

PACKAGE LEAFLET: INFORMATION FOR THE USER

Glim 1 mg tablets
Glim 2 mg tablets
Glim 3 mg tablets
Glim 4 mg tablets
Glim 6 mg tablets
Glimepride

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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- WHAT *Glim* IS AND WHAT IT IS USED FOR
- BEFORE YOU TAKE *Glim*
- HOW TO TAKE *Glim*
- POSSIBLE SIDE EFFECTS
- HOW TO STORE *Glim*
- FURTHER INFORMATION

1. WHAT *Glim* IS AND WHAT IT IS USED FOR

Glim is an orally active blood sugar lowering drug. This drug belongs to a blood sugar lowering group of medicines called sulfonylurea. *Glim* works by increasing the amount of insulin released from your pancreas. The insulin then lowers your blood sugar levels. What *Glim* is used for:

- Glim* is used to treat a certain form of diabetes (type 2 diabetes mellitus) when diet, physical exercise and weight reduction alone have not been able to control your blood sugar levels.

2. BEFORE YOU TAKE *Glim*

Do not take *Glim* and tell your doctor if:

- You are allergic (hypersensitive) to: *Glimepride* or other sulfonylureas (medicines used to lower your blood sugar such as glibenclamide) or sulfonamides (medicines for bacterial infections such as sulfamethoxazole) or any of the other ingredients of *Glim* (listed in Section 6 What *Glim* contains).
- You have insulin dependent diabetes (type 1 diabetes mellitus).
- You have diabetic ketoacidosis (a complication of diabetes when your acid level is raised in your body and you may have some of the following signs: fatigue, feeling sick (nausea), frequent urination and muscular stiffness).
- You are in a diabetic coma.
- You have severe kidney disease.
- You have a severe liver disease.
- General: Macrovascular outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction.

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking *Glim*.

Take special care with *Glim*

Check with your doctor or pharmacist before taking your medicine if:

- You are recovering from an injury, operation, infections with fever, or from other forms of stress, inform your doctor as temporary change of treatment may be necessary.
- You have a severe liver or kidney disorder.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking *Glim*.

Lowering of the haemoglobin level and breakdown of red blood cells (haemolytic anaemia) can occur in patients missing the enzyme glucose-6-phosphate dehydrogenase. The information available on the use of *Glim* in people less than 18 years of age is limited. Therefore, its use in these patients is not recommended.

Important information about hypoglycaemia (low blood sugar)
 When you take *Glim*, 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:

- Undernourishment, irregular mealtime, missed or delayed meal or period of fasting.
- Changes to your diet.
- Taking more *Glim* than needed.
- Having decreased kidney function.
- Having severe liver disease.
- If you suffer from particular hormone-induced disorders (disorders of the thyroid glands, of the pituitary gland or adrenal cortex).
- Drinking alcohol (especially when you skip a meal).
- Taking certain other medicines (See Taking other medicines below).
- If you increase your body exercise and you do not eat enough or eat food containing less carbohydrate than normal.

Signs of hypoglycaemia include:

- Hunger pangs, headache, nausea, vomiting, sluggishness, sleepiness, disordered sleep, restlessness, aggression, impaired concentration, reduced alertness and reaction time, depression, confusion, speech and visual disorders, slurred speech, shakiness, partial paralysis, sensory disturbances, dizziness, helplessness.
 - The following signs may also occur: sweating, clammy skin, anxiety, accelerated heart beat, high blood pressure, palpitations, sudden strong pain in the breast that may radiate into neighboring areas (angina pectoris and cardiac arrhythmias).
- If blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop convulsions, lose self control, breathing may be shallow and your heart beat slowed down, you may fall into unconsciousness. The clinical picture of a severe reduced blood sugar level may resemble that of a stroke.

