**DYNACAZ MR**

**SCHEDULING STATUS** S3

**1. NAME OF THE MEDICINE**
DYNACAZ 30 mg MR modified release tablets
DYNACAZ 60 mg MR modified release tablets
DYNACAZ 90 mg MR modified release tablets

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**
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).

For the full list of excipients, see section 6.1

**3. PHARMACEUTICAL FORM**
Modified release tablets.
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. Tablets may be subdivided in parts to improve patients' compliance with all the dosing regimens. Dissolution studies in different media at pH 0,1; 4,5 and 7,4, and uniformity of mass studies of divided parts were conducted.

**4. CLINICAL PARTICULARS**
**4.1 Therapeutic indications**
DYNACAZ MR is indicated in Type 2 diabetic patients, in association with dietary measures, lifestyle changes and exercise, when dietary measures, lifestyle and exercise alone are not sufficient to control blood glucose.

**4.2 Posology and method of administration**
**Posology:**
**For adult use only:**
DYNACAZ 30 mg MR: The daily dose may vary from 1 to 4 tablets a day, i.e. 30 to 120 mg taken as a single daily dose.
DYNACAZ 60 mg MR: the daily dose may vary from one half to 2 tablets a day, i.e. 30 to 120 mg taken as a single daily dose. It is recommended that DYNACAZ MR be taken with breakfast.
If a dose is forgotten, the dose taken on the next day should not be increased. The dose should be adjusted according to the individual patient's metabolic response (blood glucose levels and/or glycosylated haemoglobin $HbA_{1c}$).

**Initial dose:**
The initial recommended dose is 30 mg once daily, taken with breakfast.

**Dose adjustments:**
If fasting blood glucose levels have not decreased satisfactorily, the dosage can be increased progressively to 60, 90 or 120 mg per day, by successive increments, respecting an interval of at least one month between each increment, except in patients whose blood glucose levels have not decreased after 15 days of treatment. In this case, the dosage may be increased at the end of the $2^{nd}$ week of treatment.
The daily dose should not exceed 120 mg. Previously untreated patients should commence with a dose of 30 mg. One DYNACAZ 60 mg MR sustained release tablet is equivalent to two DYNACAZ 30 mg MR release tablets.

**Replacement of gliclazide 80 mg with DYNACAZ MR:**
In patients stabilised on gliclazide 80 mg, the replacement of gliclazide 80 mg by DYNACAZ MR may initially be based on: 1 tablet gliclazide 80 mg = 1 x 30 mg tablet of DYNACAZ MR.

**Replacement of another sulphonylurea with DYNACAZ MR:**
For replacement of another sulphonylurea treatment with DYNACAZ MR, it is recommended that the dosage and the half-life of the previous oral hypoglycaemic medicine must be taken into account.

If a patient is changed from another oral sulphonylurea with a prolonged half-life, a therapeutic window of a few days may prove to be necessary to avoid the additive effect of the two products and the subsequent risk of hypoglycaemia. During such a changeover, it is recommended that the initiation of treatment be the same as for the initial DYNACAZ MR dosage, starting with daily doses of 30 mg per day and then increase the dosage by increments, according to the patient's metabolic response.

**Association with other oral antidiabetic medicines:**
DYNACAZ MR may be given concurrently with alpha glucosidase inhibitors or insulin; however, diabetic control should be checked with blood sugar readings because of the possibility of hypoglycaemia. In combined therapy with biguanides, there may be an increased risk of cardiovascular mortality than with the use of DYNACAZ MR alone.

**Special populations**
**Elderly patients:**
The dosage is identical to that recommended for adults under the age of 65 years, and for patients with normal renal function, with careful patient monitoring.

**Patients with mild to moderate renal failure (creatinine clearance 30 - 80 mL/min):**
A reduction in dosage may be necessary in patients with renal dysfunction.
The dosage is identical to that recommended for patients with normal renal function, with careful monitoring. Use of DYNACAZ MR is contraindicated in patients with severe renal impairment (see section 4.3).

**Patients at risk of hypoglycaemia:**
It is recommended that the minimum starting dose of 30 mg is used in these patients (see section 4.4).

**Paediatric population**
The safety and efficacy of DYNACAZ MR in children and adolescents have not been established. No data is available.

**Method of administration**
It is recommended that the tablet(s) be swallowed whole.

**4.3 Contraindications**
- hypersensitivity to gliclazide, sulphonylureas, sulphonamides or to any of the ingredients of DYNACAZ MR
- type 1 diabetes mellitus (Juvenile Insulin Dependent Diabetes Mellitus), diabetic ketoacidosis, diabetic pre-coma and coma
- severe renal or hepatic insufficiency, in these cases the use of insulin is recommended
- treatment with miconazole (see section 4.5)
- children
- pregnancy and lactation (see section 4.6).

**4.4 Special warnings and precautions for use**
***Increased risk of cardiovascular mortality:***
The administration of oral hypoglycaemics may be associated with increased cardiovascular mortality, as compared to treatment with diet alone or diet with insulin.

| A reduction in dosage may be necessary in patients with mild to moderate renal dysfunction (see sections 4.2 and 4.3). |
|---|

Clinical signs of a still insufficiently lowered blood glucose (i.e. hyperglycaemia, polyuria, polydipsia, dry mouth) may require dose adjustment of DYNACAZ MR.

***Hypoglycaemia:***
Hypoglycaemia may occur following administration of sulphonylureas including DYNACAZ MR (see section 4.8). Some cases may be severe and prolonged. Hospitalisation may be necessary and glucose administration may need to be continued for several days.

Careful selection of patients, of the dose used, and clear patient directions are necessary to reduce the risk of hypoglycaemic episodes.
The administration of oral hypoglycaemics such as DYNACAZ MR may be associated with increased cardiovascular mortality as compared to treatment with diet alone or diet with insulin.

Treatment with DYNACAZ MR can cause hypoglycaemia if mealtimes are irregular and, in particular, if meals are skipped. Possible symptoms of hypoglycaemia are: headache, intense hunger, nausea, vomiting, lassitude, sleep disorders, agitation, aggression, poor concentration, reduced awareness and slowed reactions, depression, confusion, visual and speech disorders, aphasia, tremor, paresis, sensory disorders, dizziness, feeling of powerlessness, loss of self-control, delirium, convulsions, shallow respiration, bradycardia, drowsiness, and loss of consciousness, possibly resulting in coma and lethal outcome.
In addition, signs of adrenergic counter-regulation may be observed, sweating, clammy skin, anxiety, tachycardia, hypertension, palpitations, angina pectoris and cardiac dysrhythmia.
Usually, symptoms disappear after intake of carbohydrates (sugar), however, artificial sweeteners have no effect. Experience with other sulphonylureas shows that hypoglycaemia can recur even when measures prove effective initially.
If a hypoglycaemic episode is severe, or is prolonged, and even if it is temporarily controlled by intake of sugar, immediate medical treatment or even hospitalisation is required.

