

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr Mylan-Gliclazide MR

Gliclazide Modified Release Tablets

Gliclazide Modified Release Breakable Tablets

Read this carefully before you start taking **Mylan-Gliclazide MR** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Mylan-Gliclazide MR**.

What is Mylan-Gliclazide MR used for?

Mylan-Gliclazide MR is used along with diet and exercise to lower blood sugar levels in adults with type 2 diabetes.

How does Mylan-Gliclazide MR work?

Mylan-Gliclazide MR belongs to a group of medicines called hypoglycemic (antidiabetic) drugs. They are part of a subgroup of medicines called sulfonylureas. It helps improve the release of insulin in the body.

What are the ingredients in Mylan-Gliclazide MR?

Medicinal ingredients: Gliclazide.

Non-medicinal ingredients:

Mylan-Gliclazide MR 30 mg and 60 mg tablets contain: Hypromellose, magnesium stearate and microcrystalline cellulose.

Mylan-Gliclazide MR comes in the following dosage forms:

- 30 mg modified-release tablets
- 60 mg modified-release breakable tablets

Do not use Mylan-Gliclazide MR if you:

- are allergic to gliclazide, other sulfonylureas, sulfonamides, or to any of the ingredients of these medicines.
- have unstable and/or insulin dependent type 1 diabetes (particularly Juvenile diabetes)
- have diabetic ketoacidosis (DKA)
- have diabetic pre-coma and coma
- have a serious infection, trauma or surgery
- have severe liver problems
- have severe kidney problems

- are taking medicine containing miconazole (used to treat fungal or yeast infections)
- are pregnant
- are breast-feeding

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Mylan-Gliclazide MR. Talk about any health conditions or problems you may have, including 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 (this is a condition where red blood cells break down faster than they are made)
- have porphyria (a condition that results in chemicals building up in your body that results in symptoms affecting your skin, nervous system and other areas)

Other warnings you should know about:

- **Effect on Blood Sugar Levels**
 - **Low blood sugar levels (hypoglycemia):**
 - Mylan-Gliclazide MR may cause low blood sugar levels (a condition called hypoglycemia). You should talk to your healthcare professional about symptoms of low blood sugar levels and what to do if you have these symptoms. You should also test your blood sugar levels as instructed by your healthcare professional.
 - See the **Serious Side Effects Table** for symptoms of low blood sugar levels (hypoglycemia).
 - **If you experience these symptoms:**
 - **Immediately eat or drink something containing sugar. Good sources of sugar are:**
 - orange juice
 - corn syrup
 - honey
 - sugar cubes or table sugar (dissolved in water)
 - **Talk to your healthcare professional as soon as you can.**
 - **High blood sugar levels (hyperglycemia):**
 - Your blood sugar may get too high (a condition called hyperglycemia) if you experience a fever, infection, surgery, or trauma (stressful conditions).
 - In such cases, contact your healthcare professional as your medication may need to be adjusted.
 - Symptoms of high blood sugar levels include the following: thirst, frequent urination, dry mouth, dry itchy skin, skin infections and reduced performance.
- **Serious Skin Reactions:** (for example DRESS, Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, bullous pemphigoid, hypersensitivity Syndrome) that can be any combination of red itchy rash with blisters and peeling of the skin and/or of the lips, eyes, mouth, nasal passages or genitals.

- You may also have a fever, chills, headache, cough, body aches or joint pain.
 - You may have less or dark urine, yellow skin or eyes.
 - If you have these symptoms, you should stop taking Mylan-Gliclazide MR immediately and talk to your healthcare professional.
- **Children and adolescents (under 18 years of age):**
Mylan-Gliclazide MR is not recommended for use in patients under 18 years of age.
 - **Driving and Operating Machinery:**
Your alertness and reactions may be impaired due to low blood sugar levels, especially when starting to take Mylan-Gliclazide MR. This may affect your ability to drive or to operate machines.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

Mylan-Gliclazide MR (gliclazide) should not be taken if you are also taking miconazole (a medicine used to treat bacterial or yeast infections).

