

## **INFORMATION TO THE PATIENT**

Full prescribing information is available to the physicians and pharmacists.

GLICLAZIDE is available only with your physician's prescription.

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

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

Before you begin treatment with this medicine, you and your doctor should talk about the good medicine will do as well as the risks of using it. You should also find out about other possible ways to control your diabetes such as by diet alone or by diet plus insulin.

Use only as specifically directed. Do not alter the dosage unless ordered to do so by your physician.

### **Before using this medicine**

GLICLAZIDE 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 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.

GLICLAZIDE 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.

### **Proper use of this medicine**

Follow carefully the special meal plan your physician gave you. This is the most important part of controlling your condition and is necessary if the medicine is to work properly.

Take GLICLAZIDE with a meal as directed by your physician. Do not take more nor less of it than your doctor ordered, and take it at the same time each day. If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

**GLICLAZIDE is contraindicated (must not be taken) in the following conditions:**

- Allergy or hypersensitivity to gliclazide, other sulphonylureas, sulphonamides or to any of the excipients of this product.
- Unstable and/or insulin-dependent diabetes mellitus (type I diabetes), particularly juvenile diabetes, diabetes ketoacidosis, diabetes pre-coma and coma.
- Stressful conditions such as serious infection, trauma or surgery.
- Severe liver impairment.
- Severe kidney impairment.
- Treatment with miconazole.
- Pregnancy and/or breast-feeding.

The safety of GLICLAZIDE in adolescents and children has not been established.

GLICLAZIDE is prescribed for your specific medical problem and for your own use only. Do not give to other people.

Keep all medicines out of the reach of children.

Precautions while using this medicine

Your physician should check your progress at regular visits, especially during the first few weeks that you take this medicine. Please keep your appointments.

Test for sugar in your blood or urine as directed by your physician. This is a convenient way to make sure your diabetes is being controlled and provides an early warning when it is not.

Do not take any other medicine, unless prescribed or approved by your doctor. If you require medical assistance, inform the medical practitioner that you are taking GLICLAZIDE.

**Drugs that may interact with GLICLAZIDE are:**

- Other antidiabetic agents, long-acting sulfonamides, tuberculostatics, clarithromycin, NSAIDs, fibrates, monoamine oxidase inhibitors, salicylates, probenecid, beta-blockers, azole antifungal agents (oral and parenteral preparations), H<sub>2</sub>-receptor antagonists and angiotensin converting enzyme inhibitors, anticoagulants barbiturates and fluoroquinolones. Certain drugs tend to induce hyperglycemia and may lead to loss of blood sugar control. These include diuretics (thiazides, furosemide), corticosteroids, oral contraceptives (estrogen plus progestogen), chlorpromazine, ritodrine, salbutamol, terbutaline, danazol and nicotinic acid in pharmacologic doses. 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 as GLICLAZIDE, 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.

**Herbs that may interact with GLICLAZIDE are:**

- Saint John's Wort preparations tend to cause high blood sugar and may lead to loss of blood sugar control.

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 have been reported in patients taking GLICLAZIDE. 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.

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

Inform your physician about any illness which may develop during your treatment with GLICLAZIDE and about any new prescribed or non-prescribed medication you may be taking.

#### Side effects of this medicine

Along with their needed effects, oral antidiabetes medicines may cause some unwanted effects.

The more frequently reported side effects during clinical trials with gliclazide were hypoglycemia (low blood sugar) and indigestion or stomach upsets.

**You should know that the usual signs of low blood sugar level (hypoglycemia) are: anxious feeling, drowsiness, chills, cold sweats, confusion, cool pale skin, difficulty in concentration, excessive hunger, fast heartbeat, headache, nausea, nervousness, shakiness, unsteady walk, unusual tiredness or weakness. If you recognize by 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).**

In addition, some uncommon serious side effects/symptoms may happen and you should stop taking the drug and talk with your doctor or pharmacist in all cases: unexplained fever chills or sore throat; yellowing of skin or eyes, dark-coloured urine or light-coloured bowel movements (e.g. jaundice) which in most cases disappeared after withdrawal of the drug, but may lead to life-threatening liver failure in isolated cases; 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 cases of the following have been reported: 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 tissues such as eyelids, face, lips, mouth, tongue or throat that may result in breathing difficulty (angioedema); widespread blistering or peeling of the skin.

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 have been reported in patients taking gliclazide. 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.

Additional information on GLICLAZIDE may be obtained from your physician or pharmacist.

### **Reporting Side Effects**

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

#### **3 ways to report:**

- Online at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 1908C  
Ottawa, ON  
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>).

*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 Sanis Health Inc., at:

1-866-236-4076

or [quality@sanis.com](mailto:quality@sanis.com)

This leaflet was prepared by:

Sanis Health Inc.

1 President's Choice Circle

Brampton, Ontario

L6Y 5S5

Last revised: Cr tk18"4239