In the initial weeks of treatment, the risk of hypoglycaemia may be increased and careful monitoring is necessary. At risk patients and/or factors favouring hypoglycaemia include: (see section 4.2)
- patients refusing or (particularly elderly patients) being unable to co-operate
- patients who are malnourished or undernourished, with irregular mealtimes, skipping meals, periods of fasting or dietary changes
- imbalance between physical exercise and carbohydrate intake
- certain endocrine disorders: thyroid disorders, hypopituitarism and adrenocorticotrophic insufficiency, which should be controlled appropriately before therapy starts
- withdrawal of prolonged and/or high dose corticosteroid treatment
- severe vascular disease (severe coronary heart disease, severe carotid impairment, diffuse vascular disease)
- severe hepatic disease
- renal insufficiency
- concomitant administration of certain other medicines (see section 4.5)
- overdose of DYNACAZ MR.

It is recommended that the minimum starting dose of 30 mg be used.

DYNACAZ MR should be prescribed only if the patient is likely to have a regular food intake (including breakfast). It is important to have a regular carbohydrate intake due to the increased risk of hypoglycaemia, if a meal is taken late, if an inadequate amount of food is consumed or, if the food is low in carbohydrate. Hypoglycaemia is more likely to occur during low-calorie diets, following prolonged or strenuous exercise, alcohol intake or if a combination of hypoglycaemic medicine is being used.

In an exceptional stress situation e.g. trauma, fever, infection or surgical intervention, blood glucose regulation may deteriorate, and a temporary change to insulin may be necessary to maintain good metabolic control.

Gastrointestinal side effects can be avoided if DYNACAZ MR is taken with breakfast.
Hepatobiliary symptoms may disappear after discontinuation of treatment. Discontinue treatment if cholestatic jaundice appears.

Beta-blockers may decrease the efficacy of DYNACAZ MR by impairing the release of insulin. Beta-blockers may mask the typical sympathomimetic warning signs and symptoms of hypoglycaemia and may inhibit the normal physiological response to hypoglycaemia.

**Patient information:**
The risk of hypoglycaemia, together with its symptoms (see section 4.8), treatment and conditions that predispose to its development, should be explained to the patient and to family members. The patient should be informed of the importance of following dietary advice, of taking regular exercise and of regular monitoring of blood glucose levels.

**Poor blood glucose control:**
Blood glucose control may deteriorate under certain conditions, despite compliance from the patient. This occurs with exceptional stressors like fever, trauma, infection, surgery and febrile illnesses as well as St. John's Wort *(hypericum perforatum)* preparations (see section 4.5). Under these circumstances, it is prudent to convert the patient to insulin therapy temporarily to maintain good metabolic control.

The hypoglycaemic efficacy of DYNACAZ MR may be attenuated over time in many patients. This may be due to progression in the severity of the diabetes, or to a reduced response to treatment. This phenomenon is known as secondary failure which is distinct from primary failure, when an active substance is ineffective as first-line treatment. Adequate dose adjustment and dietary compliance should be considered before classifying the patient as secondary failure.

***Dysglycaemia:***
Disturbances in blood glucose, including hypoglycaemia and hyperglycaemia have been reported, in diabetic patient receiving concomitant treatment with fluoroquinolones, especially in elderly patients. Careful monitoring of blood glucose is recommended in all patients receiving DYNACAZ MR and a fluoroquinolone together.

***Renal and hepatic insufficiency:***
The pharmacokinetic and/or pharmacodynamic properties of DYNACAZ MR may be altered in patients with hepatic insufficiency or severe renal failure. A hypoglycaemic episode occurring in these patients may be prolonged, so appropriate management should be initiated.

***Skin reactions:***
There is a potential for the occurrence of erythema multiforme, toxic dermal necrolysis and allergic vasculitis.

***Laboratory tests:***
Measurement of glycosylated haemoglobin levels (for fasting venous plasma glucose) is recommended in assessing blood glucose control.
Blood glucose self-monitoring may also be useful.
Treatment of patients with G6PD-deficiency with sulphonylurea agents can lead to haemolytic anaemia. Since gliclazide belongs to the chemical class of sulfonylurea medicines, caution should be used in patients with G6PD-deficiency and a non-sulfonylurea alternative should be considered.

***Lactose:***
DYNACAZ 30/60/90 mg MR contain 73,50 mg, 93,40 mg and 140, 10 mg lactose monohydrate per tablet, respectively. This should be taken into account in patients with diabetes mellitus. Patients with the rare hereditary conditions of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take DYNACAZ MR.

**Paediatric population**
The safety and efficacy of DYNACAZ MR in children has not been established (see section 4.3).

**4.5 Interaction with other medicines and other forms of interaction**
**Hypoglycaemia may occur with concomitant use of DYNACAZ MR and the following medicines:**

***Combination which is contraindicated:***
Miconazole (systemic route, oromucosal gel) – increases the hypoglycaemic effect with possible onset of hypoglycaemic symptoms, or even coma and is therefore contraindicated (see section 4.3).

***Combinations which are not recommended:***
*Phenylbutazone* (systemic route) – increases the hypoglycaemic effect of sulphonylureas (displaces their binding to plasma proteins and/or reduces their elimination). It is preferable to use a different anti-inflammatory medicine, or else to warn the patient and emphasise the importance of self-monitoring. Where necessary, adjust the dose during and after treatment with the anti-inflammatory medicine.
*Alcohol* – increases the hypoglycaemic reaction (by inhibiting compensatory reactions) that can lead to the onset of hypoglycaemic coma. Avoid alcohol or medicines containing alcohol.

***Combinations requiring precautions during use:***
Potentiation of the blood glucose lowering effect and thus, in some instances, hypoglycaemia may occur when one of the following medicines is taken:
- anabolic steroids and androgens
- angiotensin-converting enzyme inhibitors: captopril and enalapril
- antidysrhythmics: disopyramide
- antibacterials: chloramphenicol, sulphonamides, fluoroquinolone antibiotics, tetracyclines, clarithromycin
- antidepressants and monoamine-oxidase inhibitors: fluoxetine
- appetite suppressants: fenfluramine
- azole antifungals: ketoconazole, itraconazole, voriconazole, fluconazole (systemic route, oral gel)
- H2 receptor antagonists – cimetidine and ranitidine
- fibrates: clofibrate
- insulin and other oral antidiabetic medicines (acarbose, metformin, thiazolidinediones, dipeptidyl peptidase-4 inhibitors, GLP-1 receptor agonists)
- salicylates or Non-steroidal anti-inflammatory medicines (NSAIDs)
- sulphinpyrazone
- sulphonamides.

