PATIENT INFORMATION LEAFLET

DYNACAZ MR

SCHEDULING STATUS

S3

DYNACAZ 30 mg MR modified release tablets

DYNACAZ 60 mg MR modified release tablets

DYNACAZ 90 mg MR modified release tablets

Gliclazide

DYNACAZ 30 mg MR contains sugar (73,50 mg lactose monohydrate per tablet)

DYNACAZ 60 mg MR contains sugar (93,40 mg lactose monohydrate per tablet)

DYNACAZ 90 mg MR contains sugar (140,10 mg lactose monohydrate per tablet)

Read all of this leaflet carefully before you start taking DYNACAZ MR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- DYNACAZ MR 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 DYNACAZ MR is and what it is used for

DYNACAZ MR contains gliclazide and belongs to a group of medicines called sulphonylurea antidiabetic medicine. It is used to treat a certain type of diabetes mellitus called type 2 diabetes in adults, when diet, exercise and weight loss alone do not have an adequate effect on keeping blood sugar at the correct level.

When you have type 2 diabetes, the amount of insulin your pancreas produces may not be enough or your body may not be using it properly and you may still need more. DYNACAZ MR works by causing your pancreas to release more insulin into the blood stream.

2. What you need to know before you take DYNACAZ MR

Do not take DYNACAZ MR:

- if you are hypersensitive (allergic) to gliclazide, sulphonylureas (medicine for diabetes), sulphonamides (a type of antibiotic), or to any of the ingredients of DYNACAZ MR (see section 6)
- if you have type 1 diabetes mellitus (type 1 diabetes patients cannot produce or release insulin from their pancreas)
- 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 a liver disease
- if you have a kidney disease
- if you are taking a medicine to treat fungal infections called miconazole (see Other medicines with DYNACAZ MR)
- if you are a child as the safety of DYNACAZ MR has not been studied in children
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with DYNACAZ MR:

Before taking DYNACAZ MR you should talk to your doctor. 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 DYNACAZ MR treatment regular monitoring of your blood, (and possibly urine), sugar level and also your glycated haemoglobin (HbA1c) is necessary.

In the initial weeks of treatment, the risk of low blood sugar may be increased and careful monitoring is necessary. Prolonged or serious episodes of hypoglycaemia (low blood sugar), even if controlled by sugar intake, require immediate medical treatment or even hospitalisation.

Low blood sugar (hypoglycaemia) may occur:

- if you are a patient, especially elderly or unable to cooperate
- if you do not eat meals at regular intervals 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 a significant amount of alcohol, especially when skipping meals
- if you have any severe abnormal condition of the blood vessels (arteries and veins), including severe heart disease
- if you are taking or have recently stopped taking high doses of corticosteroids (used for pain and inflammation)

- 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 take other medicines or natural remedies at the same time
- if you have taken an overdose of DYNACAZ MR.

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. Remember that artificial sweeteners are not effective. You should therefore always carry some form of sugar with you (glucose tablets, sugar cubes). Please contact your doctor or the nearest hospital if taking sugar does not help or if the symptoms recur.

In order to avoid gastrointestinal side effects (see Side effects), you should take your tablets with breakfast.

Should you experience side effects affecting the liver, your doctor may change your medicine.

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 DYNACAZ MR.

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).

It is important that you learn which symptoms of low blood sugar you usually have, so that you can treat it quickly. You must also educate your family members about the symptoms of hypoglycaemia and how to treat them.

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, or in special stress situations. 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 may include thirst, frequent urination, dry mouth, dry itchy skin, skin infections and reduced performance.

If these symptoms occur, you must contact your health care provider or pharmacist.

The effects of DYNACAZ MR may reduce over long periods of time and your doctor may

increase your dose and request you increase the frequency of monitoring of your sugar levels.

Blood glucose disturbance (low blood sugar and high blood sugar) can occur when DYNACAZ MR is prescribed at the same time as 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.

There is a potential for the occurrence of serious skin conditions to develop (toxic dermal necrolysis and allergic vasculitis).

Symptoms include a painful, red area that spreads quickly, skin peeling without blistering, raw areas of skin, discomfort, fever, purple-coloured spots and patches on the skin, blisters, hives, open sores).

Your doctor may request tests to monitor your condition before or during treatment.

The safety and efficacy of DYNACAZ MR in children has not been established (see Do not take DYNACAZ MR).

Other medicines and DYNACAZ MR

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

The following medicine increases the risk of hypoglycaemia or even coma and should not be used:

- a medicine containing miconazole (used to treat fungal infections) (see Do not take DYNACAZ MR).

The following medicines or substances may cause your blood sugar levels to fall even lower than normal when taken together with DYNACAZ MR and are therefore not recommended for use:

- phenylbutazone (used to treat pain and inflammation)
- alcohol increases the risk of hypoglycaemia (low blood sugar) and coma. Alcohol and medicines containing alcohol should be avoided.

