

## Module 1.3.3 Package Leaflet

### Glimepiride

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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#### Glimepiride Tablets

Glimepiride

- The active substance is glimepiride
- The other ingredients are Lactose, Starch, Talcum, Magnesium Stearate and Colour Red Oxide of Iron

#### Marketing Authorisation Holder and Manufacturer

### 1. WHAT IS GLIMEPIRIDE AND WHAT IT IS USED FOR

This medicine contains glimepiride. Glimepiride is one of a group of medicines called sulphonylurea hypoglycaemics. These medicines work by helping control blood sugar (glucose) levels.

Glimepiride is used with diet and exercise to treat type 2 diabetes (condition in which the body does not use insulin normally and therefore cannot control the amount of sugar in the blood). Glimepiride stimulates your pancreas to make more insulin and also makes your body more sensitive to insulin. Glimepiride may be used with or without insulin.

### 2. BEFORE YOU TAKE GLIMEPIRIDE

Do not take Glimepiride if you:

- have ever had an allergic reaction to glimepiride, other sulphonylureas (e.g. glibenclamide, gliclazide, tolbutamide) or sulphonamides (e.g. sulfamethoxazole). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue
- have type 1 insulin dependent diabetes
- have been told by your doctor that you have 'ketoacidosis' (your breath may smell fruity)
- have severe kidney or liver problems

Inform your doctor what prescription and nonprescription medications you are taking, especially other antidiabetics, antibiotics, anticoagulants ('blood thinners') such as warfarin (Coumadin), dexamethasone, diuretics ('water pills'), estrogens, isoniazid (INH), MAO inhibitors (phenelzine, tranylcypromine), medications for high blood pressure or heart disease, niacin, oral contraceptives, phenytoin, prednisone, probenecid and vitamins.

It is important to take regular meals at regular times of the day whilst taking treatment with these tablets. Skipping or taking irregular meals whilst taking glimepiride tablets may lead to hypoglycaemia (low blood sugar). You are advised NOT to drink alcohol with this medicine. Discuss this with your doctor if you have any questions.

### Pregnancy and Breast-feeding

Tell your doctor if you are pregnant or planning a family. Your doctor will probably change your treatment.

Remind your doctor if you are pregnant and diabetic as your blood glucose levels must be closely monitored.

You should not breast-feed your baby whilst taking Glimepiride.

Your ability to concentrate and react may be impaired as a result of hypoglycaemia (low blood sugar) or hyperglycaemia (high blood sugar). This may constitute a risk in situations where these abilities are of special importance (e.g. driving a car or operating machinery). You are advised to take precautions to avoid hypoglycemia while driving or operating machinery.

### **3. HOW TO TAKE GLIMEPIRIDE**

Glimepiride comes as tablets to be taken by mouth. It is usually taken once a day. The tablet should be taken with breakfast or the first big meal of the day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take this medicine exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Continue to take Glimepirid even if you feel well. Do not stop taking this medicine without talking to your doctor.

If you have the impression that the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist.

#### **If you take more of this medicine than you should:**

If you (or someone else) swallow a lot of the tablets at the same time, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

### **If you forget to take this medicine**

Take the missed dose as soon as you remember it. If you will be having a snack soon, take a dose with the snack. If it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, glimepiride can have side effects.

This medication may cause changes in your blood sugar. You should know the symptoms of low and high blood sugar and what to do if you have these symptoms.

You may experience hypoglycemia (low blood sugar) while you are taking this medication. Your doctor will tell you what you should do if you develop hypoglycemia. He or she may tell you to check your blood sugar, eat or drink a food or beverage that contains sugar, such as hard candy or fruit juice, or get medical care. Follow these directions carefully if you have any of the following symptoms of hypoglycemia:

- shakiness
- dizziness or lightheadedness
- sweating
- nervousness or irritability
- sudden changes in behavior or mood
- headache
- numbness or tingling around the mouth
- weakness
- pale skin
- hunger
- clumsy or jerky movements

If hypoglycemia is not treated, severe symptoms may develop. Be sure that your family, friends, and other people who spend time with you know that if you have any of the following symptoms, they should get medical treatment for you immediately.

- confusion
- seizures
- loss of consciousness

Call your doctor immediately if you have any of the following symptoms of hyperglycemia (high blood sugar):

- extreme thirst
- frequent urination
- extreme hunger
- weakness
- blurred vision

If high blood sugar is not treated, a serious, life-threatening condition called diabetic ketoacidosis could develop. Call your doctor immediately if you have any of the these symptoms:

- dry mouth
- upset stomach and vomiting
- shortness of breath
- breath that smells fruity
- decreased consciousness

Glimepiride may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

#### **5. STORING GLIMEPIRIDE**

Keep out of the reach and sight of children.

Do not store above 30°C

Store in the original package

Do not use after the expiry date stated on the strip