

GLIMPID TABLETS

Consumer Medication Information Leaflet (RiMUP)

Glimepiride 1 mg, 2 mg, 3 mg & 4 mg

What is in this leaflet

1. What **GLIMPID TABLETS** is used for
2. How **GLIMPID TABLETS** work
3. Before you use **GLIMPID TABLETS**
4. How to use **GLIMPID TABLETS**
5. While you are using **GLIMPID TABLETS**
6. Side Effects
7. Storage and disposal of **GLIMPID TABLETS**
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What **GLIMPID TABLETS** is used for

GLIMPID TABLETS is used:

- As additional therapy in patients whose blood sugar levels are not adequately controlled by exercise and diet changes alone.

How **GLIMPID TABLETS** works

The active ingredient of **GLIMPID TABLETS** is glimepiride, which belongs to a group of medicines called sulphonylurea, which are a type of oral hypoglycaemic drugs. Oral hypoglycaemic drugs including sulphonylurea are used for the treatment of type 2 diabetes (a disease where the body does not produce enough insulin to control the level of blood sugar). Sulphonylureas increase the secretion of insulin from your pancreas. The insulin then lowers your blood sugar levels.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you use **GLIMPID TABLETS**

When you must not use it

Do not take **GLIMPID TABLETS** if

- You have previously had an allergic reaction to glimepiride or other sulphonylureas or sulphonamides or

to any of the ingredients of your medicine (see **Product description**). An allergic reaction may include rash, itching, swelling of face, lips, tongue or hands/feet, or breathing difficulties.

- You have insulin dependent diabetes (type 1 diabetes mellitus). It is a type of diabetes that usually develops in childhood and requires insulin injection to control the blood sugar levels.
- You have serious liver or kidney problems.
- You have diabetic ketoacidosis with or without coma. In these conditions your doctor may prescribe insulin injections to prevent further worsening of the condition.

If you are not sure whether to start taking this medicine, talk to your doctor or pharmacist.

Before you start to use it

Tell your doctor if you have or have had any of the following medical conditions:

- You are recovering from an injury, operation, infections with fever, or from other forms of stress, inform your doctor as temporary change of treatment to insulin may be necessary
- Adrenal, pituitary or thyroid problems
- Serious liver problems
- Kidney problems
- You are suffering from glucose-6-phosphate dehydrogenase (G6PD) deficiency. Lowering of the haemoglobin level and breakdown of red blood cells (haemolytic anaemia) can occur in patients missing the enzyme glucose-6-phosphate dehydrogenase.
- A history of diabetic coma
- If you have heart problems
- Information available on the use of glimepiride in children is limited, therefore its use in these patients is not recommended.

Important information of some of the ingredients of **GLIMPID TABLETS**

Your medicine also contains an inactive ingredient called lactose monohydrate, which is a type of sugar. If you have been told by your doctor

that you have intolerance to some sugars, talk to your doctor before taking this medicine.

If you have not told your doctor about any of the above, tell him/her before you start taking **GLIMPID TABLETS**.

Important information about hypoglycaemia (low blood sugar)

When you take **GLIMPID TABLETS** you may get hypoglycaemia (low blood sugar). Please see below for additional information about hypoglycaemia, its signs and treatment.

Following factors could increase the risk of you getting hypoglycaemia:

- Irregular meal time, missed or delayed meal or period of fasting, changes to your diet
- If you increase the amount of exercise you do and you don't eat enough food or eat food containing less carbohydrate than usual.

Signs of hypoglycaemia include:

Weakness, shakiness, sweating, dizziness, problems with concentration, hunger, headache, numbness around the lips and tongue, nausea, vomiting, sleeping problems, restlessness, aggression, problems with your speech and sight, slurred speech, fast or increased heart-beat, change in blood pressure.

Treating hypoglycaemia:

In most cases the signs of reduced blood sugar vanish very quickly when you consume some form of sugar, e.g. sugar cubes, sweet juice, and sweetened tea.

You should therefore always take some form of sugar with you (e.g. sugar cubes). Remember that artificial sweeteners are not effective. Please contact your doctor or go to the hospital if taking sugar does not help or if the symptoms recur.

Laboratory Tests

The level of sugar in your blood or urine should be checked regularly. Your doctor may also take blood tests

to monitor your blood cell levels and liver function.

Taking other medicines

Ask your doctor or pharmacist for advice before taking GLIMPID TABLETS if you are taking any of the following medicines:

Please tell your doctor or your pharmacist if you are taking, or have recently taken, any other medicine, including medicines obtained without a prescription.