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

- sulphinpyrazone (anti-gout medicine)
- anabolic steroids (a steroid hormone which promotes muscle growth) and androgens (male sex hormone)
- certain medicines used to treat high blood pressure and heart disease called ACE inhibitors (captopril, enalapril, quinidine, quinine and clonidine), and antidysrhythmics (disopyramide)
- medicines to treat high blood pressure or heart failure (beta blockers, ACE-inhibitors such as captopril, or enalapril)
- antibiotics (chloramphenicol, sulphonamides, quinolones, tetracyclines, clarithromycin)
- certain antidepressants such as fluoxetine (monoamine-oxidase inhibitors)
- certain medicines used to treat fungal infections, such as ketoconazole, itraconazole, voriconazole, fluconazole
- the appetite suppressant fenfluramine
- ranitidine and cimetidine (medicines used to treat heartburn)
- fibrates (such as clofibrate) used to treat high cholesterol

- insulin and other oral antidiabetic medicines (such as acarbose, metformin, thiazolidinediones, GLP-1 receptor inhibitors)
- certain medicines used to treat pain and inflammation (NSAIDs and salicylates)
- beta-blockers (used to control heart rhythm, treat angina, and reduce high blood pressure) may increase the chance that high or low blood sugar can occur. Also, they can hide the symptoms of low blood sugar.

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 with DYNACAZ MR:

- danazol used to treat breast disorders, heavy menstrual bleeding and endometriosis is not recommended for use with DYNACAZ MR. If it cannot be avoided, regular urine and blood glucose monitoring must be done. Your dose of DYNACAZ MR may need to be adjusted
- epinephrine (adrenaline), asthma medicines (salbutamol, terbutaline), cough and cold medicines containing ephedrine and pseudoephedrine
- corticosteroids (cortisone-like medicines used to treat inflammation)
- calcium channel blockers, clonidine, diazoxide (cardiovascular medicines used to treat heart problems)
- chlorpromazine (tranquiliser or sedative also used for nausea or vomiting)
- lithium (used to treat certain types of depression)
- thiazide diuretics (water tablets)
- anti-epileptic medication such as phenytoin
- glucagon (a hormone that assists with the breakdown of glycogen to glucose)
- female hormones oestrogen and progesterone
- antibacterial medicines rifampicin and isoniazid
- thyroid hormones

- glucocorticoids (used to assist the body to break down carbohydrates, proteins and fats)
- medicines to treat asthma or used during labour (intravenous salbutamol, ritodrine and terbutaline).

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 DYNACAZ MR, especially in elderly patients.

DYNACAZ MR may increase the effects of anticoagulants (medicines which reduce blood clotting e.g. warfarin). Your dose of anticoagulant may need to be adjusted.

DYNACAZ MR with food and drink

DYNACAZ MR must be taken with food. The tablet must be swallowed whole with half a glass of water and should be taken immediately before a substantial breakfast or the first main meal of the day. You should not miss a meal after you have taken the tablets.

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

Pregnancy, breastfeeding and fertility

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 health care provider for advice before taking this medicine.

You should not take this medicine if you are pregnant or breastfeeding your baby (see Do not take DYNACAZ MR).

Driving and using machines:

Alertness and reactions may be impaired by hypo- or hyperglycaemia, especially when initiating treatment or altering doses. You should be aware of the symptoms of hypoglycaemia (low blood sugar) which include dizziness, poor concentration, confusion, sleepiness and blurred vision.

It is not always possible to predict to what extent DYNACAZ MR may interfere with your daily activities of a patient. You should ensure that you do not engage in the above activities until you are aware of the measure to which DYNACAZ MR affects you.

DYNACAZ MR contains lactose

DYNACAZ MR contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take DYNACAZ MR

Do not share medicines prescribed for you with any other person. Always use DYNACAZ MR exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with DYNACAZ MR will last. Do not stop treatment early because high blood sugar symptoms will return. If you have the impression that the effect of DYNACAZ MR is too strong or too weak, tell your doctor or pharmacist.

Your doctor will decide on the correct dose based on your metabolic response and blood sugar level. The tablet must be swallowed whole, do not chew them, with half a glass of water and should be taken immediately before a substantial breakfast or the first main meal

of the day (and preferably at the same time each day). You should not miss a meal after you have taken the tablets. DYNACAZ MR 90 mg tablets may be subdivided into parts to ensure that medicine is taken as directed by your doctor.

Adults:

The recommended daily dose is one to four tablets of the 30 mg or two of the 60 mg tablets (maximum 120 mg) i.e. 30 to 120 mg taken as a single daily dose, taken with breakfast.

