

Proprietary name:	Gliclazide MR 30 Ascend & Gliclazide MR 60 Ascend
Dosage form:	Modified release tablets
Active Ingredient:	Gliclazide
Strength per dosage unit:	30 mg or 60 mg Gliclazide per tablet

1.3.2.1 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Gliclazide MR 30 Ascend

Gliclazide MR 60 Ascend

Modified release tablets.

Gliclazide

Contains Sugar and mannitol.

Gliclazide MR 30 Ascend: Each tablet contains 39 mg of lactose monohydrate and 27,5 mg of mannitol.

Gliclazide MR 60 Ascend: Each tablet contains 78 mg of lactose monohydrate and 55 mg of mannitol.

Please read this leaflet carefully before taking Gliclazide MR Ascend.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **Gliclazide MR Ascend** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **Gliclazide MR Ascend** is and what it is used for

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2. What you need to know before you take **Gliclazide MR Ascend**
3. How to take **Gliclazide MR Ascend**
4. Possible side effects
5. How to store **Gliclazide MR Ascend**
6. Contents of the pack and other information

1. WHAT GLICLAZIDE MR ASCEND IS AND WHAT IT IS USED FOR

Gliclazide MR Ascend is a modified release tablet which contains the active substance called gliclazide. Gliclazide is a medicine that reduces blood sugar levels (oral antidiabetic medicine belonging to the sulfonylurea group).

Gliclazide MR Ascend, 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE GLICLAZIDE MR ASCEND

Do not take Gliclazide MR Ascend:

- if you are allergic to gliclazide or any of the other ingredients of **Gliclazide MR Ascend** (listed in section 6) 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 keto-acidosis), a diabetic pre-coma or coma;
- if you have severe kidney or liver disease;

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- if you are taking medicines to treat fungal infections (miconazole) (see section "Other medicines and **Gliclazide MR Ascend**, modified release tablet");
- if you are pregnant or breastfeeding (see section "Pregnancy and breastfeeding");
- If you are a child.

Warnings and special precautions:

Talk to your doctor before taking **Gliclazide MR Ascend**.

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 possibly urine) sugar level and also your glycated haemoglobin (HbA1c) 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.

Take special care with **Gliclazide MR Ascend**:

- **If you have low blood sugar (hypoglycaemia)**

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;

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- 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 heartbeat 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 stressful situations (accidents, surgical operations, fever etc.) your doctor may temporarily switch you to insulin therapy.

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Kidney and liver damages: the workings of gliclazide may be affected in patients with liver problems and serious kidney problems. Low blood symptoms seem to persist for longer period in these patients, so appropriate management is recommended.

- **If you have high blood sugar (hyperglycaemia)**

Symptoms of high blood sugar (hyperglycaemia) may occur when gliclazide has not yet sufficiently 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 "Other medicines and **Gliclazide MR Ascend**"), or in special stress situations. These may include thirst, frequent urination, dry mouth, 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 (dysglycaemia)) 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 medicine.

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

Children and adolescents

Gliclazide MR Ascend is not recommended in children because of lack of data.

Other medicines and Gliclazide MR Ascend:

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Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional 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, insulin, acarbose, metformin, biguanides or thiazolidinediones)
- antibiotics (sulfonamides, clarithromycin, chloramphenicol),
- medicines to treat high blood pressure or heart failure (beta blockers, ACE-inhibitors such as captopril, or enalapril),
- medicines to treat fungal infections (miconazole, ketoconazole or fluconazole),
- medicines to treat ulcers in the stomach or duodenum (H_2 -receptor antagonists such as cimetidine, ranitidine),
- medicines to treat depression (monoamine oxidase inhibitors),
- painkiller or antirheumatics (phenylbutazone, ibuprofen)
- medicines that relieve pain and reduce inflammation (non-steroidal anti-inflammatory medicines (NSAIDs)),
- 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),

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- medicines to treat breast disorders, heavy menstrual bleeding, and endometriosis (danazol)
- St John's Wart -*Hypericum perforatum*- preparations.
- medicines used to treat common cold and flu (ephedrine and pseudoephedrine)

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 **Gliclazide MR Ascend**, especially in elderly patients.

Gliclazide MR Ascend may increase the effects of medicines which reduce blood clotting (warfarin).

Consult your doctor before you start taking another medicine. If you go into hospital, tell the medical staff you are taking **Gliclazide MR Ascend**.

Gliclazide MR Ascend with food, drink and alcohol

Gliclazide MR Ascend can be taken with food and non-alcoholic drinks.

Drinking alcohol is not recommended as it can alter the gliclazide control of your diabetes in an unpredictable manner.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before taking this medicine.

You must not take **Gliclazide MR Ascend** while you are pregnant or breastfeeding (see **Do not take Gliclazide MR Ascend**).

Driving and using machines

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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).

Gliclazide MR Ascend contains lactose and mannitol.

Do not take **Gliclazide MR Ascend** if you have been told by your doctor that you have intolerance to sugars. Contact your doctor before taking **Gliclazide MR Ascend**.

Mannitol could cause diarrhoea.

3. HOW TO TAKE GLICLAZIDE MR ASCEND

Do not share medicines prescribed for you with any other person.

Always take **Gliclazide MR Ascend** exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist, or nurse 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 (weight reduction, change in lifestyle, stress) or improvements in the blood sugar control may require changed gliclazide doses.

