

Secrin[®]

Glimepiride EP

COMPOSITION

Secrin[®] 1 tablet: Each tablet contains Glimepiride EP 1 mg.

Secrin[®] 2 tablet: Each tablet contains Glimepiride EP 2 mg.

Secrin[®] 3 tablet: Each tablet contains Glimepiride EP 3 mg.

Secrin[®] 4 tablet: Each tablet contains Glimepiride EP 4 mg.

PHARMACOLOGY

The primary mechanism of action of **Secrin[®]** (Glimepiride) is lowering of blood glucose by stimulating the release of insulin from functioning pancreatic beta-cells. In addition, extrapancreatic effects may also play vital role in the activity of **Secrin[®]**. Administration of **Secrin[®]** can lead to increase sensitivity of peripheral tissues to insulin.

INDICATION

Secrin[®] is indicated as an adjunct to diet and exercise to lower blood glucose in patients with noninsulin-dependant (type 2) diabetes mellitus (NIDDM) whose hyperglycemia cannot be controlled by diet and exercise alone. **Secrin[®]** may be used concomitantly with Metformin when diet, exercise, and Glimepiride or Metformin alone do not result in adequate glycemic control. **Secrin[®]** is also indicated for use in combination with insulin to lower blood glucose in patients whose hyperglycemia can not be controlled by diet and exercise or in conjunction with an oral hypoglycemic agent.

DOSAGE AND ADMINISTRATION

There is no fixed dosage regimen for the management of diabetes mellitus with **Secrin[®]** or any other hypoglycemic agent. The initial and the maintenance dosage are set based on the results of regular check 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. *Usual starting dose:* The usual starting dose of **Secrin[®]** as initial therapy is 1-2 mg once daily, administered with breakfast or the first main meal. Those patients who may be more sensitive to hypoglycemic agents should be started with 1 mg once daily, and should be titrated carefully. There is no exact dosage relationship between **Secrin[®]** and other oral blood glucose lowering agents. The maximum starting dose of **Secrin[®]** should be no more than 2 mg. *Usual maintenance dose:* The usual maintenance dose is 1 to 4 mg once daily. The maximum recommended dose is 8 mg once daily. After reaching of a dose of 2 mg, dosage increases should be made in increments of no more than 2 mg at 1-2 weeks intervals based upon the patient's blood glucose response. *Patients receiving other oral hypoglycemic agents:* As with other sulfonylurea hypoglycemic agents, no transition period is necessary when transferring patients to **Secrin[®]**. Patients should be observed carefully (1-2 weeks) for hypoglycemia when being transferred from longer-half life sulfonylureas (e.g. chlorpropamide) to **Secrin[®]** due to potential overlapping of drug effect.

CONTRAINDICATION

Glimepiride is contraindicated in patients with

1. Known hypersensitivity to the drug.
2. Diabetic ketoacidosis, with or without coma. This condition should be treated with insulin.

PRECAUTION

Hypoglycemia: All sulfonylurea drugs are capable of producing severe hypoglycemia. Proper patient selection, dosage, and instructions are important to avoid hypoglycemic episodes. Patients with impaired renal function may be more sensitive to the glucose-lowering effect of Glimepiride. Debilitated and malnourished patients and those with adrenal, pituitary, or hepatic insufficiency are particularly susceptible to the hypoglycemic action of glucose-lowering drugs. *Loss of control of blood glucose:* When a patient is stabilized on any diabetic regimen is exposed to stress such as fever, trauma, infection, or surgery, a loss of control may occur. At such times, it may be necessary to add insulin in combination with Glimepiride or even use insulin monotherapy. *Hemolytic anemia:* Treatment of patients with glucose 6-phosphate dehydrogenase (G6PD) deficiency with sulfonylurea agents can lead to hemolytic anemia. Since Glimepiride belongs to the class of sulfonylurea agents, caution should be used in patients with G6PD deficiency and a non-sulfonylurea alternative should be considered.

SIDE EFFECT

Hypoglycemia, nausea, vomiting, diarrhea, abdominal pain, allergic skin reactions e.g. pruritus, erythema & urticaria and blurred vision may be reported.

DRUG INTERACTION

The hypoglycemic action of sulfonylureas may be potentiated by certain drugs, including NSAIDs and other drugs that are highly protein bound, such as salicylates, sulfonamides, chloramphenicol, coumarins, probenecid, MAO inhibitors, beta adrenergic blocking agents, and clarithromycin. Certain drugs tend to produce hyperglycemia and may lead to loss of control. These drugs include thiazides, and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, and isoniazide. A potential interaction between oral miconazole and oral hypoglycemic drugs leading to severe hypoglycemia has been reported.

USE IN PREGNANCY AND LACTATION

Pregnancy: Pregnancy category C. There are no adequate and well-controlled studies in pregnant women. On the basis of results from animal studies, Glimepiride should not be used during pregnancy. Patients who are planning a pregnancy should consult their physician, and it is recommended that they change over to insulin for the entire course of pregnancy and lactation. *Nursing mothers:* Although it is not known whether Glimepiride is excreted in human milk, other sulfonylureas are excreted in human milk. Because the potential for hypoglycemia in nursing infants may exist, Glimepiride should be discontinued in nursing mothers. Insulin therapy should be considered in this situation.

STORAGE

Store below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

HOW SUPPLIED

Secrin[®] 1 tablet: Each box contains 60 tablets in blister pack.

Secrin[®] 2 tablet: Each box contains 60 tablets in blister pack.

Secrin[®] 3 tablet: Each box contains 30 tablets in blister pack.

Secrin[®] 4 tablet: Each box contains 30 tablets in blister pack.