گولیاں

گلیمیکس®

گلیمیپرائیڈ

۱ ملی گرام، ۲ ملی گرام، ۳ ملی گرام، ۴ ملی گرام

گلیمیکس ذیابیطس (ٹائپ II) کیلئے نہایت موثر دوا ہے۔

خوراک:

ابتدائی خوراک: ۱ تا ۲ ملی گرام دن میں ایک مرتبہ ناشتے یا پہلی بڑی غذا کے ساتھ استعمال کریں۔ ابتدائی تجویز کردہ خوراک ۲ ملی گرام سے زیادہ نہیں ہونی چاہیئے۔

عمومی خوراک: ۱ تا ۴ ملی گرام دن میں ایک مرتبہ استعمال کریں۔ زیادہ سے زیادہ عمومی خوراک ۸ ملی گرام روزانہ ہے۔ اضافہ بتدریج یعنی ایک تا دو ہفتوں کے وقفوں سے ۲ ملی گرام کے حساب سے کیا جانا چاہیئے۔ ہر اضافہ شکرِ خونی کی باقاعدہ جانچ کی بنیاد پر کیا جانا چاہیئے۔

ہدایات:

* دوا کو تجویز کردہ خوراک سے بڑھانا خطرناک ہوسکتا ہے۔
* دوا کو صرف ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔
* دوا کو ٹھنڈی اور خشک جگہ پر رکھیں۔
* دوا کو گرمی، روشنی اور نمی سے محفوظ رکھیں۔
* تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

پیشکش:

گلیمیکس ۱ ملی گرام گولیاں (۱۰x۲) ایلو۔ایلو بلسٹر پیک میں دستیاب ہیں۔
گلیمیکس ۲ ملی گرام گولیاں (۱۰x۲) ایلو۔ایلو بلسٹر پیک میں دستیاب ہیں۔
گلیمیکس ۳ ملی گرام گولیاں (۱۰x۲) ایلو۔ایلو بلسٹر پیک میں دستیاب ہیں۔
گلیمیکس ۴ ملی گرام گولیاں (۱۰x۲) ایلو۔ایلو بلسٹر پیک میں دستیاب ہیں۔

Manufactured by:
Schazoo Zaka (Pvt) Ltd.
Kalalwala, 20-Km Lahore-Jaranwala Road,
Distt: Sheikhupura, Pakistan.

Glemex®

Tablets

Glimepiride

1 mg, 2 mg, 3 mg, 4 mg

DESCRIPTION:
Glemex (Glimepiride) is an oral blood glucose lowering drug of the sulfonylurea class. Glimepiride is a white to yellowish white crystalline powder. Practically it is insoluble in water.

COMPOSITION:
Each tablet contains:
Glimepiride Sch. Specs. ..... 1 mg.
Glimepiride Sch. Specs. ..... 2 mg.
Glimepiride Sch. Specs. ..... 3 mg.
Glimepiride Sch. Specs. ..... 4 mg.

CLINICAL PHARMACOLOGY:
Pharmacodynamics/Mechanism of Action:
The primary mode of action of glimepiride in lowering blood glucose appears to be dependent on stimulating the release of insulin from functioning pancreatic beta cells. In addition, extrapancreatic effects may also play a role in the activity of sulfonylurea as such as glimepiride. However, as with other sulfonylureas, the mechanism by which glimepiride lowers blood glucose during long-term administration has not been clearly established.

Pharmacokinetics:
Glimepiride is rapidly and completely absorbed after oral administration. Oral bio-availability is approximately 100%. Peak serum concentrations occur 2-3 hours after oral administration, are proportional to dose and are similar in healthy volunteers and in patients with Type II diabetes. After multiple doses, there is no evidence of accumulation in serum. Meals have only modest effect on fasting pharmacokinetic data. When glimepiride is administered with meals, the time to reach peak concentrations is delayed by approximately 10%; decrease in both peak concentration and AUC is also about 10%. More than 99% of glimepiride is bound to plasma proteins. Glimepiride is completely biotransformed by hepatic oxidative metabolism. The CYP2C9 enzyme transform glimepiride to the cyclohexylhydroxymethyl derivative (M1), which is further metabolized to form carboxyl derivative (M2) by cytosolic enzymes. After a single dose, the elimination half-life of glimepiride is 5 hours and increased to 9 hours after multiple doses. Urinary excretion of metabolites accounted for 60% of the total dose; the remaining is found as metabolites in faeces. M1 is the predominant urinary metabolite and M2 is the predominant faecal metabolite.

INDICATIONS:
Glemex is indicated for non-insulin dependent (Type II) diabetes mellitus (NIDDM), whenever blood glucose levels cannot be controlled adequately by diet, physical exercise and weight reduction alone.

DOSAGE & ADMINISTRATION:
- The usual starting dose of **Glemex** (glimepiride) as initial therapy is 1-2 mg once daily, administered with breakfast or the first main meal. Those patients who are more sensitive to hypoglycemic drugs should be started at 1 mg once daily, and should be titrated carefully. No exact dosage relationship exists between **Glemex** and the other oral hypoglycemic agents. The maximum starting dose of **Glemex** should not be more than 2 mg.
- The usual maintenance dose of **Glemex** is 1 to 4 mg once daily. The maximum recommended dose is 8 mg once daily. After reaching a dose of 2 mg, dose increase should be made in increments of not more than 2 mg at 1-2 week intervals based upon the patient's blood glucose response. Long-term efficacy should be monitored by measurement of HbA1c levels, for example every 3 to 6 months.
- The initial and maintenance doses are set based on the results of regular checks 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.
  The dosage of **Glemex** (glimepiride) must be the lowest which is sufficient to achieve the desired metabolic control.

