DYMAZIZ MR

SCHEDULING STATUS S4

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
DYMAZIZ 30 mg MR: Each modified release tablet contains 30 mg gliclazide
Each 30 mg tablet contains approx 125.7 mg lactose monohydrate
DYMAZIZ 60 mg MR: Each modified release tablet contains 60 mg gliclazide
Each 60 mg tablet contains approx 251.4 mg lactose monohydrate
DYMAZIZ 90 mg MR: Each modified release tablet contains 90 mg gliclazide
Each 90 mg tablet contains approx 377.1 mg lactose monohydrate

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Modified release tablets.
DYMAZIZ 30 mg MR: White to almost white, oval, slightly biconvex tablets (length: 11 mm; width: 5.5 mm) with breakline scoring.
DYMAZIZ 60 mg MR: White to almost white, oval, biconvex tablets, scored on both sides (length: 14 mm; width: 7 mm) with breakline, capsule-shaped, biconvex tablets (11 x 7.1 mm) with two sides of breakline scoring. The tablet can be divided into equal halves to facilitate ease of swallowing. Dissolution profiles for gliclazide 60 mg MR tablets are comparable to the dissolution profiles of the 30 mg MR tablets. Dissolution studies in different media at pH 1.2, 4.5 and 7.4, and at the rate of rotation of dissolution paddle were conducted.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications:
DYMAZIZ MR is indicated in type 2 diabetic patients, in association with dietary measures. Dietary changes and exercise, when dietary measures. Dietary and exercise alone are not sufficient to control blood glucose.

4.2 Posology and method of administration
Posology
For adult use only:
DYMAZIZ 30 mg MR: The daily dose may vary from 1 to 4 tablets (e.g. 30, 30 to 120 mg) taken as a single daily dose.
DYMAZIZ 60 mg MR: The daily dose may vary from one half to 2 tablets (e.g. 30 to 120 mg) taken as a single daily dose. Dosing should be adjusted on the basis of blood glucose levels.
In a dose-finding study, the most active dose was the one which produced the maximal effect. The dose should be adjusted according to the individual patient's metabolic response (blood glucose levels and/or glycosylated haemoglobin (HbA1c).
DYMAZIZ 60 mg MR: May be taken as a single dose or combined with a 30 mg tablet for a maximum dose of 150 mg a day.

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 (depending on HbA1c) to 60 mg per day, to a maximum of one tablet, depending on the result of blood glucose levels. Each increment, expect in patients with blood glucose levels have not decreased after 15 days of treatment, in this case, the dosage may be increased to the next step of the dosage.
The daily dose should not exceed 120 mg. Previously extended patients should commence with a dose of 30 mg.
DYMAZIZ 60 mg MR modified release tablet is equivalent to two DYMAZIZ 30 mg MR modified release tablets.

Replacement of gliclazide 80 mg with DYMAZIZ MR:
In patients established on gliclazide 80 mg, the replacement of gliclazide 80 mg by DYMAZIZ MR may initially be based on 1 tablet gliclazide 80 mg → 1 x 30 mg tablet of DYMAZIZ MR.

The replacement of another sulphonylurea with DYMAZIZ MR:
The replacement of another sulphonylurea treatment with DYMAZIZ MR, it is recommended that the dosage and the half-life of the previous sulphonylurea medicine must be taken into account.

If a patient is changed from another oral sulphonylurea with a prolonged half-life, a therapeutic washout 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 initial dosage of treatment be the same as for the initial DYMAZIZ MR dosage, start with daily doses of 30 mg per day and then increase the dosage in increments, according to the patient's metabolic response.

Association with other oral antidiabetic medicines:
DYMAZIZ MR may be given concurrently with other oral antidiabetic medicines or insulin. However, diabetic control should be achieved with lower sulphonylurea dosage because of the possibility of hypoglycaemia. In combination therapy with biguanides, there may be an increased risk of cardiovascular mortality than with the use of DYMAZIZ MR alone.