Sympatholytic medicines (e.g. beta-blockers, clonidine) may blunt the signs of adrenergic response to hypoglycaemia, as well as impair mechanisms that control the normal physiological response to a fall in blood glucose, thereby increasing the risk of a severe hypoglycaemic reaction.

**Hyperglycaemia may occur with concomitant use of DYNACAZ MR with the following:**
***Combination which is not recommended:***
Danazol – diabetogenic effect of danazol. If the use of gliclazide, as in DYNACAZ MR, cannot be avoided, warn the patient and emphasise the importance of urine and blood glucose monitoring. It may be necessary to adjust the dose of DYNACAZ MR during and after treatment with danazol.

***Combinations requiring precautions during use:***
- epinephrine (adrenaline) and other sympathomimetic medicines
- corticosteroids
- calcium channel blocking medicines
- phenothiazines, chlorpromazine (neuroleptic medicine): high doses (> 100 mg/day) increase blood glucose levels (reduced insulin release)
- clonidine
- diazoxide, parenteral
- diuretics
- ephedrine, pseudoephedrine and common cold products
- glucagon
- glucocorticoids (systemic and local route: intra-articular, cutaneous and rectal preparations) and tetracosactrin: increase in blood glucose levels with possible ketosis
- isoniazid
- lithium
- oestrogens and progesterones
- phenytoin
- rifampicin
- thyroid hormones
- St John's Wort *(hypericum performatum)* preparations: Gliclazide exposure is decreased by St John's Wort. Emphasise the importance of blood glucose level monitoring
- ritodrine, salbutamol, terbutaline (I.V.) and other beta-adrenergic medicines: increased blood glucose levels due to beta-2 agonist effects. Emphasise the importance of monitoring blood glucose levels. If necessary, switch to insulin.

***Combinations which must be taken into account:***
- barbiturates may prolong the effect of DYNACAZ MR.

**The following products may cause dysglycaemia:**
***Combinations requiring precautions during use:***
*Fluoroquinolones:* in case of a concomitant use of DYNACAZ MR and a fluoroquinolone, the patient should be warned of the risk of dysglycaemia, and the importance of blood glucose monitoring should be emphasised.

*Anticoagulant therapy (coumarin derivatives such as warfarin):* DYNACAZ MR may lead to weakening or potentiation of anticoagulation during concurrent treatment. Adjustment of the anticoagulant may be necessary and INR should be monitored.

**4.6 Fertility, pregnancy and lactation**
**Pregnancy**
Safety and efficacy in pregnancy has not been established (see section 4.3).

**Breastfeeding**
Safety and efficacy in lactation has not been established (see section 4.3).

**Fertility**
No effect on fertility or reproductive performance has been reported.

**4.7 Effects on ability to drive and use machines**
DYNACAZ MR has no, or negligible influence, however, alertness and reactions may be impaired by hypo- or hyperglycaemia, especially when initiating treatment or altering doses. This may affect the ability to drive or operate machinery.

**4.8 Undesirable effects**
**a). Summary of the safety profile**
The most frequent adverse reaction with DYNACAZ MR is hypoglycaemia – especially if mealtimes are irregular and, in particular, if meals are skipped.

Hypoglycaemia may range from mild to severe and life threatening with possible symptoms that may include: headache, intense hunger, nausea, vomiting, lassitude, sleep disorders, sleepiness, nightmares, agitation, aggression, poor concentration, reduced awareness and slowed reactions, restlessness, depression, delirium, apathy, confusion, visual and speech disorders, slurred speech, aphasia, seizures, tremor, paresis, sensory disorders, dizziness, feeling of powerlessness, behavioural changes that mimic drunkenness, loss of self-control, convulsions, shallow respiration, bradycardia, drowsiness, loss of consciousness, coma, adrenergic counter-regulation (cold sweats, sweating, clammy skin, anxiety, tremor, tachycardia, hypertension, palpitations, angina pectoris, cardiac dysrhythmia).
Usually, symptoms disappear after intake of carbohydrates (sugar). However, artificial sweeteners have no effect. Experience with other sulfonylureas shows that hypoglycaemia can recur even when measures prove effective initially (see section 4.4).
If a hypoglycaemic episode is severe or prolonged, even if temporarily controlled by the intake of sugar, immediate medical treatment or hospitalisation is required.

**b). Tabulated summary of adverse reactions**

| System Organ Class | Frequency | Side effects |
|---|---|---|
| **Blood and lymphatic system disorders** | *Less frequent* | Leukopenia, thrombocytopenia, aplastic or haemolytic anaemia, agranulocytosis, pancytopenia, eosinophilia, blood dyscrasias, granulocytopenia, erythrocytopenia |
| **Immune system disorders** | *Less frequent* | Rash, allergic vasculitis |
| **Endocrine disorders** | *Less frequent* | Hypoglycaemia |
| **Metabolism and nutrition disorders** | *Less frequent* | Hyponatraemia, anorexia |
| **Nervous system disorders** | *Frequent* | Headache, dizziness, drowsiness |
| **Eye disorders** | *Less frequent* | Blurred vision and/or changes in accommodation |
| **Gastrointestinal disorders** | *Frequent* | Constipation, diarrhoea, dyspepsia, flatulence, heartburn, loss of or increase in appetite, weight gain, nausea, stomach pain, fullness or discomfort, vomiting, alterations in sense of taste (metallic taste) |
| **Hepato-biliary disorders** | *Less frequent* | Increased levels of hepatic enzymes (alanine amino-transferase, aspartate amino transferase, alkaline phosphatase), hepatitis, cholestasis, cholestatic jaundice, hepatic function impairment, hepatic porphyria, porphyria cutanea tarda, liver failure |
| **Skin and subcutaneous tissue disorders** | *Frequency unknown* | Erythema multiforme, photosensitivity, pruritus, urticaria and maculopapular rashes, bullous reactions (such as Stevens-Johnson syndrome and toxic epidermal necrolysis), exfoliative dermatitis, erythema nodosum, angioedema, drug rash with eosinophilia and systemic symptoms (DRESS) |
| **Renal and urinary disorders** | *Frequent* | Polyuria |

**c). Description of selected adverse reactions**
Hypoglycaemia may be prevented if mealtimes are regular and, in particular, if no meals are skipped.
Usually, symptoms disappear after intake of carbohydrates (sugar).
If a hypoglycaemic episode is severe or prolonged, and even if it is temporarily controlled by intake of sugar, immediate medical treatment or even hospitalisation are required.

