pregnant.
Your blood glucose may become difficult to control at these times. You may also be more at risk of developing a serious condition called lactic acidosis. At these times, your doctor may replace Proglutrol G2 with insulin.

Visit your doctor regularly for check ups.

Your doctor may want to check your kidneys, liver, heart and blood levels while you are taking Proglutrol G2 make sure you check your blood glucose levels regularly. This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes educator will show you how and when to do this.

Carefully follow the advice of your doctor and dietician on diet, drinking alcohol and exercise.

Things you must not do

Do not use Proglutrol G2 to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not skip meals while taking Proglutrol G2. Do not stop taking your medicine or change the dose without checking with your doctor.

Things to be careful of

If you have to be alert, for example when driving, be especially careful not to let your blood glucose levels fall too low. Low blood glucose levels may slow your reaction time and affect your ability to drive or operate machinery. Drinking alcohol can make this worse. However, Proglutrol G2 by itself is unlikely to affect how you drive or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Proglutrol G2.

Proglutrol G2 helps most people with diabetes but it may have unwanted side effects in some people.

All medicines can have side effects. 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 or pharmacist to answer any questions you may have. Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor if you notice any of the following and they worry you:

- stomach upset such as feeling sick (nausea), vomiting
- diarrhoea
- stomach pain
- skin reactions such as redness of the skin, itching or an itchy rash (urticaria).

These are generally mild side effects which disappear after the first few weeks. Taking Proglutrol G2 with meals can help reduce nausea and diarrhoea.

Tell your doctor as soon as possible if you notice any of the following:

Symptoms of liver disease such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, yellowing of the skin and eyes (jaundice) and dark coloured urine

TELL YOUR DOCTOR IMMEDIATELY OR GO TO ACCIDENT AND EMERGENCY AT THE NEAREST HOSPITAL IF YOU NOTICE ANY OF THE FOLLOWING SYMPTOMS OF LACTIC ACIDOSIS (BUILD UP OF LACTIC ACID IN THE BLOOD):

- nausea, vomiting, stomach pain
- trouble breathing
- feeling weak, tired or generally unwell
- unusual muscle pain
- sleepiness
- dizziness or lightheadedness
- shivering, feeling extremely cold
- slow heart beat.

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Lactic acidosis is a very rare but serious side effect requiring urgent medical attention or hospitalisation. Although rare, if lactic acidosis does occur, it can be fatal. The risk of lactic acidosis is higher in the elderly, those whose diabetes is poorly controlled, those with prolonged fasting, those with certain heart conditions, those who drink alcohol and those with severe kidney or liver problems. Tell your doctor or pharmacist if you notice anything that is making you feel unwell. It is very important that you speak to your doctor immediately if a side effect is severe, occurred suddenly or gets worse rapidly. As a result of the blood-sugar lowering action of Proglutrol G2, hypoglycemia may occur and may also be prolonged.

Other side effects not listed above may also occur in some people. Some side effects (e.g. reduced vitamin B12 level) can only be found when your doctor does tests from time to time to check your progress.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of PROGLUTROL G2

Storage

Keep Proglutrol G2 where children cannot reach it.
Keep your tablets in the blister pack until it is time to take them.
If you take the tablets out of the blister pack they may not keep well.
Keep your Proglutrol G2 tablets in a cool, dry place where the temperature stays below 25°C.
Do not store Proglutrol G2 or any other medicine in the bathroom or near a sink.
Do not leave Proglutrol G2 in the car or on window sills.
Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking this medicine, or your tablets have passed their expiry date, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

Capsule shaped biconvex, bilayered tablet, plain on both the sides, with one layer white in colour & other layer yellow.

Ingredients

Active ingredient :

Glimepiride 2mg in immediate release form and Metformin hydrochloride 500mg in sustained release form.

Inactive ingredients : Hypromellose, Carboxymethylcellulose Sodium, Methacrylic acid copolymer dispersion, Macrogol, Povidone, Magnesium Stearate, Sodium starch glycolate, Lactose, Ferric oxide (yellow), Titanium dioxide, Microcrystalline cellulose, Pregelatinised Starch.

MAL No.: MAL12020010A

Manufacturer

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Product Registration Holder

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