PROGLUTROL Prolonged Release Tablets

Metformin Hydrochloride (750 mg)

What is in this leaflet

What is Proglutrol used for

Proglutrol prolonged release tablets contain the active ingredient metformin hydrochloride and belong to a group of medicines called biguanides, used in the treatment of diabetes.

Proglutrol is used to delay the onset and treat Type 2 (non- insulin dependent) diabetes mellitus when diet and exercise changes alone have not been enough to control blood glucose (sugar).

How Proglutrol works

Insulin is a hormone produced by the pancreas that makes your body take in glucose (sugar) from the blood. Your body uses glucose to produce energy or stores it for future use.
If you have diabetes, your pancreas does not make enough insulin or your body is not able to use properly the insulin it produces. This leads to a high level of glucose in your blood. Proglutrol makes the body more sensitive to insulin and helps return to normal the way your body uses glucose.

Proglutrol is associated with either a stable body weight or modest weight loss.

Proglutrol Prolonged Release Tablets are specially made to release the drug slowly in your body and therefore are different to many other types of tablet containing metformin.

Before you use Proglutrol

-When you must not use it

Do not take Proglutrol if:
• you are allergic to metformin or to any of the other ingredients which are listed later on in the leaflet.
• If you have lactic acidosis [too much lactic acid in the blood (see "Risk of lactic acidosis")] 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).
• If you are known to suffer from a genetically inherited disease affecting mitochondria (the energy-producing components within cells) such as MELAS syndrome (Mitochondrial Encephalopathy, myopathy, Lactic acidosis and Stroke-like episodes) or Maternal inherited diabetes and deafness (MIDD).
• You have severely-reduced kidney function.
• you have had serious complications with your diabetes or other serious conditions which resulted in rapid weight loss, nausea, vomiting or dehydration.
• you have a severe infection or have recently suffered a severe injury.
• you have been treated for heart problems or have recently had a heart attack or have severe circulatory problems or breathing difficulties.
• you are a heavy drinker of alcohol.
• you are under 18 years of age.

Take special care with Proglutrol.

After you have started taking your medicine:
• If you have diabetes you should have your blood or urine tested for sugar regularly. You should return to your doctor at least once a year to check the function of your kidneys (more often if you are elderly or if you have severely reduced kidney function).
• If you start to lose weight unexpectedly or suffer severe nausea or vomiting, uncontrolled rapid breathing or abdominal pains, stop taking the medicine and tell your doctor straight away. This can be a sign of a rare, but serious, complication with your diabetes called 'lactic acidosis' which means there is too much acid in the blood (see also 'Side effects'). You may see some remains of the tablets in your stools. Do not worry- this is normal for this type of tablet.

-Before you start to use it

If you need to have an X-ray examination involving the injection of a dye, tell the doctor that you take Proglutrol as you may need to stop taking it for a few days afterwards.

Tell your doctor if you are going to have an operation under general anaesthetic, as you may need to stop taking Proglutrol for a couple of days before and after the procedure. You should continue to follow any dietary advice that your doctor has given you and you should make sure that you eat carbohydrates regularly throughout the day.

Do not stop taking this medicine without speaking to your doctor.

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Risk of lactic acidosis

Proglutrol 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 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 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, 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.

-Taking other medications
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

If you are taking any of the following medicines, your blood sugar levels may need to be checked more often and your dose adjusted:
• Steroids such as prednisolone, mometasone, beclometasone.
• Diuretics (water tablets) such as furosemide.
• Sympathomimetic medicines including epinephrine and dopamine used to treat heart attacks and low blood pressure.

Epinephrine is also included in some dental anaesthetics.

How to use Proglutrol
Your doctor may prescribe Proglutrol for you to take on its own, or in combination with other oral antidiabetic medicines or insulin.

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow the tablets whole with a glass of water, do not chew.

-How much to use
Usually you will start treatment with 500 milligrams Proglutrol daily. After you have been taking Proglutrol for about 2 weeks, your doctor may measure your blood sugar and adjust the dose. The maximum daily dose is 2000 milligrams of Proglutrol.

-When to use it
Normally, you should take the tablets once a day, with your evening meal. In some cases, your doctor may recommend that you take the tablets twice a day. Always take the tablets with food.

-How long to use it
The treatment duration is not limited and depends on the severity of the disease. The duration of therapy will be determined by your doctor. Stopping treatment must be discussed with your doctor.

-If you forget to use it
Take it as soon as you remember with some food. Do not take a double dose to make up for a forgotten dose.

-If you use too much (overdose)
If you take extra tablets by mistake you need not worry, but if you have unusual symptoms, contact your doctor. If the overdose is large, lactic acidosis is more likely and this is a medical emergency requiring treatment in hospital.

While you are using it
-Things you must do
Pregnancy and breast-feeding
If you are pregnant, think you may be pregnant or are planning to have a baby, speak to your doctor in case any changes will be needed to your treatment or monitoring of your blood glucose levels.
This medicine is not recommended if you are breast-feeding or if you are planning to breast-feed your baby.

-Things you must not do
You should avoid drinking alcohol and using alcohol-containing medicines as this will increase the risk of lactic acidosis.

-Things to be careful of
Proglutrol taken on its own does not cause ‘hypos’ (symptoms of low blood sugar or hypoglycaemia, such as faintness, confusion and increased

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sweating) and therefore should not affect your ability to drive or use machinery. You should be aware, however, that Proglutrol taken with other antidiabetic medicines can cause hypos, so in this case you should take extra care when driving or operating machinery.

Side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them. If you notice any of the following, stop taking Proglutrol and see your doctor immediately:
• unexpected weight loss
• very severe nausea or vomiting
• very fast breathing which you cannot stop
• stomach pains or feeling cold

These can be signs of serious problems with your diabetes and may mean you have a very rare side effect called "lactic acidosis" (too much acid in the blood). If this happens, see a doctor as you will need treatment straight away.

Other possible side effects are listed by frequency as follows:

Very common side effects (may affect more than 1in 10 people):
• Diarrhoea, nausea, vomiting, stomach ache or loss of appetite. These undesirable effects occur most frequently during initiation of therapy and resolve spontaneously in most cases.

Common side effects (may affect up to 1 in 10 people):
• Taste disturbance
• 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.

Very rare side effects (may affect up to 1 in 10,000 people):
• Skin rashes including redness,itching and hives.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the 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
-Storage
Keep this medicine tablets out of the reach and sight of children.
Do not use this medicine after the expiry date that is printed on the pack after "Use before:". The expiry date refers to the last day of that month.
Store below 30°C.
Protect from light and moisture.

-Disposal
Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use.
These measures will help to protect the environment.

Product Description
-What it looks like
Metformin Hydrochloride 750 mg Prolonged Release Tablets are White to off white capsule shaped, biconvex, uncoated tablet plain on both sides.

-Ingredients
Active ingredient(s)
750 mg Metformin Hydrochloride
Equivalent to 585 mg Metformin

Inactive ingredient(s)
Hypromellose K100M (Anycoat-C) Ph.Eur, Carmellose Sodium (Majol 25000S) Ph.Eur, Povidone (Kollidon 90F) Ph.Eur , Methacrylic acid dispersion (EudragitL30D55) Ph. Eur., Macrogol (Polyglykol 6000 PF) Ph,Eur , Purified Water Ph.Eur & Magnesium Stearate Ph. Eur.

-MAL number
MALXXXXXXXX

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