

PROGLUTROL G2 SUSTAINED RELEASE TABLET

Glimepiride/ Metformin (2mg/ 500mg)

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What is Proglutrol G2 used for

Proglutrol G2 is used as an adjunct to diet and exercise in non-insulin dependent diabetes mellitus (NDDM Type II) patients who are unable to achieve sufficient glycemic 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 use 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 I diabetes mellitus that is well controlled by insulin alone
- Type II 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)
- If you have severely reduced kidney function or kidney disease
- If you have lactic acidosis [too much lactic acid in the blood (see "Risk of lactic acidosis" below)] or ketoacidosis. Ketoacidosis is a condition in which substances called

'ketone bodies' accumulate in the blood and which can lead to diabetic pre-coma.

Symptoms of acidosis may include stomach pain, abnormal breathing and drowsiness (if severe)

- 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.

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-Before you start to use 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 medical conditions such as kidney problems, liver problems, heart or blood vessel problems including heart failure.

Risk of lactic acidosis:

Proglutrol G2 may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration, liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease). If any of the above apply to you, talk to your doctor for further instructions.

Stop taking Proglutrol G2 for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking Proglutrol G2 and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma.

Symptoms of lactic acidosis include:

- Vomiting
- Stomach ache (abdominal pain)
- Muscle cramps

- A general feeling of not being well with severe tiredness
- Difficulty in breathing

Lactic acidosis is a medical emergency and must be treated in a hospital.

During treatment with Proglutrol G2, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have worsening kidney function.

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.

-Taking other medications

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, Diamicron, Glimel, Glyade, Melizide, Minidiab)
- Iodinated contrast agents (dyes)
- Medicines that contain alcohol, such as cough and cold syrups
- Corticosteroids such as prednisone (Panafort, 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), spironolactone (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 use Proglutrol G2

-How much to use

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

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directed by the physician. The maximum recommended daily dose of metformin in adults is 2000mg and glimepiride is 8mg once daily.

-When to use it

Take your medicine everyday. Taking 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 use 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 use 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 use 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 it

-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.

-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.

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.

Some side effects experienced while on this medication are:

- Hypoglycaemia (due to low blood sugar)
- Temporary visual impairment (especially at start of treatment)
- Nausea, vomiting, abdominal pain and diarrhoea
- Itching of skin, allergic reactions and rashes

If you notice a rash developing after taking this medicine, seek immediate medical attention.

Common side effects (may affect up to 1 in 10 people):

- Decreased or low vitamin B12 levels in the blood (symptoms may include extreme tiredness (fatigue), a sore and red tongue (glossitis), pins and needles (paraesthesia) or pale or yellow skin). Your doctor may arrange some tests to find out the cause of your symptoms because some of these may also be caused by diabetes or due to other unrelated health problems.

You may report any side effects or adverse drug reactions directly to the

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National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Proglutrol G2

-Storage

Store below 30°C. Protect from light and moisture. Keep out of reach of children.

-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. Do not dispose medicines via wastewater or household waste. This will help protect the environment from pollution.

Product Description

-What it looks like

Capsule shaped, biconvex, bi-layered tablet, plain on both sides with one layer white in colour & the other layer yellow and blister packed.

-Ingredients

- Active ingredient(s)
Metformin hydrochloride and Glimepiride
- Inactive ingredient(s)
Povidone BP, Magnesium Stearate BP, Sodium Starch Glycolate BP, Pregelatinized Starch BP, Lactose BP, Purified Water BP, Microcrystalline Cellulose BP, Titanium Dioxide BP, Methacrylic Acid Copolymer Dispersion, Carboxymethylcellulose Sodium, Macrogol, Ferric

Oxide (Yellow) and Hypromellose BP

-MAL number

MAL12020010AZ

Manufacturer

Inventia Healthcare Limited,

F1-F1/1-F75/1, Additional Ambernath M.I.D.C., Ambernath (East), Thane, Maharashtra State, Ambernath, 421506, India

Product Registration Holder

Healol Pharmaceuticals Sdn. Bhd

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