PART III: CONSUMER INFORMATION

Pr GLICLAZIDE MR
Gliclazide

Modified-release tablets
30 mg

Modified-release breakable tablets
60 mg

This leaflet is part III of a three-part "Product Monograph" published when Pr GLICLAZIDE MR was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Pr GLICLAZIDE MR. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

GLICLAZIDE MR is used to lower blood glucose level in adult patients with type 2 diabetes mellitus in addition to proper diet, exercise and weight reduction.

What it does:

GLICLAZIDE MR belongs to the family of hypoglycemic (antidiabetic) drugs and part of a sub family of medicines called sulfonylureas. It helps improve insulin secretion in the body.

When it should not be used:

GLICLAZIDE MR is contraindicated (must not be taken) if you:

- are allergic or hypersensitive to gliclazide, other sulfonylureas, sulfonamides, or to any of the ingredients of these products,
- have unstable and/or insulin-dependent diabetes mellitus, juvenile diabetes (type I diabetes), diabetic ketoacidosis, diabetes pre-coma and coma,
- have a serious infection, trauma or surgery,
- have severe liver problems,
- have severe kidney problems,
- receive treatment with miconazole,
- are pregnant and/or breast-feeding.

What the medicinal ingredient is:

Gliclazide.

What the nonmedicinal ingredients are:

GLICLAZIDE MR 30 mg tablets contain: anhydrous colloidal silica, calcium hydrogen phosphate dihydrate, hypromellose, magnesium stearate, maltodextrin.
GLICLAZIDE MR 60 mg tablets contain: anhydrous colloidal silica, hypromellose, lactose monohydrate, magnesium stearate, maltodextrin.

What dosage forms it comes in:
GLICLAZIDE MR comes in modified-release tablets of 30 mg and modified-release breakable tablets of 60 mg.

WARNINGS AND PRECAUTIONS

GLICLAZIDE MR may cause low blood sugar (hypoglycemia). You should ask your doctor, pharmacist or diabetes educator about symptoms of low blood sugar and what to do if you experience these symptoms. You should also test your blood sugar as instructed by your doctor.

BEFORE you use GLICLAZIDE MR talk to your doctor or pharmacist if you:

- have or have had liver problems,
- have or have had kidney problems,
- are pregnant or planning to get pregnant,
- are breast-feeding,
- have a blood disease called G6PD-deficiency anemia,
- have porphyria (genetic disease in which your body builds-up chemicals with skin, nervous system or other symptoms)
- have an intolerance to lactose (for GLICLAZIDE MR 60 mg).

Your blood sugar may get too high (hyperglycaemia) if you take Saint John's Wort preparations or if you experience fever, infection, surgery or trauma (stress conditions). In such cases, contact your doctor as your medication may need to be adjusted. Serious Skin Reactions (DRESS, Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, bullous pemphigoid, hypersensitivity Syndrome): any combination of red itchy rash with blisters and peeling of the skin and /or of the lips, eyes, mouth, nasal passages or genitals. It often goes with fever, chills, headache, cough, body aches or joint pain. You may have less or dark urine, yellow skin or eyes. If you suspect these, you should stop taking the drug and talk with your doctor or pharmacist.

Low blood sugar and high blood sugar can occur when GLICLAZIDE MR is prescribed at the same time as medicines belonging to a class of antibiotics called fluoroquinolones, especially if you are elderly. If you are taking these medications together, your doctor will remind you of the importance of monitoring your blood glucose.

GLICLAZIDE MR is not recommended for use in children under 18 years of age.

Driving and Operating Machinery:
Alertness and reactions may be impaired due to low blood sugar (hypoglycemia), especially at beginning of the treatment. This may affect your ability to drive or to operate machinery.

INTERACTIONS WITH THIS MEDICATION

Serious Drug Interactions

GLICLAZIDE MR (gliclazide) should not be taken if you are also taking miconazole (an anti-fungal drug).
See **"When it should not be used"** section of this leaflet.

Other drugs that may interact with GLICLAZIDE® MR include:

- other antidiabetic agents
- antibiotics (sulphonamides/sulfa drugs, clarithromycin, fluoroquinolones)
- anti-tuberculosis drugs
- anti-fungal drugs (fluconazole)
- non-steroidal anti-inflammatory drugs (NSAIDs) including phenylbutazone (used to treat inflammation and pain)
- cortiscosteroids (used to treat inflammation)
- salicylates (e.g. acetylsalicylic acid)
- angiotensin converting enzyme (ACE) inhibitors (used to treat high blood pressure and certain heart conditions)
- beta blockers (used to treat high blood pressure and certain heart conditions)
- anticoagulant therapy (blood thinners), including warfarin
- diuretics (thiazides, furosemide) (used to treat high blood pressure and certain heart conditions)
- fibrates, nicotinic acid (used to treat high levels of fats in the blood)
- H2-receptor antagonists (used to treat acid reflux/heartburn)
- monoamine oxidase inhibitors (used to treat depression)
- chlorpromazine (used to treat certain psychiatric conditions)
- probenecid (used to treat high levels of uric acid in the blood and gout)
- salbutamol, terbutaline (used to treat asthma) and ritodrine
- barbiturates (sedatives, anti-seizure medications)
- oral contraceptives (estrogen plus progestogen, used for birth control)
- danazol (used to treat breast cysts and endometriosis)
- alcohol.

Some of the drugs described above may lead to loss of blood sugar control (high blood sugar), including diuretics, corticosteroids, oral contraceptives, chlorpromazine, ritodrine, salbutamol, terbutaline, danazol and nicotinic acid.

Some herbs such as Saint John's Wort preparations may lead to high blood sugar and loss of blood sugar control.