Special populations:
Renal impairment:
The dosage is identical to that recommended for adults under the age of 65 years, and the 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 is necessary in patients with renal impairment.
The dosage is identical to that recommended for patients with normal renal function, with careful monitoring. Use of DYMAZIZ MR is contraindicated in patients with severe renal impairment (see section 4.3).

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

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

Method of administration
Oral administration of the tablets by swallowing whole.

4.3 Contraindications
- hypersensitivity to gliclazide, sulphonylurea, sulfonamides or to any of the ingredients of DYMAZIZ MR
- type 1 diabetes mellitus (Juvenile Insulin-Dependent Diabetes Mellitus, diabetes ketoacidosis, diabetic pre-coma and coma)
- significant acidosis, severe illness, severe infection or hypocaloric nutritional status
- severe hepatic impairment
- severe renal impairment; 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 hypoglycaemic 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 5.2).

Clinical signs of a stroke manifesting in multiple organs (i.e. hypoglycaemia, dysarthria, paresis) may require dose adjustment of DYMAZIZ MR.

Hypoglycaemia:
Hypoglycaemia may occur following administration of sulfonylureas including DYMAZIZ 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, and clear patient directions are necessary to reduce the risk of hypoglycaemic reactions.
The administration of this hypoglycaemic reacts to DYMAZIZ MR may be associated with increased cardiovascular mortality in relation to treatment with diet alone or diet with insulin.

Treatment with DYMAZIZ MR can cause hypoglycaemia if medicines are irregular and, in particular, if meals are skipped. Possible symptoms of hypoglycaemia are headache, intense hunger, nausea, vomiting, lassitude, sleep disturbance, agitation, aggressiveness, reduced concentration and alertness, slow reaction, depression, confusion, visual and speech disorders, aphasia, tremor, paresis, sensory disorders, dizziness, helplessness, loss of self-control, delirium, cerebral convulsions, somnolence and disturbed sleep, drowsiness, and loss of consciousness, progressing to coma and deep unconsciousness.
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 sulphonylurea shows that hypoglycaemia can occur even when reasonable care and dosage are observed.
If a hypoglycaemic episode is severe or prolonged, even if temporarily controlled by the intake of sugar, immediate medical treatment or even hospitalisation is required.

In the elderly, weakness of treatment, the risk of hypoglycaemic may increase, and careful monitoring is necessary. Elderly patients usually respond to the hypoglycaemic medicine, for example, DYMAZIZ MR.
- careful prescribing to elderly patients' refusing or unable to co-operate
- cachexia or any malnourished or undernourished, with irregular meal times, skipping meals, periods of fasting or dietary changes
- severe impairment of glucose metabolism and carbohydrate intake
- certain endocrine disorders: thyroid disorders, hypopituitarism and adrenocorticotrophic insufficiency, which should be considered 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 impairment
- concomitant administration of certain other medicines (see section 4.5)
- overdose of DYMAZIZ MR.

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

DYMAZIZ MR should be prescribed only if the patient is likely to have a regular food intake (including breakfast). It is important to have regular carbohydrate intake due to the risk of hypoglycaemia, for meal to lessen lack. It are inadequate amount of food is concerned, at the food is low in carbohydrate, hypoglycaemia may occur. This may be the case for people who are undernourished, people who have poor or incomplete or irregular food intake, or who are susceptible to hypoglycaemia, and who skip meals.

In an exceptional dose disruption (for example, fever, infection or surgical intervention, blood glucose regulation may deteriorate, and a temporary change to insulin may be necessary to maintain good metabolic control.

Sulfonylureas' side effects can be evoked if DYMAZIZ MR is taken with beta-blockers.
Hypoglycaemic symptoms may disappear after the beta-blockers' administration. Hypoglycaemia may be prolonged, and a temporary change to insulin may be necessary to maintain good metabolic control.

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Hypoglycaemic symptoms may disappear after the beta-blockers' administration. Hypoglycaemia may be prolonged, and a temporary change to insulin may be necessary to maintain good metabolic control.