Gliclazide MR 30 Ascend: The daily dose may vary from 1 to 4 tablets a day i.e. 30 mg to 120 mg taken as a single daily dose taken with breakfast.

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Gliclazide MR 60 Ascend: The daily dose may vary from half to 2 tablets a day i.e. 30 mg to 120 mg taken as a single daily dose taken with breakfast.

Gliclazide MR Ascend, modified release tablet 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 tablet(s) in one piece. Do not chew or crush. You must always eat a meal after taking your tablet(s).

If a combination therapy of **Gliclazide MR Ascend**, modified release tablet 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 regularly check your blood sugar levels to keep check on signs of developing hypoglycaemia (low blood sugar) and 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.

If you take more Gliclazide MR Ascend than you should:

In the event of overdosage, consult doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Your doctor will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

If you forget to take Gliclazide MR Ascend:

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of **Gliclazide MR Ascend**, take the next dose at the usual time.

Do not take a double dose to make up for a forgotten dose. Ask your doctor for advice.

If you stop taking Gliclazide MR Ascend:

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As the treatment for diabetes is usually life long, you should discuss with your doctor before stopping this medicine. 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.

4. POSSIBLE SIDE EFFECTS

Gliclazide MR Ascend can have side effects.

Not all side effects reported for **Gliclazide MR Ascend** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **Gliclazide MR Ascend** please consult your doctor or pharmacist for advice.

If any of the following happens, stop taking **Gliclazide MR Ascend** and tell your doctor or pharmacist immediately or go to the casualty department at your nearest hospital:

- 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). Rash may progress to widespread blistering or peeling of the skin.

These are all very serious side effects. If you have them, you may have had a serious reaction to **Gliclazide MR Ascend**. You may need urgent medical attention.

The following are serious side-effects. You might need medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Skin rash and itchiness,
- Metallic taste in mouth, increased appetite and weight gain,
- Abdominal pain, nausea, vomiting, indigestion, diarrhoea, and constipation. These effects are reduced when **Gliclazide MR Ascend** is taken with a meal as recommended.

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Less frequent side effects:

- Anorexia (eating disorder, obsession overweight),
- Hives (urticaria), abnormal redness of the skin (erythema), flat or raised skin lesions and fluid-filled blisters (maculopapular rashes and bullous reactions), signs of severe hypersensitivity reactions (DRESS) have been reported: initially as flu-like symptoms and a rash on the face then an extended rash with a high temperature.
- Decrease in the number of cells in the blood (e.g. 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.
- 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,
- Severe changes in the number of blood cells and allergic inflammation of the wall of blood vessels, reduction in blood sodium (hyponatraemia), symptoms of liver impairment (for instance jaundice, which causes yellow skin and eyes) which in most cases disappeared after withdrawal of the sulfonylurea but may lead to life-threatening liver failure in isolated cases. If you get this, see your doctor immediately. Your doctor will decide whether to stop your treatment.

Frequency unknown:

- If you develop 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,

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- Skin sensitivity to light, reddening of the skin (facial flushing), tender red nodules on the shins (erythema nodosum), severe skin peeling and inflammation (exfoliative dermatitis).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **Gliclazide MR Ascend**. All adverse events must also be reported to Ascend Laboratories via the e-mail: pharmacist.rsa@alkem.com.

5. HOW TO STORE GLICLAZIDE MR ASCEND

Store at or below 25 °C.

Keep the blister in the outer carton until required for use.

Keep the bottle tightly closed.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton and bottle label.

Do not throw away any medicines in drains or sewage systems.

Return all unused medicine to the pharmacist.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

The active ingredient is gliclazide.

Gliclazide MR 30 Ascend: Each modified release tablet contains 30 mg of Gliclazide.

Gliclazide MR 60 Ascend: Each modified release tablet contains 60 mg of Gliclazide.

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Other ingredients are colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, mannitol, sodium acetate anhydrous.

What Gliclazide MR Ascend looks like and contents of the pack:

Gliclazide MR 30 Ascend: White to off-white, round tablets, engraved with “G3” on one face and plain on the other face.

Gliclazide MR 60 Ascend: White to off-white, oblong shaped tablets, scored with a break bar on both sides, engraved with “G L” on one face and plain on the other face.

Contents of the pack:

Gliclazide MR 30 Ascend is packed in Aluminium-Aluminium blister pack (with or without dessicant) of 10, 30 and 60 tablets, the strips are packed in a printed cardboard carton and a white, opaque, round HDPE bottle closed with a white, opaque, polypropylene, child-resistant cap with liner, containing 60 or 100 tablets.

Gliclazide MR 60 Ascend is packed in Aluminium-Aluminium blister pack (with or without dessicant) of 10, 30 and 60 tablets, the strips are packed in a printed cardboard carton and a white, opaque, round HDPE bottle closed with a white, opaque, polypropylene, child-resistant cap with liner, containing 60 or 100 tablets.

Holder of certificate of registration

Ascend Laboratories (Pty) Ltd.

Ascend Laboratories (Pty) Ltd.

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This leaflet was last revised in

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Registration Numbers:

Gliclazide MR 30 Ascend: 59/21.2/0004

Gliclazide MR 60 Ascend: 59/21.2/0005

Access to the corresponding Professional Information

The professional information will be included in each unit pack of the product.