**Reporting of suspected adverse reactions**
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care professionals are asked to report any suspected adverse reactions to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8. An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

**4.9 OVERDOSE**
**Signs and symptoms:**
An overdose of DYNACAZ MR may cause hypoglycaemia which could be severe or prolonged. Moderate symptoms of hypoglycaemia, without any loss of consciousness, or neurological signs must be corrected by carbohydrate intake, dose adjustment and/or modification of diet.

**Management of overdose:**
Treatment is symptomatic and supportive.
Strict monitoring should be continued until the patient is out of danger. Severe hypoglycaemia reactions, with coma, convulsions or other neurological disorders should be treated as a medical emergency, requiring immediate hospitalisation.
If hypoglycaemic coma is diagnosed or suspected, the patient should be given a rapid IV injection of 50 mL of concentrated glucose solution (50 %). This should be followed by continuous infusion of a more dilute solution (10 %), at a rate necessary to maintain blood glucose levels above 5,5 mmol/L. Patients should be monitored closely, long enough to make sure that hypoglycaemia will not re-occur, and, depending on the patient's condition, the doctor will decide if further monitoring is necessary. Dialysis is of no benefit in these patients due to strong binding of gliclazide to proteins.

**5. PHARMACOLOGICAL PROPERTIES**
**5.1 Pharmacodynamic properties**
Pharmacotherapeutic group: Sulfonamides, urea derivative
ATC code: A10BB09
Pharmacological classification: A 21.2 Oral Hypoglycaemics

**Mechanism of action:**
Gliclazide, a second-generation sulphonylurea, lowers blood glucose concentrations by stimulating insulin release from pancreatic beta cells. In addition to this pancreatic action, it has been demonstrated that gliclazide administration may improve the metabolic utilisation of glucose at peripheral level.

**5.2 Pharmacokinetic properties**
**Absorption:**
Following oral administration, gliclazide is readily absorbed from the gastrointestinal tract. Food intake does not affect the rate or degree of absorption.
Maximum serum concentrations of gliclazide are reached approximately 6 hours after oral administration. Its effect is dose-dependent over the dosage range of 30 to 120 mg.

**Distribution:**
Gliclazide has very high plasma protein binding (~ 95 %).
The volume of distribution is around 30 litres.
A single dose of gliclazide maintains glucose lowering effects over 24 hours.

**Biotransformation:**
Gliclazide is mainly metabolised in the liver and excreted in the urine, less than 1 % of the unchanged form is found in the urine. No active metabolites have been detected in plasma.

**Elimination:**
The elimination half-life of gliclazide varies between 12 and 20 hours.

**Linearity/non-linearity:**
The relationship between the dose administered ranging up to 120 mg and the area under the concentration time curve is linear.

**Pharmacokinetics in special patient groups**
Elderly:
No clinically significant changes in pharmacokinetic parameters have been observed in elderly patients.

**5.3 Preclinical safety data**
Preclinical data reveal no special hazards for humans based on conventional studies of repeated dose toxicity and genotoxicity. Long term carcinogenicity studies have not been done. No teratogenic changes have been shown in animal studies, but lower foetal body weight was observed in animals receiving doses 25-fold higher than the maximum recommended dose in humans. Fertility and reproductive performance were unaffected after gliclazide administration in animal studies.

**6. PHARMACEUTICAL PARTICULARS**
**6.1 List of excipients**
**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.

**6.2 Incompatibilities**
Not applicable.

**6.3 Shelf life**
36 months
Store at or below 30 °C in a dry place. Protect from light.
Keep the blister in the carton until required for use.

**6.4 Special precautions for storage**
This medicine does not require any special storage conditions.

**6.5 Nature and contents of container**
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 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.

**6.6 Special precautions for disposal**
No special precautions required.

**7. HOLDER OF THE CERTIFICATE OF REGISTRATION**
Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, Cape Town
7945, South Africa

**8. REGISTRATION NUMBER(S)**
DYNACAZ 30 mg MR: A42/21.2/0249
DYNACAZ 60 mg MR: A48/21.2/1194
DYNACAZ 90 mg MR: A53/21.2/0083

**9. DATE OF FIRST AUTHORISATION**
DYNACAZ 30 mg MR: 11 November 2011
DYNACAZ 60 mg MR: 15 June 2021
DYNACAZ 90 mg MR: 15 June 2021

**10. DATE OF REVISION OF THE TEXT**
15 June 2021

| DYNACAZ 30 mg MR Namibia: |
|---|
| NAM: NS2 12/21.2/0110 |



**PATIENT INFORMATION LEAFLET**

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

**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 ($HbA_{1c}$) 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 healthcare 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 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.

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) increases the risk of (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. 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 90 mg MR 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, pharmacist or nurse. You can also report any 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 (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 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**
Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, Cape Town
7945, South Africa
Tel: +27 21 707 7000
https://www.mydynamics.co.za/

**This leaflet was last revised in**
15 June 2021

**Registration number**
DYNACAZ 30 mg MR: A42/21.2/0249
DYNACAZ 60 mg MR: A48/21.2/1194
DYNACAZ 90 mg MR: A53/21.2/0083

| DYNACAZ 30 mg MR Namibia: |
|---|
| NAM: NS2 12/21.2/0110 |



**PASIËNTINLIGTINGSBLAD**

**SKEDULERINGSTATUS** S3

**DYNACAZ 30 mg MR gewysigde vrystellingstablette**
**DYNACAZ 60 mg MR gewysigde vrystellingstablette**
**DYNACAZ 90 mg MR gewysigde vrystellingstablette**

**Gliklasied**

**DYNACAZ 30 mg MR bevat suiker (73,50 mg laktosemonohidraat per tablet)**
**DYNACAZ 60 mg MR bevat suiker (93,40 mg laktosemonohidraat per tablet)**
**DYNACAZ 90 mg MR bevat suiker (140,10 mg laktosemonohidraat per tablet)**

**Lees hierdie hele inligtingsblad deeglik deur, voordat u begin om DYNACAZ MR te neem**
- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees
- Indien u verdere vrae het, vra asseblief u dokter, apteker, verpleegkundige, of ander gesondheidsorgverskaffer
- DYNACAZ MR is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit mag skadelik wees vir hulle, selfs al is hulle simptome dieselfde as u eie.