Patient information:
The risk of hypoglycemia, together with its symptoms (see section 4.8), should be explained to patients and their carers. Attention should be paid to the additional risk to elderly members. The patient should be informed of the importance of following dietary policies, 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 stresses like fever, trauma, infection, surgery and false tolerances as well as 2 diabetic insulin-dependent patients 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 DYMAZIZ MR may be affected 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.

4.5 Interactions
Contraindications (see section 4.3):
- Miconazole: Increased risk of hypoglycaemia, which may progress to coma.

Combinations not recommended:
- Miconazole: Increased hypoglycaemic effect of sulphonylurea; gliclazide; this interaction may be of clinical significance in patients who are also treated with other medicines.
- 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:
- Phenylbutazone: Increase the blood glucose lowering effect of the sulphonylurea, which may increase the risk of hypoglycaemic symptoms, or even coma, and is therefore contraindicated (see section 4.3).

Combinations which are not recommended:
- Fluconazole: Increase the hypoglycaemic effect of sulphonylurea; gliclazide; this interaction may be of clinical significance in patients who are also treated with other medicines.
- Beta-adrenergic, sympathomimetic and diuretic medicines: Increase in blood glucose levels; in particular, beta-2 stimulants may cause a temporary increase in the blood glucose levels.
- Beta-blockers: Increase the hypoglycaemic effect of sulphonylurea; gliclazide; this interaction may be of clinical significance in patients who are also treated with other medicines.
- 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:
- Phenylbutazone: Increase the blood glucose lowering effect of the sulphonylurea; gliclazide; this interaction may be of clinical significance in patients who are also treated with other medicines.
- Danazol: Increase the hyperglycemic effect of the sulphonylurea; gliclazide; this interaction may be of clinical significance in patients who are also treated with other medicines.
- Chlorpromazine: Increase the blood glucose levels; in high doses (100 mg/day), the blood glucose levels increase and the secretion of insulin is reduced.
- Corticosteroids (glucocorticoids): Increase the blood glucose levels; in particular, beta-2 stimulants may cause a temporary increase in the blood glucose levels.
- Beta-adrenergic, sympathomimetic and diuretic medicines: Increase in blood glucose levels; in particular, beta-2 stimulants may cause a temporary increase in the blood glucose levels.
- Beta-blockers: Increase the hypoglycaemic effect of sulphonylurea; gliclazide; this interaction may be of clinical significance in patients who are also treated with other medicines.
- Calcium salts: Increase the blood glucose levels.
- Cimetidine: Increase the hypoglycaemic effect of sulphonylurea; gliclazide; this interaction may be of clinical significance in patients who are also treated with other medicines.
- Danazol: Increase the hyperglycemic effect of the sulphonylurea; gliclazide; this interaction may be of clinical significance in patients who are also treated with other medicines.
- Diazoxide: Increase the blood glucose levels.
- Diuretics: Increase the blood glucose levels; potassium-sparing diuretics may be exceptional but cause problems in individual cases with diabetes mellitus or impaired glucose tolerance.
- Fluoxetine: Increase the hypoglycaemic effect of sulphonylurea; gliclazide; this interaction may be of clinical significance in patients who are also treated with other medicines.
- Glucagon: Increase the blood glucose levels; in high doses (100 mg/day), the blood glucose levels increase and the secretion of insulin is reduced.
- Isoniazid: Increase the blood glucose levels; in high doses (100 mg/day), the blood glucose levels increase and the secretion of insulin is reduced.
- Lithium: Increase the blood glucose levels; in high doses (100 mg/day), the blood glucose levels increase and the secretion of insulin is reduced.
- Nicotinic acid (vitamin B3): Increase the blood glucose levels; in high doses (100 mg/day), the blood glucose levels increase and the secretion of insulin is reduced.
- Phenothiazines: Increase the blood glucose levels; in high doses (100 mg/day), the blood glucose levels increase and the secretion of insulin is reduced.
- Rifampicin: Increase the blood glucose levels; in high doses (100 mg/day), the blood glucose levels increase and the secretion of insulin is reduced.
- Sympathomimetics: Increase the blood glucose levels; in high doses (100 mg/day), the blood glucose levels increase and the secretion of insulin is reduced.
- Thiazides: Increase the blood glucose levels; in high doses (100 mg/day), the blood glucose levels increase and the secretion of insulin is reduced.
- Thyroid hormones: Increase the blood glucose levels; in high doses (100 mg/day), the blood glucose levels increase and the secretion of insulin is reduced.

