Diaryl®

(Glimepiride Tablet)

Description

Diaryl contains Glimepiride which is an oral blood-glucose-lowering drug of the sulphonylurea class. Chemically Glimepiride is identified as 1-[[p-[2-(3-ethyl-4-methyl-2-oxo-3-pyrroline-1-carboxamido) ethyl]phenyl] sulphonyl]-3-(trans-4-methylcyclohexyl) urea. The primary mechanism of action of Glimepiride is lowering of blood glucose by stimulating the release of insulin from functioning pancreatic β cells. In addition, extra-pancreatic effects may also play vital role in the activity of Glimepiride. Administration of Diaryl can lead to increase sensitivity of peripheral tissues to insulin.

Indications

Non-insulin dependent (type-III) diabetes, whenever blood sugar levels cannot be controlled adequately by diet, physical exercise and weight reduction.

Diaryl is also indicated for use in combination with Insulin to lower blood glucose in patients whose hyperglycaemia can not be controlled by diet and exercise or in conjunction with an oral hypoglycaemic agent.

Dosage and Administration

In principle, the dosage of Diaryl is governed by the desired blood sugar level. The dosage of Diaryl must be the lowest which is sufficient to achieve the desired metabolic control.

The initial and the maintenance doses are set based on the results of regular checking of glucose in blood and urine. Monitoring of glucose levels in blood and urine also serves to detect either primary or secondary failure of therapy.

Initial dose and dose titration : Usual initial dose is 1 mg once daily. If necessary, the daily dose can be increased. Any increase can be based on regular blood sugar monitoring, and should be gradual, i.e., at intervals of one to two weeks and carried out stepwise at follows : 1 mg-2 mg-3 mg-4 mg-6 mg.

Dose range in patients with well controlled diabetes : Usual dose range in patients with well controlled diabetes is 1 to 4 mg daily.

Distribution of doses : Timing and distribution of doses are decided by the physician, in consideration of the patient's current life style. Normally, a single daily dose is sufficient. This should be taken immediately before a substantial breakfast or - if none is taken - immediately before the first main meals. It is very important not to skip meals after taking the drug.

Secondary dosage adjustment : As the control of diabetes improves, sensitivity to insulin increases; therefore, Diaryl requirement may fall as treatment proceeds. To avoid hypoglycaemia, timely dose reduction or cessation of Glimepiride therapy must be considered.

A dose adjustment must also be considered whenever the patient's weight or life style changes, or other factors arise which cause an increased susceptibility to hypo- or hyperglycaemia.

Changeover from other oral antidiabetics to Diaryl : There is no exact dosage relationship between Glimepiride and other oral blood sugar lowering agents. When substituting Glimepride for other such agents, the initial daily dose is 1 mg; this applies even in changeover from the maximum dose of other oral blood sugar lowering agents. Any dose increase should be in accordance with guideline given above in initial dose and dose titration.

Consideration must be given to the potency and duration of action of the previous blood sugar lowering agent. It may be necessary to interrupt treatment to avoid additive effects which would increase the risk of hypoglycaemia.

Administration : Diaryl tablet must be swallowed without chewing and with sufficient amount of liquid (approximately ½ glass).

Contraindications

Glimepiride is not suitable for the treatment of insulin dependent (type-I) diabetes mellitus, or of diabetic pre-coma or coma. Glimepiride must not be used in patients hypersensitive to Glimepiride or other sulphonylureas.

Precautions

In the initial weeks of treatment, the risk of hypoglycaemia may be increased and necessitates careful monitoring. If such risk is present it may be necessary to adjust the dosage of Glimepiride. Hypoglycaemia can almost always be promptly controlled by immediate intake of carbohydrates (glucose or sugar, e.g., sugar sweetened fruit juice or sugar sweetened tea).

Drug Interactions

Potentiation of the blood-sugar-lowering effect may occur with Insulin and other oral anti-diabetics, ACE inhibitors, Allopurinol, anabolic steroids and male sex hormones, Chloramphenicol, coumarin derivatives, Fluoxetine, MAO inhibitors, Miconazole, Para-aminosalicyclic acid, Pentoxifylline (high dose parenteral), Phenylbutazone, Oxyphenbutazone, quinolones, salicylates, sulphonamides, tetracyclines, β blockers.

Weakening of the blood-sugar-lowering effect may occur with Acetazolamide, barbiturates, corticosteroids, Diazoxide, diuretics, Epinephrine and other sympathomimetic agents, laxative, oestrogens and progestogens, phenothiazines, Phenytoin, Rifampicin, and thyroid hormones.

H_2 -receptor antagonists, Clonidine and Reserpine may lead to either potentiation or weakening of the blood-sugar-lowering effect.

Both acute and chronic alcohol intake may potentiate or weaken the blood-sugar-lowering action of Glimepiride unpredictably.

Side Effects

Hypoglycaemia, temporary visual impairment, nausea, vomiting, diarrhoea, abdominal pain, urticaria, fall in blood pressure.

Use in Special Populations

Pregnancy : Glimepiride must not be taken during pregnancy; a changeover to Insulin is necessary. Patients planning a pregnancy must inform their physician, and should be shifted to Insulin.

Lactation : Ingestion of Glimepiride with breast milk may harm the child. Therefore, Glimepiride must not be taken by lactating women. Either a changeover or a complete discontinuation of breast-feeding is necessary.

Commercial Packs

Diaryl® 1 Tablet : Each box contains 3 x 10's tablets in blister strips. Each tablet contains Glimepiride INN 1 mg.

Diaryl® 2 Tablet : Each box contains 3 x 10's tablets in blister strips. Each tablet contains Glimepiride INN 2 mg.