PRICHEK TABLETS

Consumer Medication Information Leaflet (RiMUP)

(Glimepiride 1mg and 2mg)

What is in this leaflet?

What PRICHEK is used for

PRICHEK is a medicine taken by mouth to help lower blood sugar.

PRICHEK 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.

How PRICHEK works

PRICHEK belongs to a group of medicines called sulfonylureas. It works by increasing the amount of insulin released from your pancreas. This insulin removes sugar from the blood.

Before you use PRICHEK

- When you must not use it

PRICHEK must not be used in patients hypersensitive to PRICHEK, other sulfonylureas, other sulfonamides, or to any of the excipients.

PRICHEK is not suitable for the treatment of Insulin-dependent (type I) diabetes mellitus (e.g. for the treatment of diabetics with a history of ketoacidosis), of diabetic ketoacidosis, or of diabetic precoma or coma.

- Before you start to use it

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 PRICHEK if you are taking other medicines, which may weaken or strengthen the effect of PRICHEK on the level of sugar in your blood.

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 problem with your liver or kidneys.

- Taking other medicines

If PRICHEK is taken simultaneously with certain other medicines, both undesired increases and decreases in the hypoglycaemic action of PRICHEK can occur. For this reason, other medicines should only be taken with the knowledge (or at the prescription) of the doctor.

PRICHEK is metabolized by cytochrome. This should be taken into account when glimepiride is coadministered with inducers (e.g. rifampicin) or inhibitors (e.g. fluconazole) of cytochrome

H2 antagonists, betablockers, clonidine and reserpine may lead to either potentiation or weakening of the blood glucose lowering effect.

Drugs such as, beta blockers, clonidine, guanethidine and reserpine, may reduce the signs of counter regulation to low blood sugar.

PRICHEK may either potentiate or weaken the effects of coumarin derivatives

Potentiation of the blood-glucose-lowering effect and, thus, in some instances hypoglycaemia may occur when one of the following drugs is taken, for example:

Phenybutazone, azapropazone, oxyfenbutazone, insulin ,oral antidiabetic products, metformin, salicylates, p-amino-salicylic acid, anabolic steroids, male sex hormones, chloramphenicol, coumarin anticoagulant, fenfluramine, fibrates, sulphinpyrazone, certain long acting sulphonamides, tetracyclines, MAO-inhibitors, quinolone antibiotics, probenecid, miconazole, pentoxifylline (high dose parenteral), and tritoqualine.

Weakening of the blood-glucose-lowering effect and, thus raised blood glucose levels may occur when one of the following drugs is taken, for example:

oestrogens and progestagens, saluretics, thiazide diuretics, thyroid stimulating agents,

glucocorticoids, phenothiazine derivatives, chlorpromazine, adrenaline and sympathomimetics, nicotinic acid (high dosages) and nicotinic acid derivatives, laxatives (long term use), phenytoin, diazoxide, glucagon, barbiturates and rifampicin, acetazolamide.

Use in combination with insulin: whenever blood sugar levels cannot be controlled adequately with the minimum daily dose of PRICHEK, insulin may be given concomitantly. In this case, the current dose of PRICHEK remains unchanged. Insulin treatment is started at a low dose, which is subsequently increased stepwise according to the desired blood sugar level. Combined treatment should be initiated under close medical supervision.

How to use PRICHEK

- How much to use

The usual initial dose is 1 mg PRICHEK once daily. If necessary, the doctor will increase your dose based on regular blood sugar monitoring, and should be gradual, i.e., at intervals of one to two weeks, and carried out stepwise, as follows; 1mg – 2mg – 3mg – 4 mg – 6 mg, and – in exceptional cases – 8 mg.

In patients with well controlled diabetes the usual dose range is 1 to 4 mg PRICHEK daily. Some patients may be put on doses of more than 6 mg daily

If your control of diabetes improves, the doctor may reduce your dose of PRICHEK.

- When to use it

Before, or with the first main meal of the day (usually breakfast). 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 PRICHEK.

- How long to use it

Treatment with PRICHEK is normally a long-term therapy. Keep taking PRICHEK until your doctor tells you to stop.

- If you forget to use it

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

- If you use too much (overdose)

PRICHEK overdose may lead to severe and sometimes life-threatening hypoglycaemia and may require hospitalisation even as a precautionary measure.