Combinations requiring precautions during use:
- Beta-blockers: Increase the hypoglycaemic effect of sulphonylurea; gliclazide; this interaction may be of clinical significance in patients who are also treated with other medicines.
- Alcohol – Increases the hypoglycaemic reaction by inhibiting compensatory reactions; that can lead to the onset of hypoglycaemic coma. Avoid alcohol or medicines containing alcohol.

4.6 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 effects on fertility or reproductive performance have been reported.

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

4.8 Undesirable effects
Blood and lymphatic system disorders
The most frequent adverse reactions associated with DYMAZIZ MR is hypoglycaemia – especially if medicines are missed or irregular and if meals are skipped.

Hypoglycaemia may occur shortly after taking a medicine containing sulfonylurea; it may also occur later, delayed, intense hunger, nausea, vomiting, lassitude, sleep disturbance, agitation, aggressiveness, concentration difficulties, reduced awareness and alertness, reactions, depression, confusion, visual and speech disorders, aphasia, tremor, paresis, sensory disorders, dizziness, helplessness, loss of self-control, delirium, cerebral convulsions, somnolence and disturbed sleep, drowsiness, and loss of consciousness, progressing to coma and deep unconsciousness.
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 sulphonylurea shows that hypoglycaemia can occur even when reasonable care and dosage are observed.
If a hypoglycaemic episode is severe or prolonged, even if temporarily controlled by the intake of sugar, immediate medical treatment or even hospitalisation is required.

a) Tabulated summary of adverse reactions

System Organ Class	Frequency	Side effects
Blood and lymphatic system disorders	Least frequent	Thrombocytopenia, leukopenia, haemolytic or haemolytic anaemia, agranulocytosis, pancytopenia, erythrocyte, white blood cell, platelet disorders, myelosuppression
Immune system disorders	Least frequent	Allergic skin reactions
Endocrine disorders	Least frequent	Hypoglycaemia
Metabolism and nutrition disorders	Least frequent	Hyponatraemia, anorexia
Nervous system disorders	Frequent	Headache, dizziness, drowsiness
Eye disorders	Frequent	Blurred vision (under changes in accommodation)
Gastrointestinal disorders	Frequent	Constipation, diarrhoea, dyspepsia, flatulence, heartburn, loss of appetite, nausea, vomiting, pain, nausea, stomach pain, fullness or discomfort, vomiting, abnormal sensations in the stomach
Hepato-biliary disorders	Least frequent	Increased levels of hepatic enzymes (alanine aminotransferase, aspartate amino transferase, alkaline phosphatase, hepatic, cholestasis, cholestatic jaundice, hepatic function impairment, hepatic cytolysis, generic cutaneous lesions, liver hepatitis
Skin and subcutaneous tissue disorders	Frequency unknown	Erythema multiforme, pityriasis lichenoides, pruritus, urticaria, maculopapular rash, rash, skin reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis, exfoliative dermatitis, hypersensitivity reactions, angioedema, drug rash with eosinophilia and systemic symptoms (DRESS)
Renal and urinary disorders	Frequent	Polyuria

c) Description of selected adverse reactions
Hypoglycaemia may be prominent if medicines are irregular and, in particular, if no meals are skipped. Usually, symptoms disappear after intake of carbohydrates (sugar).
Hypoglycaemia may be severe and prolonged, 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. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the online service for adverse drug reaction reporting, following the link: https://www.sahpra.org.za/Publications/Detail/1-Adverse-Drug-Reaction-Reporting-Guideline-May-2018 and quality-problem reporting form:
An email can be sent directly to the company, pharmacovigilance@dynamicsynergy.co.za to secure safety of the product.