The following medicines can increase the blood sugar lowering effect of glimepiride. This can lead to a risk of hypoglycaemia (low blood sugar):

- Other antidiabetic medicines (e.g. insulin, pramlintide acetate or metformin)
- Medicines to treat pain and inflammation (phenylbutazone, azapropazone, oxyfenbutazone, salicylates, nonsteroidal anti-inflammatory drugs and propoxyphene)
- Medicines to treat bacterial infections (tetracyclines, chloramphenicol, sulfonamides, quinolones, clarithromycin)
- Medicines inhibiting blood clotting (coumarins)
- Medicines to treat fungal infections (fluconazole, miconazole)
- Medicines to lower blood cholesterol (fibrates)
- Medicine to increase blood flow in the arms and legs through blood vessels (pentoxifylline)
- Medicines used for inhibiting the excessive growth hormone production (somatostatin analogs)
- Medicines supporting muscle build up (anabolic steroids)
- Medicines used for male sex hormone replacement therapy (androgens)
- Medicine used to relax your muscle (phenylramidol)
- Medicines used to treat depression and/or certain mental illnesses (fluoxetine, MAO inhibitors such as isocarboxazid, phenelzine)
- Medicines to treat high blood pressure, heart failure, or prostate symptoms (sympatholytics e.g. clonidine, Guanfacine, Methyldopa; ACE inhibitors such as ramipril, enalapril, lisinopril; guanethidine)
- Medicines to treat gout (allopurinol, probenecid, sulfinpyrazone).

- Medicines to treat cancer (cyclophosphamide, ifosfamide, trofosfamide)
- Medicines used to reduce weight (fenfluramine)
- Medicines to treat nasal allergies such as hay fever (tritoqualine)
- Medicines to treat abnormal heart rhythms (disopyramide).

The following medicines may decrease the blood sugar lowering effect of glimepiride. This can lead to a risk of hyperglycaemia (high blood sugar level):

- Medicines containing oestrogens (female sex hormone) and birth control pills (progestogens, oral contraceptives)
- Medicines inhibiting estrogens (danazol)
- Medicines used for promoting growth hormone production (somatropin)
- Medicines used to treat fits (eg. Phenytoin)
- Medicines to treat high blood pressure called thiazide and other diuretics including saluretics (water tablets)
- Medicine to treat high blood pressure (diazoxide)
- Medicines used to suppress inflammation and allergies (Glucocorticoids, corticosteroids)
- Medicines used to stimulate the thyroid gland (thyroid products such as levothyroxine)
- Medicines to treat severe mental disorders (chlorpromazine and other phenothiazine derivatives; atypical antipsychotics: olanzapine, clozapine)
- Medicines used to treat asthma or nasal congestion, coughs and colds, used to reduce weight, or used in life threatening emergencies (adrenaline and sympathomimetics, albuterol, terbutaline)
- Medicine to treat severe low blood sugar levels (glucagon)
- Medicines to treat tuberculosis (rifampin and isoniazid)
- Medicine to treat glaucoma (acetazolamide)
- Medicines to treat nervousness and sleep problems (barbiturates)
- Medicine to treat high cholesterol level (nicotinic acid)
- Medicines to treat constipation when they are used long term (laxatives)
- Medicine used to treat AIDS (protease inhibitors)

The following medicines can increase or decrease the blood sugar lowering effect of glimepiride:

- Medicines to treat stomach ulcers, (e.g. ranitidine, famotidine).
- Medicines used to treat high blood pressure or heart failure such as beta-blockers (e.g. atenolol, metoprolol), clonidine and reserpine.

These medicines can hide the signs of hypoglycaemia, so special care is needed when taking these medicines.

Alcohol intake may increase or decrease the blood sugar lowering action of **GLIMPID TABLETS** in an unpredictable way.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking **GLIMPID TABLETS**

How to use GLIMPID TABLETS

Follow all directions given to you by your doctor or pharmacist carefully.

How much to use

Your doctor would usually start the treatment with glimepiride 1 mg taken once daily.

The maximum recommended daily dose is 6 mg. Depending on your blood sugar levels, your doctor may decide to increase the dose gradually at intervals of 1-2 weeks.

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

When to use it

Glimepiride Tablets are to be swallowed whole with a glass of water. You should always take the tablets every day at the same time immediately before or during breakfast. If you are not in the habit of taking breakfast, then take your medicine before or during the first main meal.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Do not skip or delay your meals, as this may increase chances of developing hypoglycemia.

How long to use it

Continue taking **GLIMPID TABLETS** for as long as your doctor tells you.

Do not stop taking your medicine just because you feel better. If you stop taking your tablets too soon, your symptoms may return.

Your doctor will periodically assess the benefits and may discontinue your medicine, if it is not found to be effective.

If you forget to use it

If you forget to take a tablet, do not take a double dose to make up for the one you have missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

Immediately telephone your doctor for advice, or go to Emergency department at the nearest hospital, if you think that you or anyone else may have taken too much **GLIMPID TABLETS**. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using GLIMPID TABLETS**Things you must do**

Continue taking **GLIMPID TABLETS** every day as directed by your doctor.

Tell your doctor immediately if you become pregnant while taking GLIMPID TABLETS.

Clinical experience in pregnant women is limited.

There is no information as to whether the active substance passes into human breast milk. If you are pregnant, or think you may be pregnant, or if you are breast-feeding, **GLIMPID TABLETS** should not be taken during pregnancy & breast feeding. Ask your doctor for advice on the use of this medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use **GLIMPID TABLETS** to treat any other complaints unless your doctor says to.

