

AUROCLAZ 60 (Gliclazide Modified Release Tablets 60mg)

Gliclazide 60mg

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What is AUROCLAZ 60 used for

AUROCLAZ 60 is used in a certain form of diabetes (type 2 diabetes mellitus) in adults, when diet, exercise and weight loss alone do not have an adequate effect on keeping blood sugar at the correct level.

How AUROCLAZ 60 works

AUROCLAZ 60 is a medicine that reduces blood sugar levels (oral antidiabetic medicine belonging to the sulfonylurea group)

Before you use AUROCLAZ 60

-When you must not use it

Do not take AUROCLAZ 60:

- > If you are allergic to gliclazide or any of the other ingredients of AUROCLAZ 60, or to other medicines of the same group (sulfonylurea), or to other related medicines (hypoglycaemic sulfonamides);
- > If you have insulin-dependent diabetes (type 1);
- > If you have ketone bodies and sugar in your urine (this may mean you have diabetic ketoacidosis), a diabetic pre-coma or coma;
- > If you have severe kidney or liver disease;

> If you are taking medicines to treat fungal infections (miconazole, see section 'Taking other medicines');

> If you are breastfeeding (see section 'Pregnancy and breastfeeding')

-Before you start to use it

Warnings and precautions:

Talk to your doctor before taking AUROCLAZ 60. You should observe the treatment plan prescribed by your doctor to achieve proper blood sugar levels. This means, apart from regular tablet intake, to observe the dietary regimen, have physical exercise and, where necessary, reduce weight.

During gliclazide treatment, regular monitoring of your blood (and possible urine) sugar level and also your glycated haemoglobin (HbA_{1c}) is necessary.

In the first few weeks of treatment the risk of having reduced blood sugar levels (hypoglycaemia) may be increased. So particularly close medical monitoring is necessary.

Low blood sugar (hypoglycaemia) may occur:

- > If you take meals irregularly or skip meals altogether,
- > If you are fasting,
- > If you are malnourished,
- > If you change your diet,
- > If you increase your physical activity and carbohydrate intake does not match this increase,
- > If you drink alcohol, especially in combination with skipped meals,
- > If you take other medicines or natural remedies at the same time,
- > If you take too high doses of gliclazide,
- > If you suffer from particular hormone-induced disorders (functional disorders of the thyroid gland, of the pituitary gland or adrenal cortex),
- > If your kidney function or liver function is severely decreased.

If you have low blood sugar you may have the following symptoms: headache, intense hunger, nausea, vomiting, weariness, sleep disorders, restlessness, aggressiveness, poor concentration, reduced alertness and reaction time, depression, confusion, speech or visual disorders, tremor, sensory disturbances, dizziness and helplessness.

The following signs and symptoms may also occur: sweating, clammy skin, anxiety, fast or irregular heartbeat, high blood pressure, sudden strong pain in the chest that may radiate into nearby areas (angina pectoris)

If blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop convulsions, lose self-control, your breathing may be shallow and your heart beat slowed down, you may become unconscious.

In most cases the symptoms of low blood sugar vanish very quickly when you consume some form of sugar (for instance glucose tablets, sugar cubes, sweet juice, sweetened tea). You should therefore always carry some form of sugar with you (glucose tablets, sugar cubes). Remember that artificial sweeteners are not effective. Please contact your doctor or the nearest hospital if taking sugar does not help or if the symptoms recur.

Symptoms of low blood sugar may be absent, less obvious or develop very slowly or you are not aware in time that your blood sugar level has dropped. This may happen if you are an elderly patient taking certain medicines (for instance those acting on the central nervous system and beta blockers).

If you are in stress-situations (e.g., accidents, surgical operations, fever, etc.) your doctor may temporarily switch you to insulin therapy.

Symptoms of high blood sugar (hyperglycaemia) may occur when gliclazide has not yet sufficiently

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reduced the blood sugar, when you have not complied with the treatment plan prescribed by your doctor, if you take St. John's Wort (*hypericum perforatum*) preparations (see section 'Taking other medicines'), or in special stress situations. These may include dry itchy skin, skin infections and reduced performance. If these symptoms occur, you must contact your doctor or pharmacist.