**Wat hierdie inligtingsblad bevat**
1. Wat DYNACAZ MR is en waarvoor dit gebruik word
2. Wat u nodig het om te weet, voordat u DYNACAZ MR gebruik
3. Hoe om DYNACAZ MR te gebruik
4. Moontlike newe-effekte
5. Hoe om DYNACAZ MR te bewaar
6. Inhoud van die verpakking en ander inligting

**1. Wat DYNACAZ MR is en waarvoor dit gebruik word**
DYNACAZ MR bevat gliklasied en behoort aan 'n groep medisyne, wat sulfonielureum antidiabetiese medisyne, genoem word. Dit word gebruik om 'n sekere tipe diabetes mellitus genoem tipe 2 diabetes by volwassenes te behandel, wanneer dieet, oefening en gewigsverlies alleen nie 'n voldoende uitwerking op die behoud van bloedsuiker op die korrekte vlak het nie.
Indien u tipe 2 diabetes het, mag die hoeveelheid insulien, wat deur u pankreas vervaardig word, nie genoeg wees, of nie behoorlik deur u liggaam gebruik word nie en u mag steeds meer benodig. DYNACAZ MR werk deur u pankreas te stimuleer om meer insulien in die bloedstroom vry te laat.

**2. Wat u nodig het om te weet, voordat u DYNACAZ MR neem**
**Moet nie DYNACAZ MR neem:**
- indien u hipersensitief (allergies) is vir gliklasied, sulfonielureums (medisyne vir diabetes), sulfoonamiede ('n tipe antibiotikum), of vir enige van die ander bestanddele van DYNACAZ MR (kyk afdeling 6)
- indien u tipe 1 diabetes mellitus het nie (tipe 1 diabetes pasiënte, kan nie insulien vervaardig of vrystel vanuit die pankreas nie)
- indien u ketoonliggaampies en suiker in u uriene het nie (dit mag beteken dat u diabetiese keto-asidose het), 'n diabetiese pre-koma, of koma
- indien u 'n lewersiekte het nie
- indien u 'n niersiekte het nie
- indien u 'n medisyne, om swaminfeksies te behandel (genaamd mikonasool), neem nie (kyk Ander medisyne en DYNACAZ MR)
- indien u 'n kind is nie, aangesien die veiligheid van DYNACAZ MR nie vir kinders nagevors is nie
- indien u swanger is of u baba borsvoed nie.

**Waarskuwings en voorsorgmaatreëls**
**Neem spesiale sorg met DYNACAZ MR:**
Voordat u DYNACAZ MR neem, raadpleeg u dokter. U moet die voorgestelde behandelingsplan, soos deur u dokter aanbeveel is, volg om gepaste bloedsuikervlakke te bereik. Dit beteken, behalwe vir gereelde tabletinname, om 'n dieetplan te volg, gereeld te oefen en waar nodig, gewig te verloor.

Gereelde monitering van u bloed (en moontlik uriene), suikervlakke en ook geglikoleerde hemoglobien ($HbA_{1c}$), word benodig tydens DYNACAZ MR behandeling.

Tydens die aanvangsweke van behandeling, mag die risiko vir lae bloedsuiker toeneem en noukeurige observasie word aanbeveel. Voortdurende, of ernstige gevalle van hipoglisemie (lae bloedsuiker), selfs al word dit beheer deur suikerinname, vereis onmiddellike mediese behandeling, of selfs hospitalisasie.

Lae bloedsuiker (hipoglisemie) mag voorkom:
- indien u 'n pasiënt is, veral bejaard, wat nie in staat is om saam te werk nie
- indien u nie maaltye op vasgestelde intervalle eet nie, of maaltye algeheel oorslaan
- indien u vas
- indien u ondervoed is
- indien u u dieet verander
- indien u fisiese aktiwiteit verhoog en u koolhidraatinname kom nie ooreen met hierdie verhoging nie
- indien u 'n beduidende hoeveelheid alkohol inneem, veral wanneer maaltye oorgeslaan word
- indien u aan enige erge, abnormale toestand van die bloedvate ly (arteries en are), insluitend erge hartsiekte
- indien u tans hoë doserings kortikosteroïede neem (gebruik vir pyn en inflammasie), of dit onlangs gestaak het
- indien u ly aan spesifieke hormoon-geïnduseerde versteurings (funksionele versteurings van die skildklier, of die pituïtêre klier, of adrenale korteks)
- indien u nier- of lewerfunksie erg belemmer is
- indien u ander medisyne, of natuurlike middels op dieselfde tydstip neem
- indien u 'n oordosis DYNACAZ MR neem.

Indien u lae bloedsuiker het, mag u die volgende simptome hê:
hoofpyn, intense honger, naarheid, braking, traagheid, slaapversteurings, rusteloosheid, aggressiwiteit, swak konsentrasievermoë, afname in waaksaamheid, en reaksietyd, depressie, verwarring, spraak-, of sigsteurings, tremor, sensoriese versteurings, duiseligheid en hulpeloosheid.

Die volgende tekens en simptome mag ook voorkom: sweet, klammerige vel, angstigheid, vinnige, of onreëlmatige hartklop, hoë bloeddruk, skielike, intense pyn in die bors, wat mag versprei na nabygeleë areas (angina pectoris).

Indien u bloedsuikervlakke aanhou val, mag u ly aan beduidende verwarring (delirium), konvulsies ontwikkel, selfbeheer verloor, u asemhaling mag vlak voorkom en u hartklop stadiger word. U mag u bewussyn verloor.

In meeste gevalle verdwyn lae bloedsuiker simptome baie vinnig sodra u enige vorm van suiker inneem, bv. glukose tablette, suikerblokkies, soet sap, of versoete tee. Onthou kunsmatige versoeters is nie doeltreffend nie. U moet dus altyd 'n vorm van suiker by u hou (glukose tablette of suikerblokkies). Raadpleeg asseblief u dokter of die naaste hospitaal, indien suikerinname nie help nie, of simptome weer voorkom.

Om die moontlikheid van gastroïntestinale newe-effekte te verhoed (kyk Newe-effekte), moet u die tablette saam met ontbyt neem.
Sou u enige newe-effekte ervaar wat die lewer beïnvloed, mag die dokter u medisyne verander.

Indien u 'n familiegeskiedenis het, of u is bewus van die feit dat u die oorerflike toestand genaamd glukose-6-fosfaatdehidrogenase (G6PD) tekort (abnormaliteit van rooibloedselle) het, mag 'n afname in hemoglobienvlakke en afbraak van rooibloedselle (hemolitiese anemie), voorkom. Kontak u dokter, voordat u DYNACAZ MR neem.

Simptome van lae bloedsuiker mag afwesig wees, minder opvallend wees, of baie stadig ontwikkel, of u mag nie betyds opmerk dat u bloedsuikervlakke gedaal het nie. Dit mag voorkom indien u 'n bejaarde pasiënt is wat sekere medisyne neem (veral die wat op die sentrale senuweestelsel werk en beta-blokkers).