Things to be careful of

GLIMPID TABLETS may cause hypoglycaemia or hyperglycaemia that may affect your ability to concentrate or cause disturbances of vision. These may affect your ability to drive and use machines. To avoid hypoglycemia do not miss or delay meals or change your diet, or take more **GLIMPID TABLETS** than needed, or do a more intense, or rigorous physical exercise or more work than normal. Make sure you know how you react to this medicine before you drive, use machines, or engage in any other activity that could be dangerous if you are not alert.

Side Effects

Like all medicines **GLIMPID TABLETS** can cause side effects, although not everybody gets them.

Serious side effects**If any of the following happen, stop taking GLIMPID TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital**

- If you get a raised, often itchy, red welts on the surface of the skin, trouble breathing, low blood pressure, fainting and swelling of the face and throat. You may be having an allergic reaction. You may need emergency treatment.
- Allergic reactions with sulphonylurea, sulphonamide or related drug may occur.
- Rare skin condition with redness, blisters
- Low blood sugar (hypoglycaemia) with loss of consciousness, seizures or coma.
- Yellowing of skin and whites of eyes with decreased appetite, abdominal pain, unusual tiredness and dark

urine (these may be manifestations of a liver/bile problems).

- Inflammation of blood vessels, often with skin rash.

Other side effects

Tell your doctor if you notice any of the following

- Decrease in the number of certain blood cells and platelets which may be manifested by weakness, frequent infections or increase tendency for bleeding and bruising
- Visual disturbances may occur at the beginning due to changes in the blood glucose levels.
- Feeling sick (nausea), being sick (vomiting), diarrhoea (loose stools), fullness of stomach, stomach disturbance and stomach pain
- Oversensitivity of the skin to sunlight or other forms of light (photosensitivity)
- Itching, hives
- Weakness (asthenia)
- Weight gain
- Giddiness, headache
- Body aches and pains, chills, cough, fatigue, fever, headache, nasal congestion, sore throat (Flu syndrome)
- Accidental injury.
- Feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be an illness called 'syndrome of inappropriate antidiuretic hormone secretion' (SIADH).

Laboratory abnormalities

- Increase in liver enzymes
- Decrease in blood sodium levels
- Low blood sugar (hypoglycaemia)
- Change in blood cell counts.

Tell your doctor if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→ Reporting)

Storage and disposal of GLIMPID TABLETS**Storage**

Keep **GLIMPID TABLETS** where children cannot reach it.

Store below 25°C, protected from moisture

Disposal

Return any unused or expired medicine to your doctor, pharmacist or health care professional for safe disposal.

Product Description**What GLIMPID TABLETS looks like**

GLIMPID TABLETS 1 mg : Pink coloured, capsule shaped, flat bevelled edge tablets with breakline on one side and 'GLT' debossed on the other side.

GLIMPID TABLETS 2 mg: Green coloured, capsule shaped, flat bevelled edge tablets with breakline on one side and 'GLT' debossed on the other side.

GLIMPID TABLETS 3 mg : Yellow coloured, capsule shaped, flat bevelled edge tablets with breakline on one side and 'GLT' debossed on the other side.

GLIMPID TABLETS 4 mg: Blue coloured, capsule shaped, flat bevelled edge tablets with breakline on one side and 'GLT' debossed on the other side.

Ingredients

Active ingredient: Glimepiride

Inactive ingredients:

GLIMPID tablet 1 mg contains:
Microcrystalline Cellulose, Sodium Starch Glycollate, Povidone (K-30), Lactose, Magnesium Stearate, Ferric Oxide (red), Purified Water.

Active ingredient: Glimepiride

Inactive ingredients:

GLIMPID tablet 2 mg contains:
Microcrystalline Cellulose, Sodium Starch Glycollate, Povidone (K-30), Lake of indigocarmine, Lactose, Magnesium Stearate, Ferric Oxide (Yellow), Purified Water.

Active ingredient: Glimepiride

Inactive ingredients:

GLIMPID tablet 3 mg contains:
Microcrystalline Cellulose, Sodium Starch Glycollate, Povidone (K-30), Lactose, Magnesium Stearate, Ferric Oxide (Yellow), Purified Water.

Active ingredient: Glimepiride

Inactive ingredients:

GLIMPID tablet 4 mg contains:
Microcrystalline Cellulose, Sodium Starch Glycollate, Povidone (K-30), Lactose, Magnesium Stearate, Lake of indigocarmine, Purified Water.

MAL Number:

- **GLIMPID TABLETS 1MG**
MAL07031131A
- **GLIMPID TABLETS 2MG**
MAL07031132A
- **GLIMPID TABLETS 3MG**
MAL07031134A
- **GLIMPID TABLETS 4MG**
MAL07031135A

Manufacturer and Product Registration Holder

RANBAXY (MALAYSIA) SDN. BHD.

Lot 23, Bakar Arang Industrial Estate, 08000 Sungai Petani, Kedah, Malaysia.

Date of Revision:

09/10/2014

Serial Number:

BPFK(R4/1)091014/00029