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

Management of overdose:
Treatment is symptomatic and supportive.
Skill: modifying should be continued with the patient's out of danger. Severe hypoglycaemia reactions with coma, convulsions or other neurological disorders should be treated as a medical emergency, requiring immediate hospitalisation.
If hypoglycemic 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 at 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, a period of observation in hospital may be necessary. Dialysis is of no benefit in this condition due to strong binding of gliclazide to proteins.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Sulfonamides, urea derivative
ATC code: A10BB09
Pharmacotherapeutic group: A 2.1.2 Oral hypoglycemics

Mechanism of action:
Gliclazide, a new sulphonylurea sulphonylurea, lowers blood glucose concentrations by stimulating insulin release from pancreatic beta-cells. In addition to this pancreatic action, it has extrapancreatic effects. Gliclazide, a sulfonylurea, may improve the metabolic attributes of glucose of patients at risk.

5.2 Pharmacokinetic properties
Absorption:
After 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 (~ 97 %).
The volume of distribution is around 30 litres.
A single oral gliclazide medication causes 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. Six urine 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
Toxicity studies in several species for humans based on conventional studies of repeated dose toxicity and genotoxicity. Long term carcinogenicity studies have not been carried out. No teratogenic changes have been observed in animal studies, but lower foetal body weight was observed in the presence of maternal toxicity at higher than the maximum recommended dose in humans. Fertility and reproductive performance were not affected by gliclazide, nor was there any evidence of embryotoxicity.

6. PHARMACEUTICAL PARTICULARS
6.1 List of Excipients
DYMAZIZ 30 mg MR:
Hypromellose
Cellulose silica dihydrate
Hypromellose
Lactose monohydrate
Magnesium stearate

DYMAZIZ 60 mg MR and DYMAZIZ 90 mg MR:
Hypromellose
Lactose monohydrate
Magnesium stearate
Silica colloidal anhydrous

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store at or below 30 °C in a dry place. Protect from light.
Keep the blister in the carton and register for use.
This medicine does not require any special storage conditions.

6.5 Nature and contents of container
DYMAZIZ 30 mg MR and DYMAZIZ 60 mg MR: PVC/PVDC and aluminium foil blister strips. 60 tablets will be packed in 1 x 60 tablets pack.
DYMAZIZ 90 mg MR: PVC/PVDC and aluminium foil blister strips. 90 tablets will be packed in 1 x 90 tablets pack.

DYMAZIZ 30 mg MR tablets are packed into clear OPA/AlPVC and aluminium blister foil strips. 25 or 30 tablets will be packed into a cardboard box.

DYMAZIZ 60 mg MR tablets are packed into OPA/AlPVC and aluminium foil blister strips. Blister strips are packed into a cardboard box. 60 tablets will be packed in a cardboard box.

All packsizes may not be marketed.

6.6 Special precautions for disposal
No special precautions are required.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION
Pharmachem (PTY)Ltd
1st Floor Bayswater House, Bayswater Office Park
Bayswater Avenue
Westlake, Cape Town
7945, South Africa

8. REGISTRATION NUMBER(S)
DYMAZIZ 30 mg MR: A47/21.2.1/0197
DYMAZIZ 60 mg MR: A47/21.2.1/0198
DYMAZIZ 90 mg MR: A47/21.2.1/0199

9. DATE OF FIRST AUTHORISATION
DYMAZIZ 30 mg MR: 25 November 2011
DYMAZIZ 60 mg MR: 16 June 2021
DYMAZIZ 90 mg MR: 16 June 2021

10. DATE OF REVISION OF THE TEXT
Approved date: 01/01/2021

NAMIBIA
DYMAZIZ 30 mg MR: 22/21.2.1/0197

MOZAMBIQUE
DYMAZIZ 30 mg MR: A0317*
DYMAZIZ 60 mg MR: A0318*

*DYMAZIZ 30 mg MR will not market in Mozambique
*DYMAZIZ 60 mg MR: DYMAZIZ 30 mg MR will not marketed in Namibia.

