APPROVED PIL

For

GLICLAZIDE UNICORN MR 30 mg

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Confidential Information

SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD
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Approved PIL
Applicant Servier Laboratories SA (Pty) Ltd
Product **Gliclazide Unicorn MR 30 mg tablets**
Approval date 10 November 2017

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Gliclazide Unicorn® MR 30 mg modified release tablet.

Read this leaflet carefully before you start taking GLICLAZIDE UNICORN® MR 30 mg.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- Gliclazide Unicorn® MR 30 mg has specifically been prescribed for you, and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT GLICLAZIDE UNICORN® MR 30 mg CONTAINS:

The active substance is gliclazide. One tablet contains 30 mg of gliclazide, in a modified release formulation.
The other ingredients are: calcium hydrogen phosphate dihydrate, maltodextrin, hypromellose, magnesium stearate, anhydrous colloidal silica.

WHAT GLICLAZIDE UNICORN® MR 30 mg IS USED FOR:

Gliclazide Unicorn® MR 30 mg is a medicine that reduces blood sugar levels (oral antidiabetic medicine belonging to the sulphonylurea group).
Gliclazide Unicorn® MR 30 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. **Gliclazide Unicorn® MR 30 mg**is used to reduce the risk of diabetic complications such as cardiovascular and renal events.

BEFORE YOU TAKE GLICLAZIDE UNICORN® MR 30 mg:

Do not take Gliclazide Unicorn® MR 30 mg:

- if you are hypersensitive (allergic) to gliclazide or any of the other ingredients
- **Gliclazide Unicorn® MR 30 mg**, or to other medicines of the same group (sulphonylureas),
- 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
- 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 pregnant or breastfeeding (see Section "Pregnancy and breastfeeding").
- if you are a child.

Take special care with Gliclazide Unicorn® MR 30 mg:

Talk to your doctor before taking **Gliclazide Unicorn® MR 30 mg**.

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 glycosylated 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.

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 and 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, *e.g.* 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 (*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 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 with **Gliclazide Unicorn® MR 30 mg**) 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 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 known you have the hereditary condition glucose-6-phosphate dehydrogenase (G6PD) deficiency (abnormality of red blood cells), lowering of the haemoglobin level and breakdown or red blood cells (haemolytic anaemia) can occur. Contact your doctor before taking this medicinal product.
Gliclazide Unicorn® MR 30 mg is not recommended for use in children due to a lack of data.

Taking Gliclazide Unicorn® MR 30 mg with food and drink:
Gliclazide Unicorn® MR 30 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:
Gliclazide Unicorn® MR 30 mg is not recommended for use 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 **Gliclazide Unicorn® MR 30 mg** while you are breastfeeding. 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).

Taking other medicines with Gliclazide Unicorn® MR 30 mg:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
The blood sugar lowering effect of **Gliclazide Unicorn® MR 30 mg** may be strengthened and signs of low blood sugar levels may occur when one of the following medicines are taken:
- other medicines used to treat high blood sugar (oral antidiabetics 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),
- medicines to treat depression (monoamine oxidase inhibitors),
- painkiller or antirheumatics (phenylbutazone, ibuprofen),
- medicines containing alcohol.
- medicines to treat certain infections (chloramphenicol),

The blood glucose lowering effect of **Gliclazide Unicorn® MR 30 mg** 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, terbutaline),

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

Blood glucose disturbance (low blood sugar or high blood sugar) can occur when a medicine belonging to a class of antibiotics called fluoroquinolones is taken the same time than **Gliclazide Unicorn® MR 30 mg**, especially in elderly patients.
Gliclazide Unicorn® MR 30 mg may increase the effects of medicines which reduce blood clotting (*e.g*. warfarin).
Consult your doctor before you start taking another medicinal product. If you go into hospital tell the medical staff you are taking **Gliclazide Unicorn® MR 30 mg**.

HOW TO TAKE GLICLAZIDE UNICORN® MR 30 mg:
Dosage:
Do not share medicines prescribed for you with any other person.
Always take **Gliclazide Unicorn® MR 30 mg** exactly as your doctor has ~~told~~ instructed you.
You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with **Gliclazide Unicorn® MR 30 mg** will last. Do not stop treatment early because it can cause high blood sugar. If you have the impression that the effect of **Gliclazide Unicorn® MR 30 mg** is too strong or too weak, tell your doctor or pharmacist.
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 one (30 mg) to four tablets (maximum 120 mg) in a single daily dose at breakfast time. This depends on the response to treatment.
If a combination therapy of **Gliclazide Unicorn® MR 30 mg** with metformin, an alpha glucosidase inhibitor or insulin is initiated, your doctor will determine the correct dose of each medicine individually for you.

Method of administration:

Swallow your tablets whole. Do not chew them.

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. The tablet can be divided into equal doses. You must always eat a meal after taking your tablet(s).

If you take more Gliclazide Unicorn® MR 30 mg than you should:

If the event of an over dosage, 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). 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, *e.g*. a child, has taken the product unintentionally. Unconscious patients must not be given food or drink.

It should be ensured that there is always a pre-informed person that can call a doctor in case of emergency.

If you forget to take Gliclazide Unicorn® MR 30 mg:

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of **Gliclazide Unicorn® MR 30 mg**, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

Effects when treatment with Gliclazide Unicorn® MR 30 mg is stopped:

As the treatment for diabetes is usually life long, you should discuss with your doctor before stopping **Gliclazide Unicorn® MR 30 mg**. 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.

POSSIBLE SIDE EFFECTS:

Gliclazide Unicorn® MR 30 mg can have side effects.

Not all side effects reported for **Gliclazide Unicorn® MR 30 mg** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, 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 section "TAKE SPECIAL CARE".

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, ~~and~~ hives and angioedema (rapid swelling of tissues such as eyelids, face, lips, mouth, tongue or throat that may result in breathing difficulty) have been reported. The rash may progress to widespread blistering or peeling of the skin.

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 **Gliclazide Unicorn® MR 30 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.
With sulphonylureas, cases of severe changes in the number of blood cells and allergic inflammation of the wall of blood vessels have been described. Symptoms of liver impairment (*e.g*. jaundice) have been observed which in most cases disappeared after withdrawal of the sulphonylureas but may lead to life-threatening liver failure in isolated cases.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

STORAGE AND DISPOSING OF GLICLAZIDE UNICORN® MR 30 mg:
Store all medicines out of reach of children. Store at or below 25 °C.
Do not store in bathrooms.
Do not use after the expiry date on the blister.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

PRESENTATION OF GLICLAZIDE UNICORN® MR 30 mg:
The tablets are available in aluminium/PVC blister packs of 60 tablets.

IDENTIFICATION OF GLICLAZIDE UNICORN® MR 30 mg:
Gliclazide Unicorn® MR 30 mg tablets are white oblong tablets, engraved on both faces, 'DIA 30' on one face and  on the other face.

REGISTRATION NUMBER:
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