TM Secrin

Glimepiride USP

COMPOSITION:

Secrin[®] 1 tablet: Each tablet contains Glimepiride USP 1 mg. Secrin® 2 tablet: Each tablet contains Glimepiride USP 2 mg. Secrin[®] 3 tablet: Each tablet contains Glimepiride USP 3 mg. Secrin[®] 4 tablet: Each tablet contains Glimepiride USP 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 hyperglycaemia 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. 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.

SIDE EFFECT:

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

USE IN PREGNANCY AND LACTATION:

Pregnancy: Pregnancy category C. There are no adequate and well-controlled studies in pregnant women.

STORAGE:

Store at a cool and dry place, protected from light and moisture.

HOW SUPPLIED

Secrin[®] 1 : Box containing 1 X 15 / 2 x 15 / 3 x 15 / 5 x 15 / 10 x 15 tablets in blister pack.

Secrin[®] 2 : Box containing 1 X 15 / 2 x 15 / 3 x 15 / 5 x 15 / 10 x 15 tablets in blister pack.

Secrin[®] 3 : Box containing 1 X 15 / 2 x 15 / 3 x 15 / 5 x 15 / 10 x 15 tablets in blister pack.

Secrin[®] 4 : Box containing 1 x 10 / 2 x 10 / 3 x 10 / 5 x 10 / 10 x 10 tablets in blister pack.

Manufactured by



PHARMACEUTICALS LTD. BANGLADESH