Avoid drinking alcoholic beverages and taking medicines containing alcohol while you are taking GLICLAZIDE MR as this can lead to a drop in blood sugar (hypoglycaemia).

Tell your doctor if you have recently taken any of the medicines listed above or any other medicines, including those obtained without a prescription. Do not take other medicines unless prescribed or approved by your doctor. Tell any health care professionals that you see that you are taking GLICLAZIDE MR.

PROPER USE OF THIS MEDICATION

Usual dose:

The recommended starting dose of GLICLAZIDE MR is 30 mg per day (a half tablet of GLICLAZIDE MR 60 mg or a tablet of GLICLAZIDE MR 30 mg), even in elderly patients (over 65 years old). The daily dose should not exceed 120 mg.

Take GLICLAZIDE MR once daily at breakfast. The 30 mg tablets cannot be split in half and should be swallowed whole with a glass of water. The 60 mg tablets can be halved. Do not crush or chew the tablets of either strength.

You should test your sugar level as directed by your physician to make sure that your blood sugar is being controlled. Your physician should check your progress at regular visits, especially during the first few weeks that you take this medicine.

Overdose:

Taking too much of any medicine can be dangerous. If you take too many GLICLAZIDE MR tablets at once, call your doctor or your nearest poison control center, or go to the emergency room of your local hospital.

Missed Dose:

If you miss a dose of this medicine, skip the missed dose. Take your next dose at the regular time. Do not double doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

GLICLAZIDE MR is associated with some side effects. It may, however, affect different people in different ways.

Common side effects reported during clinical trials with GLICLAZIDE MR included:

- hypoglycemia (low blood sugar)
- hyperglycemia (high blood sugar)
- viral infection
- upper respiratory infection, runny nose, sore throat, cough
- back, muscle and joint pain
- headache
- high blood pressure
- angina (chest pain)
- leg swelling

- diarrhea, constipation, abdominal pain, nausea
- dizziness
- skin rash/itching
- depression

You should know that the usual signs of low blood sugar level (hypoglycemia) are: anxious feeling, drowsiness, dizziness, chills, cold sweats, confusion, cool pale skin, difficulty in concentration, excessive hunger, fast heartbeat, headache, nausea, depression, nervousness, shakiness, unsteady walk, unusual tiredness or weakness. The following signs and symptoms may also occur: clammy skin, anxiety, irregular heart beat, high blood pressure, chest pain or pressure, and/or shortness of breath (angina pectoris). Serious Skin Reactions (DRESS, Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, bullous pemphigoid, hypersensitivity Syndrome): any combination of red itchy rash with blisters and peeling of the skin and /or of the lips, eyes, mouth, nasal passages or genitals. It often goes with fever, chills, headache, cough, body aches or joint pain. You may have less or dark urine, yellow skin or eyes. If you suspect these, you should stop taking the drug and talk with your doctor or pharmacist.

If you recognize some of these signs of the drop in blood sugar, immediately eat or drink something containing sugar and notify your doctor without delay. Good sources of sugar are: orange juice, corn syrup, honey, or sugar cubes or table sugar (dissolved in water).

SERIOUS SIDE EFFECTS, AND WHAT TO DO ABOUT THEM

Symptom / Effect		Talk with your healthcare professional		Stop taking the drug and get immediate medical help
		Only if severe	In all cases	
Common	**Low blood sugar level (hypoglycemia)** The usual signs are:		✓	
	Anxious feeling		✓	
	Drowsiness		✓	
	Chills		✓	
	Cold sweats		✓	
	Confusion		✓	
	Cool pale skin		✓	
	Difficulty in concentration		✓	
	Excessive hunger		✓	
	Fast heartbeat		✓	
	Headache		✓	
	Nausea		✓	
	Dizziness		✓	
	Nervousness		✓	
	Shakiness		✓	
	Unsteady walk		✓	
	Unusual tiredness or weakness		✓	
Uncommon	**Unexplained fever,** chills or sore throat			✓
	Yellowing of skin or eyes, dark-coloured urine or light-coloured bowel movements (e.g. jaundice)			✓
	Skin rash, redness, itching or hives			✓
	Oedema, swelling of the legs or unexpected weight gain		✓	
	Chest pain or pressure, and/or shortness of breath			✓
Very rare	**Blood abnormalities** with symptoms of sore throat, fever, mouth sore, unusual bleeding or bruising, low level of red blood cells (anemia)			✓
	Allergic inflammation of blood vessels (vasculitis)			✓

SERIOUS SIDE EFFECTS, AND WHAT TO DO ABOUT THEM

Symptom / Effect	Talk with your healthcare professional		Stop taking the drug and get immediate medical help
	Only if severe	In all cases	
Low sodium level in blood combined with symptoms of tiredness, weakness and confusion (hyponatraemia)			✓
Rapid swelling of tissues such as eyelids, face, lips, mouth, tongue or throat that may result in breathing difficulty (angioedema)			✓
Serious Skin Reactions (DRESS, Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, bullous pemphigoid, hypersensitivity Syndrome): any combination of red itchy rash with blisters and peeling of the skin and /or of the lips, eyes, mouth, nasal passages or genitals. It often goes with fever, chills, headache, cough, body aches or joint pain. You may have less or dark urine, yellow skin or eyes			✓

This is not a complete list of side effects. For any unexpected effects while taking GLICLAZIDE MR, contact your doctor or pharmacist.

HOW TO STORE IT

Keep out of reach or sight of children and pets.

GLICLAZIDE MR should be stored at room temperature (15°C-30°C).

Medicines should not be disposed of down the drain or in household garbage. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- **Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or**
- **Calling toll-free at 1-866-234-2345.**

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the manufacturer, Sanis Health Inc. at:

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