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

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Your doctor may wish to change your dose of *Glim* if you are taking other medicines, which may weaken or strengthen the effect of *Glim* on the level of sugar in your blood. The following medicines can increase the blood sugar lowering effect of *Glim*. This can lead to a risk of hypoglycaemia (low blood sugar):

- Other medicinal products to treat diabetes mellitus (such as insulin or metformin).
- Medicinal products to treat pain and inflammation (phenylbutazone, acetopropazone, oxphenbutazone, aspirin-like medicines).
- Medicinal products to treat urinary infections (such as some long acting sulfonamides).
- Medicinal products to treat bacterial and fungal infections (tetracyclines, chloramphenicol, fluconazole, miconazole, quinolones, clarithromycin).
- Medicinal products to inhibit blood clotting (coumarin derivatives such as warfarin).
- Medicinal products supporting muscle build up (anabolics).
- Medicinal products used for male sex hormone replacement therapy.
- Medicinal products to treat depression (flouxetine, MAO-inhibitors).
- Medicinal products lowering high cholesterol level (fibrates).
- Medicinal products lowering high blood pressure (ACE inhibitors).
- Medicinal products to treat gout (allopurinol, probenecid, sulfinpyrazone).
- Medicinal products to treat cancer (cyclophosphamide, ifosfamide, trofosfamide).
- Medicinal products used to reduce weight (fenfluramine).
- Medicinal product to increase circulation when given in a high dose intravenous infusion (pentoxifylline).
- Medicinal products to treat nasal allergies such as hay fever (tritoqualine).
- Medicinal products called sympatholytics to treat high blood pressure, heart failure, or prostate symptoms.

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

- Medicinal products containing female sex hormones (oestrogens, progestogens).
- Medicinal products supporting urine production (thiazide diuretics).
- Medicinal products used to stimulate the thyroid gland (such as levothyroxine).
- Medicinal products to treat allergies and inflammation (glucocorticoids).
- Medicinal products to treat severe mental disorders (chlorpromazine and other phenothiazine derivatives).
- Medicinal products used to raise heart beat, to treat asthma or nasal congestion, coughs and colds, used to reduce weight, or used in life-threatening emergencies (adrenaline and sympathomimetics).
- Medicinal products to treat high cholesterol level (nicotinic acid).
- Medicinal products to treat constipation when they are used long term (laxatives).
- Medicinal products to treat seizures (phenytoin).
- Medicinal products to treat nervousness and sleep problems (barbiturates).
- Medicinal products to treat increased pressure in the eye (azetazolamide).
- Medicinal products to treat high blood pressure or lowering blood sugar (diazoxide).
- Medicinal products to treat infections, tuberculosis (rifampicin).
- Medicinal products to treat severe low blood sugar levels (glucagon).

The following medicinal products can increase or decrease the blood sugar lowering effect of *Glim*:

- Medicinal products to treat stomach ulcers (called H2 antagonists).
- Medicinal products to treat high blood pressure or heart failure such as beta-blockers, clonidine, guanethidine and reserpine. These can also hide the signs of hypoglycaemia, so special care is needed when taking these medicines.
- Colesevelam, a medicine used to reduce cholesterol, has an effect on the absorption of *Glim*. To avoid this effect, you should be advised to take *Glim* at 4 hours before colesevelam.

***Glim* may either increase or weaken the effects of the following medicines:**

- Medicinal products inhibiting blood clotting (coumarin derivatives such as warfarin).

Taking *Glim* with food and drink

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

Pregnancy and breast-feeding

Pregnancy

Glim should not be taken during pregnancy. Tell your doctor if you are, you think you might be or are planning to become pregnant.

Breast feeding

Glim may pass into breast milk. *Glim* should not be taken during breast feeding.

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

Children and adolescents

Glim is not recommended for use in children under 18 years of age.