While you are using it

- Things you must do

If hypoglacemia happens, usually it can be treated by consuming sugar, such as eating candy, drinking fruit juice or taking glucose tablets to raise your blood sugar level.

Swallow the tablets whole with at least half a glass of water. Do not crush or chew the tablets.

- Things you must not do

Your ability to concentrate or react may be reduced if your blood sugar is lowered (hypoglycaemia) or if you develop visual problems as a result of such conditions. Do not drive or handle or use any machine that you could endanger yourself or others.

PRICHEK may pass into breast milk. Ingestion of PRICHEK in the breast milk may harm the child. Therefore, PRICHEK must not be taken by breast-feeding women, and a changeover to insulin or discontinuation of breast-feeding is necessary.

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

Not to take any alcohol as it may increase or decrease the blood sugar lowering, action of PRICHEK in an unpredictable way.

- Things to be careful of

Hypoglycemia may happen when glucose in the body is too low. Some of the leading factors include under nutrition, irregular mealtimes or missed meals or periods of fasting. Please talk to your doctor or pharmacist if this happens to you.

No experience has been gained concerning the use of PRICHEK in patients with severe impairment of liver function and in dialysis patients. In patients with severe impairment of renal or hepatic function, a changeover to insulin is necessary, not least to achieve optimal metabolic control.

Side effects

Immune system disorders:

In very rare cases mild hypersensitivity reactions may develop into serious reactions with dyspnoea, fall in blood pressure and sometimes shock. Allergic vasculitis is also possible in very rare cases. Cross allergenicity with sulphonylureas, sulphonamides or related substances is possible as well.

Blood and lymphatic system disorders:

Changes in blood picture (haematology) are rare during PRICHEK treatment. Moderate to severe thrombocytopenia, (decrease in blood platelets) leucopenia(abnormal reduction in white blood cells), erythrocytopenia (deficiency in production of red blood cells),granulocytopenia(decrease in granulocytes), agranulocytosis, (decrease in special white blood cells) haemolytic anaemia (breakdown of red blood cells) and pancytopenia (low level of all blood cells) may occur. These are in general reversible upon discontinuation of medication.

Metabolism and nutrition disorders:

In rare cases hypoglycaemic reactions such as visual disturbances, heart palpitations, shakiness, anxiety and sweating have been observed after administration of PRICHEK. These reactions mostly occur immediately, may be severe and are not always easy to correct. The occurrence of such reactions depends, as with other hypoglycaemic therapies, on individual factors such as dietary habits and the dosage

Eye disorders:

Transient visual disturbances may occur especially on initiation of treatment, due to changes in blood glucose levels.

Gastrointestinal disorders:

Gastrointestinal complaints like nausea, vomiting and diarrhoea, pressure or a feeling of fullness in the stomach and abdominal pain are very rare and seldom lead to discontinuation of therapy.

Hepato-biliary disorders:

Elevation of liver enzymes may occur. In very rare cases, impairment of liver function (e.g. with cholestasis and jaundice) may develop, as well as hepatitis which may progress to liver failure.

Skin and subcutaneous tissue disorders:

Hypersensitivity reactions of the skin may occur as itching, rash and urticaria.

In very rare cases hypersensitivity to light may occur.

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 PRICHEK

- Storage

Store below 30°C, in a cool dry place.

- Disposal

Medicines should not be disposed of via wastewater or household water. Ask your pharmacist how to dispose of medicines no longer required.

Product Description

- What it looks like

PRICHEK 1 mg tablets:

Pale pink coloured, circular, tablets with beveled edges.

PRICHEK 2 mg tablets: Light green coloured, circular, uncoated tablets with beveled edges.

- Ingredients
  - Active ingredient (s) Glimepiride
  - Inactive ingredients Microcrystalline cellulose BP, maize starch BP, lactose BP, sodium starch glycolate USP, colloidal silicon dioxide BP, Iron oxide red (1mg), Yellow oxide of Iron and indigo carmine (2mg) povidone (PVP K30), polysorbate 80 BP, crospovidone NF, magnesium stearate BP, purified water BP.
- MAL number:

Prichek 1mg Tablet
MAL09111738A

Prichek 2mg Tablet
MAL09111739A

Manufacturer

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