Blood glucose disturbance (low blood sugar and high blood sugar) can occur when gliclazide is prescribed at the same time than medicines belonging to a class of antibiotics called fluoroquinolones, especially in elderly patients. In this case, your doctor will remind you the importance of monitoring your blood glucose.

If you have a family history of or know you have the hereditary condition glucose-6-phosphate dehydrogenase (G6PD) deficiency (abnormality of red blood cells), lowering of the haemoglobin level and breakdown of red blood cells (haemolytic anaemia) can occur. Contact your doctor before taking this medicinal product.

Cases of acute porphyria have been described with some other sulfonylurea drugs, in patients who have porphyria (inherited genetic disorders with accumulation in the body of porphyrins or porphyrin precursors).

Children and Adolescents:

AUROCLAZ 60 is not recommended for use in children due to lack of data.

-Taking other medications

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The blood sugar lowering effect of gliclazide may be strengthened and signs of low blood sugar levels may occur when one of the following medicines is taken:

- > Other medicines used to treat high blood sugar (oral antidiabetics GLP-1 receptor agonists or insulin)
- > Antibiotics (sulphonamides, clarithromycin)
- > Medicines to treat high blood pressure or heart failure (beta blockers, ACE-inhibitors such as captopril or enalapril)
- > Medicines to treat fungal infections (miconazole, fluconazole)
- > Medicines to treat ulcers in the stomach or duodenum (H₂ receptor antagonists)
- > Medicines to treat depression (monoamine oxidase inhibitors)
- > Painkiller or antirheumatics (phenylbutazone, ibuprofen)
- > Medicines containing alcohol

The blood glucose lowering effect of gliclazide may be weakened and raised blood sugar levels may occur when one of the following medicines is taken:

- > Medicines to treat disorders of the central nervous system (chlorpromazine)
- > Medicines reducing inflammation (corticosteroids)
- > Medicines to treat asthma or used during labour (intravenous salbutamol, ritodrine and terbutaline)
- > Medicines to treat breast disorders, heavy menstrual bleeding and endometriosis (danazol)
- > St. John's Wort (*Hypericum perforatum*) preparations

Blood glucose disturbance (low blood sugar and high blood sugar) can occur when a medicine belonging to a class of antibiotics called fluoroquinolones is taken at the same time than AUROCLAZ 60, especially in elderly patients.

AUROCLAZ 60 may increase the effects of medicines which reduce blood clotting (warfarin)

Consult your doctor before you start taking another medicinal product. If you go into hospital tell the medical staff you are taking AUROCLAZ 60.

How to use AUROCLAZ 60

-How much to use

Always take AUROCLAZ 60 exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The dose is determined by the doctor, depending on your blood and possibly urine sugar levels. Change in external factors (e.g., weight reduction, change in lifestyle, stress) or improvements in the blood sugar control may require changed gliclazide doses.

The recommended daily dose is half to two tablets (maximum 120mg) in a single intake at breakfast time. This depends on the response to treatment. The tablet can be divided into equal doses.

If a combination therapy of AUROCLAZ 60 with metformin, an alpha glucosidase inhibitor, a thiazolidinedione, a dipeptidyl peptidase-4 inhibitor, a GLP-1 receptor agonist or insulin is initiated your doctor will determine the proper dose of each medicine individually for you.

If you notice that your blood sugar levels are high although you are taking the medicine as prescribed, you should contact your doctor or pharmacist.

-When to use it

AUROCLAZ 60 is for oral use. Take your tablet(s) with a glass of water at breakfast time (and preferably at the same time each day). Swallow your half tablet or whole tablet(s) in one piece. Do not chew or crush. You must always eat a meal after taking your tablet(s).

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-How long to use it

As the treatment for diabetes is usually life long, you should discuss with your doctor before stopping this medicinal product. Stopping could cause high blood sugar (hyperglycaemia) which increases the risk of developing complications of diabetes.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

-If you forget to use it

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of AUROCLAZ 60, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

-If you use too much (overdose)

If you take too many tablets, contact your doctor or the nearest hospital Accident & Emergency department immediately. The signs of overdose are those of low blood sugar (hypoglycaemia) described in Section 2. The symptoms can be helped by taking sugar (4 to 6 lumps) or sugary drinks straight away, followed by a substantial snack or meal. If the patient is unconscious immediately inform a doctor and call the emergency services. The same should be done if somebody (for instance a child), has taken the product unintentionally. Unconscious patients must not be given food or drink. It should be ensured that there is a pre-informed person that can call a doctor in case of emergency.

