	Approved PIL
Applicant:	Servier Laboratories SA (Pty) Ltd
Product:	Gluctam MR 60 mg tablets
Date:	1 May 2020

PATIENT INFORMATION LEAFLET

Gluctam MR 60 mg modified release tablet

gliclazide

Contains sugar (lactose monohydrate 71,36 mg)

SCHEDULING STATUS: S3

Read this leaflet carefully before you start taking GLUCTAM MR 60 mg.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- **Gluctam MR 60 mg** 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 **Gluctam MR 60 mg** is and what it is used for
2. What you need to know before you take **Gluctam MR 60 mg**
3. How to take **Gluctam MR 60 mg**
4. Possible side effects
5. How to store **Gluctam MR 60 mg**
6. Contents of the pack and other information

1. What GLUCTAM MR 60 mg is and what it is used for

Gluctam MR 60 mg is a medicine that reduces blood sugar levels (oral antidiabetic medicine belonging to the sulphonylurea group).

Gluctam MR 60 mg 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 Gluctam MR 60 mg

Do not take Gluctam MR 60 mg:

- if you are allergic (hypersensitive) to gliclazide or any of the other ingredients of **Gluctam MR 60 mg**, or to other medicines of the same group (sulfonylurea), or to other related medicines (hypoglycaemic sulphonamides);
- 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;
- if you are taking medicines to treat fungal infections (miconazole, see “other medicines and Gluctam MR 60 mg”);
- if you are pregnant or breastfeeding (see Pregnancy and breastfeeding).
- If you are a child.

Warnings and precautions

You should observe the treatment plan prescribed by your doctor to achieve proper blood sugar levels. This means, apart from regular tablet intake, you 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 (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 heart beat, 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 (e.g. those acting on the central nervous system and beta blockers).

If you are in stress-situations (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 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 "Other medicines and **Gluctam MR 60 m**g) or other medicines that may affect the level of gliclazide in your blood 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) can occur when **Gluctam MR 60 mg** 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 of 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 active porphyria have been described with other sulfonylurea medicines, in patients who have porphyria (inherited genetic disorders with accumulation in the body of porphyrins or porphyrin precursors).

Certain blood pressure medications, like beta-blockers, may reduce the release of insulin and could reduce the normal physiological response to low blood sugar.

Children

Gluctam MR 60 mg is not recommended for use in children due to a lack of data.

Other medicines and Gluctam MR 60 mg

Always tell your healthcare professional if you are taking any other medicine. (This includes complimentary or traditional medicines).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, as they may interact with your **Gluctam MR 60 mg**.

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 (e.g. 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 (H_2 receptor antagonists like cimetidine, ranitidine),
- medicines to treat depression (monoamine oxidase inhibitors),
- painkillers 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 and terbutaline),
- medicines to treat breast disorders, heavy menstrual bleeding and endometriosis (danazol),
- medicines to treat colds (ephedrine and pseudoephedrine).
- 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 **Gluctam MR 60 mg**, especially in elderly patients.

Gluctam MR 60 mg may increase the effects of medicines which reduce blood clotting (warfarin). INR testing should be done more frequently.

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

Gluctam MR 60 mg with food, drink and alcohol:

Gluctam MR 60 mg 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.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice, before taking this medicine.

Gluctam MR 60 mg should not be taken during pregnancy. If you are planning a pregnancy, or become pregnant, inform your doctor so that he may prescribe a more suitable treatment for you.

You must not take **Gluctam MR 60 mg** while you are breastfeeding your baby.

Ask your doctor or pharmacist for advice before taking any medicine.

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 (e.g. 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).

Gluctam MR 60 mg contains lactose

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

3. How to take Gluctam MR 60 mg

Dose

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

Always take **Gluctam MR 60 mg** exactly as your doctor has told you. You should 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 life style, stress) or improvements in the blood sugar control may require changed gliclazide doses.

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

Gluctam MR 60 mg 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).

If a combination therapy of **Gluctam MR 60 mg** with metformin, an alpha glucosidase inhibitor, 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.

Please talk to your doctor or pharmacist if you have the impression that **Gluctam MR 60 mg** is acting too strongly or not strongly enough.

If you take more Gluctam MR 60 mg than you should:

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

The signs of overdose are those of low blood sugar (hypoglycaemia) (described in Take special care with **Gluctam MR 60 mg**). 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.

If you forget to take Gluctam MR 60 mg:

It is important to take your medicine every day as regular treatment works better.

However, if you forget to take a dose of **Gluctam MR 60 mg**, take the next dose at the usual time.

Do not take a double dose to make up for forgotten individual doses.

Do not share medicines prescribed for you with others.

If you stop taking GLUCTAM MR 60 mg

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.

If you have any further questions on the use of **Gluctam MR 60 mg**, ask your doctor or pharmacist.

Possible side effects

Gluctam MR 60 mg can have side effects. Not all side effects reported for **GLUCTAM MR 60 mg** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **GLUCTAM MR 60 mg**, please consult your doctor, pharmacist or other healthcare professional for advice.

The most commonly observed side effect is low blood sugar (hypoglycaemia). For symptoms and signs see “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 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 **GLUCTAM MR 60 mg**, 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 flu-like 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 (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.

Digestive disorders:

Abdominal pain, nausea, vomiting, indigestion, diarrhoea and constipation. These effects are reduced when **Gluctam MR 60 mg** is taken with a meal as recommended.

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.

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 (hyponatraemia), symptoms of liver impairment (for instance jaundice) which in most cases disappeared after withdrawal of the sulfonylurea, but may lead to life-threatening liver failure in isolated cases.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via **the "6.04 Adverse Drug Reaction Reporting Form"** found online under SAHPRA's publications https//www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **GLUCTAM MR 60 mg.**

4. How to store GLUCTAM MR 60 mg

Store all medicine out of reach of children.

Store at or below 30 °C.

Keep the blister in the carton until required for use.

Do not use after the expiry date stated on the carton and the blister strip.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

5. Contents of the pack and other information

What GLUCTAM MR 60 mg contains:

The active substance is gliclazide. Each modified release tablet contains 60 mg of gliclazide,

The other ingredients are: lactose monohydrate, maltodextrin, hypromellose, magnesium stearate, silica colloidal anhydrous.

What GLUCTAM MR 60 mg looks like and contents of the pack:

Gluctam MR 60 mg: White, oblong, tablet, 15 mm long and 7 mm wide, scored and engraved, with 'DIA 60' on both faces.

Blister packs of clear PVC and aluminium with 30 tablets in a carton.

Holder of certificate of registration

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