If a combination therapy of DYNACAZ MR 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.

Dose adjustments:

If your fasting blood glucose levels have not decreased satisfactorily, your doctor may increase the dosage progressively to 60, 90 or 120 mg per day (2 to 4 tablets of 30 mg). Your doctor will instruct you how to increase your dosage, but usually you should increase the number of tablets at an interval of at least one month between each increment.

The daily dose should not exceed 120 mg.

Children:

The safety and efficacy of DYNACAZ MR in children and adolescents have not been established and should therefore not be used in children.

If you take more DYNACAZ MR 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.

Symptoms of overdose may include:

Low blood sugar (also called 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, 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 always a pre-informed person that can call a doctor in case of emergency.

If you forget to take DYNACAZ MR

If you forget to take DYNACAZ MR, take a dose as soon as you remember, then continue to take DYNACAZ MR at the usual times. Do not take a double dose to make up for forgotten individual doses.

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

If you stop taking DYNACAZ MR

Stopping this medicine could cause high blood sugar (hyperglycaemia) which increases the risk of developing complications of diabetes.

4. Possible side effects

Not all side effects reported for DYNACAZ MR are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking DYNACAZ MR, please consult your health care provider for advice.

If any of the following happens, stop using DYNACAZ MR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DYNACAZ MR. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Stevens-Johnson syndrome or other serious skin disorder (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters)
- low blood sugar levels — hypoglycaemia (see Take special care with DYNACAZ MR for the list of symptoms)
- liver failure (signs include yellow discolouration of the skin and eyes (jaundice) and pain in the upper right abdomen)
- kidney problems (passing more urine than is normal for you or more frequently).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache, dizziness, drowsiness
- constipation, diarrhoea, stomach pain or discomfort, stomach spasms, decreased or increased appetite, heartburn, bloating, flatulence (gas), weight gain, nausea, vomiting, changes in sense of taste (metallic taste).

Less frequent side effects:

- decrease in the number of cells in the blood resulting in abnormal blood test results including anaemia
- low sodium levels in the blood, anorexia
- blurred vision, worsening eyesight
- abnormal liver function (clay coloured stool, dark urine, itching, loss of appetite, yellow eyes or skin).

The following side effects have been reported but the frequency for them to occur is not known:

- hives, itching, inflammation of the skin, rash, redness of the skin, sensitivity to light, dry skin, blistering or peeling of the skin, thinning of the skin, pale skin, unusual bruising

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 or pharmacist. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link:

https://www.sahpra.org.za/Publications/Index/8 By reporting side effects, you can help provide more information on the safety of DYNACAZ MR. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store DYNACAZ MR

Store all medicines out of reach of children.

Store at or below 30 °C in a dry place. Protect from light.

Keep blisters in carton until required for use.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What DYNACAZ MR contains

The active substance is gliclazide.

DYNACAZ 30 mg MR: Each modified release tablet contains 30 mg gliclazide. Each 30 mg tablet contains sugar (73,50 mg lactose monohydrate per tablet).

DYNACAZ 60 mg MR: Each modified release tablet contains 60 mg gliclazide. Each 60 mg tablet contains sugar (93,40 mg lactose monohydrate per tablet).

DYNACAZ 90 mg MR: Each modified release tablet contains 90 mg gliclazide. Each 90 mg tablet contains sugar (140,10 mg lactose monohydrate per tablet).

The other ingredients are

DYNACAZ 30 mg MR:

Calcium carbonate, colloidal silica dioxide, hypromellose, lactose monohydrate, magnesium stearate.

DYNACAZ 60 mg MR and DYNACAZ 90 mg MR:

Hypromellose, lactose monohydrate, magnesium stearate, silica colloidal anhydrous.

What DYNACAZ MR looks like and contents of the pack

DYNACAZ 30 mg MR: White to almost white, oval, slightly biconvex tablets of (length: 11 mm x width 5,5 mm) with bevelled edges.

DYNACAZ 60 mg MR: White to almost white, oval, biconvex tablets of

13 mm.

DYNACAZ 90 mg MR: White to almost white, capsule shaped, biconvex tablets of 17 - 17,5 mm with two score lines around the tablet.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

DYNACAZ 30 mg MR tablets are packed in Aluminium/PVC blister packs of 10 tablets per blister strip; each printed outer carton contains 60 tablets.

DYNACAZ 60 mg MR tablets are packed into clear OPA/Al/PVC and aluminium foil blister strips. 28 (2 x 14) or 30 (2 x 15) tablets will be packed into a cardboard box.

DYNACAZ 90 mg MR tablets are packed into OPA/Al/PVC and aluminium foil blister strips.

Blister strips containing a total of either 30, 60 or 90 tablets will be packed into a cardboard box.

Holder of Certificate of Registration

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