While you are using it

Taking AUROCLAZ 60 with food, drink and alcohol: AUROCLAZ 60 can be taken with food and non-alcoholic drinks. Drinking alcohol is not recommended as it can alter the control of your diabetes in an unpredictable manner.

-Things you must do

Pregnancy and breastfeeding:

AUROCLAZ 60 is not recommended for use during pregnancy. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You must not take AUROCLAZ 60 while you are breastfeeding.

-Things you must not do

Do not stop taking the medicine unless advised by your doctor. Do not take any new medicines without consulting your doctor. Do not give AUROCLAZ 60 to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Driving and using machines: Your ability to concentrate or react may be impaired if your blood sugar is too low (hypoglycaemia), or too high (hyperglycaemia) or if you develop visual problems as a result of such conditions. Bear in mind that you could endanger yourself or others (for instance when driving a car or using machines). Please ask your doctor whether you can drive a car if you:

- > Have frequent episodes of low blood sugar (hypoglycaemia)
- > Have few or no warning signals of low blood sugar (hypoglycaemia)

AUROCLAZ 60 contains lactose:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most commonly observed side effect is low blood sugar (hypoglycaemia). For symptoms and signs see section 'Warnings and precautions'

If left untreated these symptoms could progress to drowsiness, loss of consciousness or possibly coma. If an episode of low blood sugar is severe or prolonged, even if it is temporarily controlled by eating sugar, you should seek immediate medical attention.

Liver disorders

There have been isolated reports of abnormal liver function, which can cause yellow skin and eyes. If you get this, see your doctor immediately. The symptoms generally disappear if the medicine is stopped. Your doctor will decide whether to stop your treatment.

Skin disorders

Skin reactions such as rash, redness, itching, hives, blisters, angioedema (rapid swelling of tissues such as eyelids, face, lips, mouth, tongue or throat that may result in breathing difficulty) have been reported. Rash may progress to widespread blistering or peeling of the skin. If you develop this, stop taking AUROCLAZ 60, seek urgent advice from a doctor and tell him that you are taking this medicine.

Exceptionally, signs of severe hypersensitivity reactions (DRESS) have been reported: initially as flulike symptoms and a rash on the face then an extended rash with a high temperature.

Blood disorders

Decrease in the number of cells in the blood (for instance platelets, red and white blood cells) which may cause paleness, prolonged bleeding, bruising, sore throat and fever have been reported. These symptoms usually vanish when the treatment is discontinued.

Digestive disorders

Abdominal pain, nausea, vomiting, indigestion, diarrhoea and constipation. These effects are reduced when taking AUROCLAZ 60 is taken with a meal as recommended.

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Eye disorders

Your vision may be affected for a short time especially at the start of treatment. This effect is due to changes in blood sugar levels.

As for other sulfonylureas, the following adverse events have been observed: cases of severe changes in the number of blood cells and allergic inflammation of the wall of blood vessels, reduction in blood sodium (hyponatremia), symptoms of liver impairment (for instance jaundice) which in most cases disappeared after withdrawal of the sulfonylureas, but may lead to life threatening liver failure in isolated cases.

You may report any side effects or adverse drug reaction 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 AUROCLAZ 60

-Storage

Keep out of sight and reach of children.

Do not use this medicine after the expiry date. The expiry date refers to the last day of that month.

Store below 30°C.

-Disposal

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

Product Description

-What it looks like

White to off white, uncoated tablets approximately 15.1 x 7.1 mm oblong shaped, biconvex, debossed with 'G' on left break-line and '60' on right of break line on one side and break line on other side.

-Ingredients

- Active ingredient(s)
Gliclazide
- Inactive ingredient(s)
Calcium carbonate, Lactose monohydrate, Hypromellose 2208 (100mPas controlled release grade), Hypromellose 2208 (4000mPas controlled release grade), Colloidal anhydrous silica, Magnesium stearate & Purified water.

-MAL number

MAL24096035AZ

Manufacturer

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Product Registration Holder

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