Driving and using machines

Your ability to concentrate or react may be impaired if your blood sugar is lowered (hypoglycaemia), or raised (hyperglycaemia) or if you develop visual problems as a result of such conditions. Bear in mind that you could endanger yourself or others (e.g. when driving a car or using machines). Please ask your doctor whether you can drive a car if you:

- have frequent episodes of hypoglycaemia,
- have fewer or no warning signals of hypoglycaemia

Important information about some of the ingredients of *Glim*
Glim contains lactose. If you have been told by your doctor that you cannot tolerate some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE *Glim*

Always take *Glim* exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth, just before or with the first main meal of the day. If you do not have breakfast you should take the product on schedule as prescribed by your doctor. It is important not to leave out any meal when you are on *Glim*.
- Swallow the tablets whole with at least half glass of water. Do not crush or chew the tablets.

How much to take

The dose of *Glim* depends on your needs, condition and results of blood and urine sugar tests and is determined by your doctor. Do not take more tablets than your doctor has prescribed.

- The usual starting dose is one *Glim* 1 mg tablet once a day.
- If necessary, your doctor may increase the dose after each 1 - 2 weeks of treatment.
- The maximum recommended dose is 6 mg *Glim* per day.
- A combination therapy of *Glimepride* plus metformin or of *Glimepride* plus insulin may be initiated. In such a case your doctor will determine the proper doses of *Glimepride*, metformin or insulin individually for you.
- If your weight changes or if you change your lifestyle, or you are in a stress situation this may require changed *Glim* doses, therefore inform your doctor.
- If you feel the effect of your medicine is too weak or too strong do not change the dose yourself, but ask your doctor.

If you take more *Glim* than you should

If you happen to have taken too much *Glim* or an additional dose there is a danger of hypoglycaemia (signs of hypoglycaemia see Section 2 - Take special care with *Glim*) and therefore you should instantly consume enough sugar (e.g. a small bar of sugar cubes, sweet juice, sweetened tea) and inform a doctor immediately. When treating hypoglycaemia due to accidental intake in children, the quantity of sugar given must be carefully controlled to avoid the possibility of producing dangerous hyperglycaemia. Persons in a state of unconsciousness must not be given food or drink.

Since the state of hypoglycaemia may last for some time it is very important that the patient is carefully monitored until there is no more danger. Admission into hospital may be necessary, also as a measure of precaution. Show the doctor the package or remaining tablets, so the doctor knows what has been taken.

Severe cases of hypoglycaemia accompanied by loss of consciousness and severe neurological failure are cases of medical emergency requiring immediate medical treatment and admission into hospital. It should be ensured that there is always a pre-informed person that can call a doctor in case of emergency.

If you forget to take *Glim*

If you forget to take a dose, do not take a double dose to make up for forgotten doses.

If you stop taking *Glim*

If you interrupt or stop the treatment you should be aware that the desired blood sugar lowering effect is not achieved or that the disease will deteriorate again. Keep taking *Glim* until your doctor tells you to stop.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Tell your doctor immediately if you experience any of the following symptoms:

- Allergic reactions (including inflammation of blood vessels, often with skin rash) which may develop into serious reactions with difficulty in breathing, fall in blood pressure and sometimes progressing to shock.
- Abnormal liver function including yellowing of the skin and eyes (jaundice), problems with the bile flow (cholestasis), inflammation of the liver (hepatitis) or liver failure.
- Allergy (hypersensitivity) of the skin such as itching, rash, hives and increased sensitivity to sun. Some mild allergic reactions may develop into serious reactions.
- Severe hypoglycaemia including loss of consciousness, seizures or coma.

Some patients experienced the following side effects whilst taking *Glim*:

- Rare side effects (affects more than 1 patient in 10,000 and less than 1 patient in 1000 people)
 - Lower blood sugar than normal (hypoglycaemia) (See Section 2 - Take special care with *Glim*).
- Decrease in the number of blood cells:
 - Blood platelets (which increases risk of bleeding or bruising).
 - White blood cells (which makes infections more likely).
 - Red blood cells (which can make the skin pale and cause weakness or breathlessness).

These problems generally get better after you stop taking *Glim*.

