

PROGLUTROL 500

METFORMIN HYDROCHLORIDE EXTENDED-RELEASE TABLETS 500 MG

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What is Proglutrol 500 used for

Proglutrol 500 is used to treat type 2 diabetes mellitus in adults, when dietary management and exercise alone does not result in adequate control of blood sugar. Proglutrol 500 may be used as monotherapy or in combination with other oral antidiabetic agents or with insulin.

How Proglutrol 500 works

Proglutrol 500 belongs to a group of medicines called biguanides.

It 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 500

-When you must not use it

Do not take Proglutrol 500 if you are allergic to:

- medicines containing metformin or any other biguanide
- 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 500 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 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).
- Severely reduced kidney function
- 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 500 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 500 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 Proglutrol 500 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 500, ask your doctor.

-Before you start to use it

Risk of lactic acidosis

Proglutrol 500 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 500 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 500 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.

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During treatment with Proglutrol 500, 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 have allergies to any other medicines, foods, dyes or preservatives.

Before starting Proglutrol 500 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 500 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 500.

-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 500 may interfere with each other. These include:

- other medicines used to treat diabetes such as insulin, glitinides and sulfonylureas
- iodinated contrast agents (dyes)
- medicines that contain alcohol, such as cough and cold syrups
- corticosteroids such as prednisone and cortisone
- medicines used to treat high blood pressure and some heart conditions, such as beta-blockers, metoprolol, calcium channel

blockers such as nifedipine, ACE inhibitors such as captopril, enalapril, fosinopril, lisinopril, perindopril, quinapril

- some medicines used to treat asthma such as salbutamol or terbutaline.
- diuretics, also called fluid tablets, such as amiloride, bumetanide, frusemide, hydrochlorothiazide, spirinolactone.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Proglutrol 500.

How to use Proglutrol 500

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 use

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

The usual starting dose is 1 tablet (500 mg) once daily with the evening meal. Your doctor may increase the dose slowly, depending on your blood glucose levels.

The maximum recommended dose is 4 tabs daily.

In patients already treated with metformin tablets, the starting dose of Proglutrol 500 should be equivalent to the daily dose of metformin immediate-release tablets.

If transfer from another oral antidiabetic agent is intended, discontinue the other agent and initiate Proglutrol 500 at the dose indicated previously.

Combination with Insulin: Metformin and insulin may be used in combination therapy to achieve better blood glucose control. Usual Starting Dose: 1 tab once daily, while insulin dosage is adjusted on the basis of blood glucose measurements.

Children: Proglutrol 500 should not be used in children.

Elderly: Due to the potential for decreased renal function in elderly subjects, the metformin dosage should be adjusted based on renal function. Regular assessment of renal function is necessary.

-When to use it

Take your medicine everyday with the evening meal.

Taking Proglutrol 500 during or with your evening meal will reduce the chance of a stomach upset.

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 500 for as long as your doctor recommends.

Proglutrol 500 will help control diabetes but will not cure it. Most people will need to take Proglutrol 500 for long periods of time. When you start treatment with Proglutrol 500, 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 are not sure what to do, ask your doctor or pharmacist.

-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 500, 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

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emergency and must be treated in hospital.

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 500. 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 500 before you have these procedures and when to start again.

HYPOGLYCAEMIA

Proglutrol 500 does not normally cause hypoglycaemia (low blood sugar), although you may experience it while taking 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 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.

You can do this by doing one of the following:

- eating 5 to 7 jelly beans
- eating 3 teaspoons of sugar or honey
- drinking half a can of non-diet soft drink
- taking 2 to 3 concentrated glucose tablets.

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 500 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 an 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 500 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 500.

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 500 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 500.

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 500 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 500.

Proglutrol 500 helps most people with diabetes but it may have unwanted side effects in some people.

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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
- taste disturbance, loss of appetite
- 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 500 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 heartbeat

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.

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.

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.

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 visiting the website npra.moh.gov.my [Consumers - > Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Proglutrol 500

-Storage

Keep Proglutrol 500 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 500 in a cool, dry place where the temperature stays below 30°C.

Do not store Proglutrol 500 or any other medicine in the bathroom or near a sink. Do not leave Proglutrol 500 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

White to off white capsule shaped tablet plain on both sides

-Ingredients

Active ingredient(s): 500 mg of Metformin hydrochloride in extended release form

Inactive ingredient(s): Hypromellose, Sodium Carboxymethylcellulose, Methacrylic acid copolymer, Macrogol, Povidone, Magnesium stearate.

-MAL number

MAL10110013AZ

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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