Dit is belangrik dat u, u eie simptome van lae bloedsuiker besef, sodat u dit vinnig kan behandel. U moet ook u familielede omtrent die simptome van hipoglisemie inlig, asook hoe om dit te behandel.

Simptome van hoë bloedsuiker (hiperglisemie) mag voorkom, indien gliklasied nog nie die bloedsuiker doeltreffend verlaag het nie, wanneer u nie die behandelingsplan, soos aanbeveel deur u dokter, nagekom het nie, indien u Johanneskruid-middels neem *(hypericum perforatum)*, of u onder spesifieke stres-toestande verkeer. Indien u onder 'n stres-situasie verkeer (ongelukke, chirurgiese operasies, koors ens.), mag u dokter u tydelik na insulienbehandeling oorskakel.

Simptome van hoë bloedsuiker mag dors, gereelde urinering, droë mond, droë, jeukerige vel, velinfeksies en vermindering in aktiwiteit, insluit.
U moet u gesondheidsorgverskaffer, of apteker kontak, indien hierdie simptome voorkom.

Die uitwerking van DYNACAZ MR mag oor lang tydperke, verminder. U dokter mag u dosis verhoog en aanbeveel dat u bloedsuikervlakke meer gereeld gemonitor word.

Bloedglukoseversteurings (lae bloedsuiker en hoë bloedsuiker) mag voorkom, indien DYNACAZ MR op dieselfde tydstip as medisyne wat behoort aan 'n klas antibiotika, genaamd fluoorkinolone geneem word, veral by bejaarde pasiënte. In hierdie geval, sal u dokter u herinner aan die noodsaaklikheid van die monitering van u bloedglukose.

Daar is 'n moontlikheid vir die ontwikkeling van ernstige veltoestande (toksiese dermale nekrolise en allergiese vaskulitis). Simptome sluit 'n pynlike, rooi area, wat vinnig versprei, velafskilfering, sonder blasievorming, rou areas op die vel, ongemak, koors, perskleurige kolletjies en vlekke op die vel, blase, jeukbulte en oop sere, in.
U dokter mag toetse aanvra, om u toestand voor en tydens behandeling te monitor.

Die veiligheid en doeltreffendheid van DYNACAZ MR in kinders, is nie vasgestel nie (kyk Moet nie DYNACAZ MR neem).

**Ander medisyne en DYNACAZ MR**
Vertel altyd u gesondheidsorgverskaffer, indien u enige ander medisyne neem (dit sluit aanvullende, of tradisionele medisyne in).

Die volgende medisyne verhoog die risiko vir hipoglisemie, of selfs koma en moet dus nie gebruik word nie:
- 'n medisyne wat mikonasool bevat (gebruik om swaminfeksies te behandel), verhoog die risiko vir hipoglisemie (kyk Moet nie DYNACAZ MR neem).

Die volgende medisyne, of middels mag veroorsaak dat u bloedsuikervlakke selfs na onder normaal daal, wanneer dit saam met DYNACAZ MR geneem word en word dus nie aanbeveel vir gebruik nie:
- fenielbutasoon (gebruik om pyn en inflammasie te behandel)
- alkohol verhoog die risiko vir hipoglisemie (lae bloedsuiker) en koma. Alkohol en medisyne wat alkohol bevat, moet vermy word.

Die bloedsuiker-verlagende uitwerking van DYNACAZ MR mag versterk word en tekens van lae bloedsuikervlakke mag voorkom, indien een van die volgende medisyne geneem word:
- sulfienpirasoon (anti-jig medisyne)
- anaboliese steroïede ('n steroïedhormoon wat spiergroei bevorder) en androgene (manlike geslagshormone)
- sekere medisyne om hoë bloeddruk, of hartsiekte te behandel, wat AOE-inhibitors genoem word (kaptopril, enalapril, kinidien, kinien en klonidien) en antidisritmiese middels (disopiramied)
- medisyne om hoë bloeddruk, of hartversaking te behandel (beta-blokkers, AOE-inhibitors soos kaptopril of enalapril)
- antibiotika (chlooramfenikol, sulfoonamiede, kinolone, tetrasikliene, klaritromisien)
- sekere antidepressante soos fluoksetien (monoamienoksidase-inhibitor)
- sekere medisyne wat gebruik word om swaminfeksies te behandel, soos ketokonasool, itrakonasool, vorikonasool, flukonasool
- die eetlusdemper, fenfluramien
- ranitidien en simetidien (medisyne wat gebruik word om sooibrand te behandel)
- fibrate (soos klofibraat), wat gebruik word om hoë cholesterol te behandel
- insulien en ander orale antidiabetiese medisyne (soos akarbose, metformien, tiasolediendione, GLP-1-reseptor-inhibitors)
- sekere medisyne wat gebruik word om pyn en inflammasie te behandel (NSAIMs en salisilate)
- beta-blokkers (gebruik om hartritme te beheer, angina te behandel en hoë bloeddruk te verlaag) mag die moontlikheid dat hoë of lae bloedsuikervlakke voorkom, verhoog. Dit mag ook die simptome van lae bloedsuiker verskans.

Die bloedglukose-verlagende uitwerking van gliklasied, mag verswak en 'n verhoging in bloedsuikervlakke mag voorkom, indien een van die volgende medisyne saam met DYNACAZ MR geneem word:
- danasol, wat gebruik word om borsteversteurings, swaar menstruele bloeding en endometriose te behandel, word nie aanbeveel vir gebruik saam met DYNACAZ MR nie. Indien dit nie vermy kan word nie, moet gereelde urien- en bloedglukosemonitering gedoen word. Dit mag nodig wees om u DYNACAZ MR dosis, aan te pas.
- epinefrien (adrenalien), asma medisyne (salbutamol, terbutalien), hoes- en verkouemedisyne wat efedrien en pseudoefedrien bevat
- kortikosteroïede (kortisoon-tipe medisyne, wat gebruik word om inflammasie te behandel)
- kalsiumkanaal-blokkers, klonidien, diasoksied (kardiovaskulêre medisyne, om hartprobleme te behandel)
- chloorpromasien (kalmeermiddel, of sedeermiddel, wat ook gebruik word vir naarheid en braking)
- litium (gebruik om sekere tipes depressie te behandel)
- tiasied diuretika (watertablette)
- anti-epileptiese medisyne, soos fenitoïen
- glukagon ('n hormoon wat bydra tot die afbraak van glikogeen na glukose)
- vroulike hormone, estrogeen en progesteroon
- antibakteriële medisyne, rifampisien en isoniasied
- tiroïedhormone
- glukokortikosteroïede (word gebruik om die liggaam te help om koolhidrate, proteïene en vette, af te breek)
- medisyne wat gebruik word om asma te behandel, of gebruik word tydens kraam (intraveneuse salbutamol, ritodrien en terbutalien).