CONTRA-INDICATIONS:
Glemex is contraindicated in patients with:
- Known hypersensitivity to the drug.
- Diabetic ketoacidosis, with or without coma. This condition should be treated with insulin.

WARNINGS/PRECAUTIONS:
Treatment with **Glemex** must be initiated and monitored by a physician. The patient must take **Glemex** at times and in the doses prescribed by the doctor normally at the same time every day. In initial weeks of treatment the risk of hypoglycemia may be increased and necessitates especially careful monitoring. To achieve the treatment goal of **Glemex** (optimal control of blood glucose) adherence to correct diet, regular and sufficient physical exercise and, if necessary, reduction of body weight are just as necessary as regular ingestion of **Glemex**.
- **Use in pregnancy:** There are no adequate and well-controlled studies in pregnant women therefore **Glemex** should not be used during pregnancy.
- **Nursing mothers:** Because the potential for hypoglycemia in nursing infants may exist therefore **Glemex** should be discontinued in nursing mothers.
- **Pediatric use:** Safety and effectiveness in pediatric patients have not been established.
- **Kidney patients:** The drug is known to be substantially excreted by the kidneys, and the risk of the toxic reactions to this drug may be greater in patients with impaired renal function. A starting dose of 1mg followed by appropriate dose titration is recommended in these patients.

SIDE EFFECTS:
- **Gastrointestinal Reactions:** Vomiting, gastrointestinal pain, diarrhoea, and cholestatic jaundice have been reported to occur rarely with glimepiride.
- **Dermatologic Reactions:** Allergic skin reactions, *e.g.,* pruritus, urticaria, and maculopapular eruptions, occur in less than 1% of treated patients. These may be transient and may disappear despite continued use of glimepiride. Photosensitivity reactions have also been reported with glimepiride.
- **Hematologic Reactions:** Leukopenia, thrombocytopenia, hemolytic anemia, aplastic anemia and pancytopenia have been reported with glimepiride.
- **Metabolic Reactions:** Hepatic porphyria reactions and disulfiram-like reactions have been reported with glimepiride.
- **Vision:** Changes in accomodation and/or blurred vision may occur with the use of glimepiride.

DRUG INTERACTIONS:
- **Hypoglycemic action:** The hypoglycemic action of glimepiride may be potentiated by certain drugs, including nonsteroidal anti-inflammatory drugs and other drugs that are highly protein bound, such as salicylates, sulfonamides, chloramphenicol, coumarins, probenecid, monoamine oxidase inhibitors and beta adrenergic blocking agents. When these drugs are administered to a patient receiving glimepiride, the patient should be observed closely for hypoglycemia. When these drugs are withdrawn from a patient receiving Glemex, the patient should be observed closely for loss of glycemic control.
- **Hyperglycemic action:** Certain drugs tend to produce hyperglycemia and may lead to loss of control. These drugs include the thiazides and other diurectics, corticosteroids, phenothiazines, thyroid products, estrogens, contraceptives, phenytoin, nicotinic acid, sympathomimetics and isoniazid. When these drugs are administered to a patient receiving glimepiride, the patient should be closely observed for loss of control. When these drugs are withdrawn from a patient receiving glimepiride, they should be observed closely for hypoglycemia.
- **Action with Aspirin:** Co-administration of aspirin (1 g tid) and glimepiride led to a 34% decrease in the mean glimepiride AUC and, therefore, a 34% increase in the mean CL/f. The mean Cmax had a decrease of 4%. Blood glucose and serum C-peptide concentrations are unaffected and no hypoglycemic symptoms are reported.
- **Action with Cimetidine:** Co-administration of cimetidine (800 mg once daily) with a single 4-mg oral dose of glimepiride did not significantly alter the absorption and disposition of glimepiride.
- **Action with propranolol:** Concomitant administration of propranolol (40 mg tid) and glimepiride significantly increase Cmax, AUC and T½ of glimepiride by 23%, 22% and 15% respectively and it decrease CL/f by 18%. The recovery of M1 and M2 from urine however did not change.
- **Action with ACE inhibitors:** The response of serum glucose, insulin, C-peptide and plasma glucagons to 2 mg glimepiride are unaffected by co-administration of ramipril (an ACE inhibitor) 5 mg once daily. No hypoglycemic symptoms are reported.
- **Action with ß-blocker:** If beta blockers are used, caution should be exercised and patients should be warned about the potential for hypoglycemia.

STORAGE:
* Store in a cool and dry place.
* Protect from heat, light and moisture.
* Keep all medicines out of the reach of children.

PACKING:
Glemex 1mg tablets are available in (2x10) Alu-Alu blister pack.
Glemex 2mg tablets are available in (2x10) Alu-Alu blister pack.
Glemex 3mg tablets are available in (2x10) Alu-Alu blister pack.
Glemex 4mg tablets are available in (2x10) Alu-Alu blister pack.