pharmadynamics

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

DYMAZIZ 30 mg MR modified release tablets
DYMAZIZ 60 mg MR modified release tablets
DYMAZIZ 90 mg MR modified release tablets
Gliclazide

DYMAZIZ 30 mg MR contains sugar (71,30 mg lactose monohydrate per tablet)
DYMAZIZ 60 mg MR contains sugar (142,60 mg lactose monohydrate per tablet)
DYMAZIZ 90 mg MR contains sugar (142,60 mg lactose monohydrate per tablet)

Read all of this leaflet carefully before you start taking DYMAZIZ 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 worker.
- DYMAZIZ 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 DYMAZIZ MR is and what it is used for
2. What you need to know before you take DYMAZIZ MR
3. How to use DYMAZIZ MR
4. Possible side effects
5. How to store DYMAZIZ MR
6. Contents of the pack and other information

1. WHAT DYMAZIZ MR IS AND WHAT IT IS USED FOR
DYMAZIZ MR contains a medicine called gliclazide, which belongs to the group of medicines called sulphonylurea antidiabetic medicines. It is used to treat a certain form of diabetes mellitus called type 2 diabetes in adults, where diet, exercise and weight loss alone do not lower blood sugar levels sufficiently to avoid the long-term effects of diabetes.
When you have type 2 diabetes, the amount of insulin your pancreas produces may not be sufficient to control your blood sugar levels. Your pancreas may also not respond to insulin properly. DYMAZIZ MR helps by causing your pancreas to release more insulin into the blood stream.

2. What you need to know before you take DYMAZIZ MR
Do not take DYMAZIZ MR:
- if you are hypersensitive (allergic) to gliclazide, other sulfonylureas (medicines for diabetes), sulfonamides (a type of antibiotic), or to any of the ingredients of DYMAZIZ MR (see section 6)
- if you have type 1 diabetes mellitus (type 1 diabetes patients cannot produce or release insulin into their blood stream)
- if you have ketoacidosis (a type of diabetes complication that may cause you have diabetic ketoacidosis), a diabetic pre-coma or coma
- if your diabetes is very severe, or if you have a condition affecting your digestion or other medicines you take, which may cause sugar (glucose) to be absorbed more slowly than normal
- if you have severe liver or kidney problems, or severe infection or had a major surgery (you may need insulin)
- if you are a diabetic patient
- if you are taking a medicine to treat fungal infections called miconazole (see other medicines with DYMAZIZ MR)
- if you are a child, as the safety of DYMAZIZ MR has not been studied in children
- if you are pregnant or breastfeeding (see below)

Warnings and precautions:
Talk to your doctor, pharmacist or nurse before taking DYMAZIZ MR if you:
- have liver problems, or have had a liver disease. You should always tell your doctor if you have liver problems, because your doctor may need to adjust your dosage.
- have kidney problems, or have had a kidney disease. Your doctor may need to adjust your dosage.
- have a severe illness, a severe infection or a hypocaloric nutritional status (you may need insulin)
- have a severe disease of the heart, blood vessels, or brain (such as coronary heart disease, severe narrowing of the blood vessels, or stroke)
- have a severe disease of the thyroid, pituitary or adrenal glands
- have had a prolonged and/or high dose treatment with corticosteroids
- have severe diabetes (a disease in which your body does not produce enough insulin)
- have a tendency to develop ketosis (a condition in which your body does not properly use sugar)
- have a significant amount of alcohol drunk, especially when skipping meals (alcohol may cause a dangerous condition of the blood vessels, particles and clots in the blood, and affect the liver)
- are an elderly person (you may need a lower dose)
- are a patient who suffers from glucose-6-phosphate dehydrogenase deficiency, a rare genetic disorder (medicines such as DYMAZIZ MR may cause a haemolytic reaction in patients who are affected by this disorder)
- are a patient who is being treated for a heart condition (the medicine DYMAZIZ MR may cause a heart condition to worse