Bloedglukoseversteuring (lae bloedsuiker en hoë bloedsuiker) mag voorkom wanneer 'n medisyne, wat aan die klas antibiotika wat fluoorkinolone genoem word, behoort, op dieselfde tydstip as DYNACAZ MR, veral by bejaarde pasiënte, geneem word.

DYNACAZ MR kan die effek van anti-koagulante (bloedverdunners: medisyne wat die moontlikheid van bloedklonte verminder bv. warfarien) verhoog. Dit mag nodig wees om u dosis van anti-koagulante (bloedverdunners) aan te pas.

**DYNACAZ MR saam met kos en drinkgoed**
DYNACAZ MR moet saam met kos geneem word. Die tablet moet heel, saam met 'n halwe glas water, onmiddellik voor 'n vullende ontbyt, of die eerste hoofmaaltyd van die dag, geneem word. U moet nie 'n maaltyd oorslaan, nadat u die tablette geneem het nie.
Alkoholinname word nie aanbeveel nie, aangesien dit die beheer van diabetes op 'n onvoorspelbare wyse mag verander.

**Swangerskap, borsvoeding en fertiliteit**
Indien u swanger is, of u baba borsvoed, dink u is swanger of beplan om 'n babe te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffervir advies, voordat u DYNACAZ MR neem.
U moet nie hierdie medisyne neem, indien u swanger is, of u baba borsvoed nie (kyk Moet nie DYNACAZ MR neem).

**Bestuur en die hantering van masjiene**
Waaksaamheid en reaksies mag belemmer word deur hipo-, of hiperglisemie, veral wanneer behandeling begin word, of doserings aangepas word. U moet bewus wees van die simptome van hipoglisemie (lae bloedsuiker), wat duiseligheid, swak konsentrasievermoë, verwarring en versteurde visie, insluit.
Dit is nie altyd moontlik om te voorspel, tot watter mate DYNACAZ MR met u daaglikse aktiwiteite sal inmeng nie. U moet verseker dat u nie betrokke raak by bogenoemde aktiwiteite, totdat u seker is tot watter mate DYNACAZ MR u beïnvloed nie.

**DYNACAZ MR bevat laktose**
DYNACAZ MR bevat laktose. Indien u dokter aangedui het, dat u 'n onverdraagsaamheid teenoor sekere suikers toon, kontak u dokter, voordat u hierdie medisyne neem.

**3. Hoe om DYNACAZ MR te neem**
Moet nie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem DYNACAZ MR altyd presies soos deur u dokter, of apteker aanbeveel is. Raadpleeg u dokter, of apteker, indien u onseker is.

U dokter sal u vertel vir hoe lank u behandeling met DYNACAZ MR sal duur. Moet nie behandeling vroeg staak nie, aangesien hoë bloedsuikersimptome sal terugkeer. Indien u onder die indruk is dat die uitwerking van DYNACAZ MR té sterk, of té swak is, vertel u dokter of apteker.

U dokter sal op u gepaste dosis besluit, gebaseer op u metaboliese reaksie en bloedsuikervlak. Die tablet moet heel ingesluk word, met 'n halwe glas water, onmiddellik voor 'n vullende ontbyt, of die eerste hoofmaaltyd van die dag (verkieslik op dieselfde tydstip elke dag). Moet nie die tablet kou nie. U moet nie 'n maaltyd oorslaan, nadat u die tablette geneem het nie. DYNACAZ 90 mg MR tablette mag in dele verdeel word, om te verseker dat die medisyne geneem word, soos voorgeskryf deur u dokter.
*Volwassenes:*
Die aanbevole daaglikse dosis is een tot vier tablette van die 30 mg of twee van die 60 mg (maksimum 120 mg) d.i. 30 tot 120 mg geneem as 'n enkeldosis, saam met ontbyt.
U dokter sal die gepaste dosis van elke medisyne individueel vir u bepaal, indien kombinasiebehandeling van DYNACAZ MR saam met metformien, 'n alfa-glukosidase-inhibitor, 'n tiasolidinedioon, 'n dipeptidielpeptidase-4-inhibitor, 'n GLP-1-reseptor-agonis geneem word, of insulienbehandeling begin word.

Dosisaanpassings:
Indien u vastende bloedglukosevlakke nie bevredigend verlaag nie, mag u dokter die dosis geleidelik verhoog na 60, 90 of 120 mg per dag (2 tot 4 tablette van die 30 mg). U dokter sal aanbeveel hoe om u dosis te verhoog, maar die hoeveelheid tablette word gewoonlik verhoog met ten minste een maand tussenposes, tussen elke verhoging.
Die daaglikse dosis moet nie 120 mg oorskry nie.
*Kinders:*
Die veiligheid en doeltreffendheid van DYNACAZ MR in kinders en adolessente is nie vasgestel nie en moet dus nie gebruik word vir kinders nie.

**Indien u meer DYNACAZ MR neem as wat u behoort**
In die geval van 'n oordosering, raadpleeg u dokter of apteker. Indien beide nie beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Simptome van oordosering, mag die volgende insluit:
Lae bloedsuiker (ook hipoglisemie genoem).
Die simptome kan verlig word, deur dadelik suiker (4 tot 6 klontjies) of suikerdrankies te neem, gevolg deur 'n vullende peuselhappie of maaltyd. Indien die pasiënt bewusteloos is, kontak u dokter onmiddellik en ontbied die nooddienste. Dieselfde geld indien iemand, byvoorbeeld 'n kind, die medisyne onopsetlik geneem het.
Bewustelose pasiënte moet nie kos of drankies toegedien word nie.
Verseker dat daar altyd 'n voorafingeligte persoon teenwoordig is, wie 'n dokter kan kontak tydens 'n noodgeval.

**Indien u vergeet om DYNACAZ MR te neem**
Indien u vergeet om DYNACAZ MR te neem, neem die dosis so gou as wat u onthou. Gaan daar voort om DYNACAZ MR op die gewone tydstip te neem. Moet nie 'n dubbel dosis neem, om op te maak vir die vergete, individuele doserings nie.
Dit is belangrik dat u u medisyne elke dag neem, aangesien gereelde behandeling beter werk.

**Indien u die gebruik van DYNACAZ MR staak**
Indien die medisyne gestaak word, mag dit ly tot hoë bloedsuiker (hiperglisemie), wat die risiko vir die ontwikkeling van komplikasies van diabetes, verhoog.

**4. Moontlike newe-effekte**
Nie alle newe-effekte wat vir DYNACAZ MR aangemeld is, word in hierdie inligtingsblad ingesluit nie. Sou u algemene gesondheid versleg, of indien u enige ongewenste effekte ervaar, terwyl u DYNACAZ MR neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van DYNACAZ MR en vertel u dokter onmiddellik, of gaan na die ongevalle afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat sluk en asemhaling mag bemoeilik
- uitslag of gejeuk.