The following may interact with Mylan-Gliclazide MR:

- medicines that are used to treat diabetes such as other antidiabetic agents
- medicines used to treat bacterial infections (antibiotics) such as sulfonamides/sulfa drugs, clarithromycin and fluoroquinolones.
 - If Mylan-Gliclazide MR is taken at the same time as fluoroquinolones, low and high blood sugar can occur.
 - Talk to your healthcare professional about monitoring your blood sugar levels if taking these medicines together. This is especially important if you are elderly.
- medicines used to treat tuberculosis (anti-tuberculosis)
- medicines used to treat fungal infections (anti-fungal) such as fluconazole.
- medicines used to treat inflammation (non-steroidal anti-inflammatory drugs (NSAIDs)) such as phenylbutazone or corticosteroids.
- salicylates (used to treat pain, fever and inflammation) such as acetylsalicylic acid.
- medicines used to treat high blood pressure and certain heart conditions like:
 - angiotensin converting enzyme (ACE) inhibitors,
 - beta blockers
 - diuretics such as thiazides and furosemide
- medicines used to thin blood (anticoagulant therapy) such as warfarin
- medicines used to treat high levels of fats in the blood such as fibrates and nicotinic acid
- 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)
- medicines used to treat asthma such as salbutamol and terbutaline
- ritodrine (used to stop premature labor)
- medicines used to treat seizures (barbiturates) such as sedatives and anti-seizure medications.

- oral contraceptives used for birth control such as estrogen plus progestogen.
- danazol (used to treat breast cysts and endometriosis, a condition where tissue similar to the lining of the uterus grows outside the uterus)
- St. John's Wort, a herbal product used to treat depression
 - Using St. John's Wort with Mylan-Gliclazide MR may lead to high blood sugar levels and loss of blood sugar control.
- alcohol
 - Avoid drinking alcohol and taking medicines containing alcohol while you are taking Mylan-Gliclazide MR. This can lead to a drop in blood sugar levels.

Medicines like diuretics, corticosteroids, oral contraceptives, chlorpromazine, ritodrine, salbutamol, terbutaline, danazol and nicotinic acid may lead to high blood sugar levels. See **Other Warnings** for more information on high blood sugar levels (hyperglycemia).

How to take Mylan-Gliclazide MR:

- Take Mylan-Gliclazide MR exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Take Mylan-Gliclazide MR once daily at breakfast.
- The 30 mg tablets cannot be split in half. Swallow the tablet whole with water.
- The 60 mg tablets can be halved.
- Do not crush or chew the tablets of either strength.

Usual Dose:

30 mg per day. This is one tablet of Mylan-Gliclazide MR 30 mg or half tablet of Mylan-Gliclazide MR 60 mg.

The daily dose should not exceed 120 mg.

Talk to your healthcare professional about checking your blood sugar levels. You should test your blood sugar levels as instructed by your healthcare professional to make sure that your blood sugar levels are being controlled.

Your healthcare professional will check your blood sugar levels during regular visits, especially when you start taking this medicine.

Overdose:

If you think you, or a person you are caring for, have taken too much Mylan-Gliclazide MR, contact a healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

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

What are possible side effects from using Mylan-Gliclazide MR?

These are not all the possible side effects you may have when taking Mylan-Gliclazide MR. If you experience any side effects not listed here, tell your healthcare professional.

- low blood sugar (hypoglycemia)
- high blood sugar (hyperglycemia)
- viral infection
- infection of the nose, sinuses, or throat (upper respiratory infection)
- runny nose
- sore throat
- cough
- back, muscle and joint pain
- headache
- high blood pressure (hypertension)
- chest pain (angina)
- leg swelling
- diarrhea
- constipation
- abdominal pain
- nausea
- dizziness
- skin rash
- itching
- depression
- urinary tract infection
- pink eye (conjunctivitis)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Low blood sugar level (hypoglycemia): anxious feeling, chest pain or pressure, chills, clammy skin, cold sweats, confusion, cool pale skin, depression, difficulty in concentration, dizziness, drowsiness, excessive hunger, fast or irregular heartbeat, headache, high blood pressure, nausea, nervousness, shakiness, shortness of breath, unsteady walk, unusual tiredness or weakness		✓	
UNCOMMON			
Chest pain or pressure, and/or shortness of breath			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Oedema , swelling of the legs or unexpected weight gain		✓	
Skin rash , redness, itching or hives			✓
Unexplained fever , chills or sore throat			✓
Yellowing of skin or eyes, dark-coloured urine or light-coloured bowel movements (e.g. jaundice)			✓
VERY RARE			
Allergic inflammation of blood vessels (vasculitis)			✓
Blood abnormalities with symptoms of sore throat, fever, mouth sore, unusual bleeding or bruising, low level of red blood cells (anemia)			✓
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			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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.

Storage:

- Keep out of reach and sight of children and pets.
- Mylan-Gliclazide MR should be stored at room temperature between (15°C to 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.

If you want more information about Mylan-Gliclazide MR:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.mylan.ca or by calling 1-844-596-9526.

This leaflet was prepared by Mylan Pharmaceuticals ULC.

Last Revised MAR 08, 2024