

PART III: CONSUMER INFORMATION

Pr DIAMICRON® 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 DIAMICRON® 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 DIAMICRON® MR. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

DIAMICRON® 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:

DIAMICRON® 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:

DIAMICRON® 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,
- if you have unstable and/or insulin-dependent diabetes mellitus, juvenile diabetes (type I diabetes), diabetic ketoacidosis, diabetes pre-coma and coma,
- if you have a serious infection, trauma or surgery,
- if you have severe liver problems,
- if you have severe kidney problems,
- if you receive treatment with miconazole,
- if you are pregnant and/or breast-feeding.

What the medicinal ingredient is:

Gliclazide.

What the nonmedicinal ingredients are:

DIAMICRON® MR 30 mg tablets contain: anhydrous colloidal silica, calcium hydrogen phosphate dihydrate, hypromellose, magnesium stearate, maltodextrin.

DIAMICRON® MR 60 mg tablets contain: anhydrous colloidal

silica, hypromellose, lactose monohydrate, magnesium stearate, maltodextrin.

What dosage forms it comes in:

DIAMICRON® MR comes in modified-release tablets of 30 mg and modified-release breakable tablets of 60 mg.

WARNINGS AND PRECAUTIONS

DIAMICRON® 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 DIAMICRON® MR talk to your doctor or pharmacist if:

- you have or have had liver problems,
- you have or have had kidney problems,
- you are pregnant or planning to get pregnant,
- you are breast-feeding,
- you have a blood disease called G6PD-deficiency anemia,
- you have an intolerance to lactose (for DIAMICRON® 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, 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 DIAMICRON® 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.

DIAMICRON® 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

DIAMICRON 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 DIAMICRON® 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)
- corticosteroids (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 DIAMICRON® 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 DIAMICRON® MR.

PROPER USE OF THIS MEDICATION

Usual dose:

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

Take DIAMICRON® 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 DIAMICRON® 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

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

Common side effects reported during clinical trials with DIAMICRON® 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, 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, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking the drug and call your doctor or pharmacist
		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		✓		

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking the drug and call your doctor or pharmacist
		Only if severe	In all cases	
	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)			✓
	Low sodium level in blood combined with symptoms of tiredness, weakness and confusion (hyponatraemia)			✓
	Rapid swelling of			

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking the drug and call your doctor or pharmacist
	Only if severe	In all cases	
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, 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 DIAMICRON® MR, contact your doctor or pharmacist.

HOW TO STORE IT

Keep out of reach or sight of children and pets.

DIAMICRON® 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 SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to:

**Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. 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 sponsor Servier Canada Inc. at: 1-800-363-6093

This leaflet was prepared by Servier Canada Inc.

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