Very rare side effects (affects less than 1 patient in 10,000)

- Allergic reactions (including inflammation of blood vessels, often with skin rash) which may develop into serious reactions with difficulty in breathing fall in blood pressure and sometimes progressing to shock. If you experience any of these symptoms, tell your doctor immediately.
- Abnormal liver function including yellowing of the skin and eyes (jaundice), impairment of the bile flow (cholestasis), inflammation of the liver (hepatitis) or liver failure. If you experience any of these symptoms, tell your doctor immediately.
- Feeling or being sick, diarrhoea, feeling full or bloated, and abdominal pain.
- Decrease in the amount of sodium level in your blood (shown by blood tests).

Other side effects include:

- Allergy (hypersensitivity) of the skin may occur such as itching, rash, hives and increased sensitivity to sun. Some mild allergic reactions may develop into serious reactions with swallowing or breathing problems, swelling of your lips, throat or tongue. Therefore in the event of one of these side effects, tell your doctor immediately.
- Allergic reactions with sulfonylureas, sulfonamides, or related drugs may occur.
- Problems with your sight may occur when beginning treatment with *Glim*. This is due to changes in blood sugar levels and should soon improve.
- Increased liver enzymes.
- Severe unusual bleeding or bruising under the skin.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Post marketing experience:

Thrombocytopenia (including severe cases with platelet count less than 10,000/µL) and Thrombocytopenic purpura.

5. HOW TO STORE *Glim*

Keep out of the reach and sight of children.

Do not use *Glim* after the expiry date which is stated after 'EXP' on the blister and carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in the original package.

6. FURTHER INFORMATION

What *Glim* contains

- The active substance is 1, 2, 3, 4 or 6 mg of Glimepride.
- The other ingredients are:

***Glim* 1mg Tablets:** Lactose BP 200, sodium starch glycolate, magnesium stearate, Povidone K-30, Avicel PH 101 and Iron Oxide Yellow.

***Glim* 2mg Tablets:** Lactose BP 200, sodium starch glycolate, magnesium stearate, Povidone K-30, Avicel PH 101 Spectracol Brilliant Blue LK 815030 and Iron Oxide Yellow.

***Glim* 3mg Tablets:** Lactose BP 200, sodium starch glycolate, magnesium stearate, Povidone K-30, Avicel PH 101 and Iron Oxide Red.

***Glim* 4mg Tablets:** Lactose BP 200, sodium starch glycolate, magnesium stearate, Povidone K-30, Avicel PH 101 and Spectracol Brilliant Blue LK 815030.

***Glim* 6mg Tablets:** Lactose BP 200, sodium starch glycolate, magnesium stearate, Povidone K-30, Avicel PH 101.

What *Glim* looks like and contents of the pack

They are supplied in blister packs of 30 tablets.

***Glim* 1mg Tablets:** A light yellow, uniform to mottled, oblong, flat bevelled edge uncoated tablet with a breakline on one side and engraved with "15" on other side.

***Glim* 2mg Tablets:** A light green, uniform to mottled, oblong, flat bevelled edge uncoated tablet with a breakline on one side and engraved with "16" on other side.

***Glim* 3mg Tablets:** A light red, uniform to mottled, oblong, flat bevelled edge uncoated tablets with breakline on one side and engraved with "17" on other side.

***Glim* 4mg Tablets:** A light blue, uniform to mottled, oblong, flat bevelled edge uncoated tablet with a breakline on one side and engraved with "18" on other side.

***Glim* 6mg Tablets:** A white, oblong flat, bevelled edge uncoated tablet with a breakline on one side and debossed with "10" on the other side.

They are supplied in blister packs of 30 tablets.

Marketing Authorization Holder and Manufacturer

SPIMACCO

Al-Qassim Pharmaceutical Plant

Saudi Arabia

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"*Glim*" is a trade mark
 34G1689

To report any side effect(s):

- The National Pharmacovigilance and Drug Safety Centre (NPC)
- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sdfa.gov.sa
- Website: www.sdfa.gov.sa/npc

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacists who sold the medicament.
- The doctor and the pharmacists are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children

Council of Arab Health Ministers
 Union of Arab Pharmacists