Hierdie is alles baie ernstige newe-effekte. Indien u dit het, kon u 'n ernstige allergiese reaksie teenoor DYNACAZ MR gehad het. U mag dringende mediese aandag of hospitalisasie benodig.

Vertel u dokter onmiddellik, of gaan na die ongevalle afdeling by u naaste hospitaal, indien u enige van die volgende opmerk:
- Stevens-Johnson sindroom, of ander ernstige velversteurings (begin met griep-soortige simptome, gevolg deur 'n pynlike rooi, of perserige uitslag, wat versprei en blasies vorm)
- lae bloedsuikervlakke – hipoglisemie (kyk Neem spesiale sorg met DYNACAZ MR vir die lys van simptome)
- lewerversaking (tekens sluit geel verkleuring van die vel en oë in (geelsug) en pyn in die boonste, regterkantste abdomen)
- nierprobleme (urineer meer as wat normaal is vir u, of meer gereeld).

Hierdie is alles ernstige newe-effekte. U mag dringende mediese aandag benodig.

Vertel u dokter indien u enige van die volgende opmerk:
Newe-effekte wat dikwels voorkom:
- hoofpyn, duiseligheid, lomerigheid
- hardlywigheid, diarree, maagpyn of ongemak, maagspasmas, afname of toename in eetlus, sooibrand, opgeblasenheid, winderigheid (wind), gewigstoename, naarheid, braking, veranderinge in smaaksensasie (metaalsmaak).

Newe-effekte wat minder dikwels voorkom:
- afname in die hoeveelheid bloedselle wat lei tot abnormale bloedtoetsresultate, insluitend anemie
- lae natriumvlakke in die bloed, anoreksia
- versteurde visie, verslegtende sig
- abnormale lewerfunksie (klei-gekleurde stoelgang, donker uriene, gejeuk, aptytverlies, geel oë of vel).

Die volgende newe-effekte is aangemeld, maar die frekwensie van voorkoms, is onbekend:
- galbulte, gejeuk, inflammasie van die vel, uitslag, rooiheid van die vel, ligsensitiwiteit, droë vel, blaasvorming of afskilfering van die vel, verdunning van die vel, bleek vel, ongewone kneusing.

Indien u enige newe-effekte opmerk, wat nie in hierdie inligtingsblad genoem is nie, lig asseblief u dokter of apteker in.

**Aanmelding van newe-effekte**
Indien u newe-effekte ervaar, praat met u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA via die aanlyn skakel rapporteer: https://www.sahpra.org.za/Publications/Index/8
Deur die aanmelding van newe-effekte, kan u help om meer inligting aangaande die veiligheid van DYNACAZ MR in te win. U kan ook 'n epos direk na die maatskappy stuur, pharmacovigilance@pharmadynamics.co.za om veiligheid van die produk te verseker.

**5. Hoe om DYNACAZ MR te bewaar**
Bewaar alle medisyne, buite die bereik van kinders.
Bewaar teen of benede 30 °C op 'n droë plek. Beskerm teen lig.
Hou die stulpstroke in die kartonhouer, totdat dit benodig word vir gebruik.
Moet nie gebruik na die vervaldatum, wat op die kartonhouer aangedui word nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moet nie ongebruikte medisyne in dreine, of rioolstelsels (bv. toilette) weggooi nie.

**6. Inhoud van die verpakking en ander inligting**
**Wat DYNACAZ MR bevat**
Die aktiewe bestanddeel is gliklasied.
DYNACAZ 30 mg MR: Elke gewysigde vrystellingstablet, bevat 30 mg gliklasied.
Elke 30 mg tablet bevat suiker (73,50 mg laktosemonohidraat per tablet).
DYNACAZ 60 mg MR: Elke gewysigde vrystellingstablet bevat 60 mg gliklasied.
Elke 60 mg tablet bevat suiker (93,40 mg laktosemonohidraat per tablet).
DYNACAZ 90 mg MR: Elke gewysigde vrystellingstablet bevat 90 mg gliklasied.
Elke 90 mg tablet bevat suiker (140,10 mg laktosemonohidraat per tablet).

**Die ander bestanddele is:**
DYNACAZ 30 mg MR: Hipromellose, kalsiumkarbonaat, kolloïdale silikoondioksied, laktosemonohidraat, magnesiumstearaat.
DYNACAZ 60 mg MR and DYNACAZ 90 mg MR: Anhidriese kolloïdale silikoon, hipromellose, laktosemonohidraat, magnesiumstearaat.

**Hoe DYNACAZ MR lyk en die inhoud van die verpakking**
DYNACAZ 30 mg MR: Wit, tot naaswit, ovaal, effens bikonvekse skuinskantige tablette (lengte: 11 mm x breedte: 5,5 mm).
DYNACAZ 60 mg MR: Wit tot naaswit, ovaal, bikonvekse tablette van 13 mm.
DYNACAZ 90 mg MR: Wit, tot naaswit, kapsuulvormige, bikonvekse tablette van 17-17,5 mm, met twee groeflyne rondom die tablet.
Die groeflyn is slegs teenwoordig om die tablet gemaklik te breek, vir slukdoeleindes en nie om in gelyke doserings te verdeel nie.

DYNACAZ 30 mg MR tablette word verpak in Aluminium/PVC stulpverpakkings van 10 tablette per stulpstrook; elke gedrukte buitenste kartonhouer bevat 60 tablette.
DYNACAZ 60 mg MR tablette word verpak in helder, OPA/Al/PVC en aluminiumfoelie stulpstroke. 28 (2 x 14) of 30 (2 x 15) tablette word verpak in 'n kartonhouer.
DYNACAZ 90 mg MR tablette word verpak in OPA/Al/PVC en aluminiumfoelie stulpstroke. Stulpstroke van of 30, 60 of 90 tablette word verpak in 'n kartonhouer.

**Houer van die Registrasiesertifikaat**
Pharma Dynamics (Edms) Bpk
1ste Vloer Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, Kaapstad
7945, Suid-Afrika
Tel: +27 21 707 7000
https://www.mydynamics.co.za/

**Hierdie inligtingsblad was voorheen hersien**
15 Junie 2021

**Registrasienommers**
DYNACAZ 30 mg MR: A42/21.2/0249
DYNACAZ 60 mg MR: A48/21.2/1194
DYNACAZ 90 mg MR: A53/21.2/0083

| DYNACAZ 30 mg MR Namibië: |
|---|
| NAM: NS2 12/21.2/0110 |