PRESCRIBING INFORMATION

LIMORIDE® 1mg/2mg/3mg/4mg Tablets

(Glimepiride Tablets USP)

لیموراٹڈ

1ملی گرام / **2**ملی گرام / **3**ملی گرام / **4**ملی گرام ٹیبلیٹس

COMPOSITION:

LIMORIDE 1mg Tablets
Each tablet contains:
Glimepiride USP……..1mg

LIMORIDE 2mg Tablets
Each tablet contains:
Glimepiride USP……..2mg

LIMORIDE 3mg Tablets
Each tablet contains:
Glimepiride USP……..3mg

LIMORIDE 4mg Tablets
Each tablet contains:
Glimepiride USP……..4mg

DESCRIPTION:
Limoride (Glimepiride Tablets USP) is an oral blood-glucose-lowering drug of the sulfonylurea class. The primary mechanism of action of Limoride (Glimepiride Tablets USP) tablets 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 sulfonylureas. Limoride (Glimepiride Tablets USP) tablets can lead to increased sensitivity of peripheral tissues to insulin. Clinical findings are consistent with improved postprandial insulin/C-peptide responses and overall glycemic control without producing clinically meaningful increases in fasting insulin/C-peptide levels. However, as with other sulfonylureas, the mechanism by which Limoride (Glimepiride Tablets USP) tablets lowers blood glucose during long-term administration has not been clearly established. Limoride (Glimepiride Tablets USP) is effective as initial drug therapy. In patients where monotherapy not produced adequate glycemic control, the combination of Limoride (Glimepiride Tablets USP) and metformin may have a synergistic effect, since both agents act to improve glucose tolerance by different primary mechanisms of action.

PHARMACOLOGY:
After oral administration, Limoride (Glimepiride Tablets USP) is completely (100%) absorbed from the GI tract. Peak drug levels (Cmax) achieve at 2 to 3 hours. Limoride (Glimepiride Tablets USP) is completely metabolized by oxidative biotransformation. The major metabolites are the cyclohexyl hydroxy methyl derivative (M1) and the carboxyl derivative (M2). M1 possesses about 1/3 of the pharmacological activity in comparison. Limoride (Glimepiride Tablets USP) is excreted with its metabolites in urine and feaces.

INDICATIONS:
- Limoride (Glimepiride Tablets USP) is indicated as an adjunct to diet and exercise to lower the blood glucose in patients with non-insulin-dependent (Type 2) diabetes mellitus (NIDDM) whose hyperglycemia cannot be controlled by diet and exercise alone.
- Limoride (Glimepiride Tablets USP) may be used concomitantly with metformin when diet, exercise, and Limoride (Glimepiride Tablets USP) or metformin alone do not result in adequate glycemic control.
- Limoride (Glimepiride Tablets USP) is also indicated for use in combination with insulin to lower blood glucose in patients whose hyperglycemia cannot be controlled by diet and exercise in conjunction with an oral hypoglycemic agent.

DOSAGE AND ADMINISTRATION:
There is no fixed dosage regimen for the management of diabetes mellitus with Limoride (Glimepiride Tablets USP) or any other hypoglycemic agent. The patient's fasting blood glucose and HbA1c must be measured periodically to determine the minimum effective dose for the patient. The usual starting dose of Limoride (Glimepiride Tablets USP) as initial therapy is 1–2 mg once daily, administered with breakfast or the first main meal. The usual maintenance dose Limoride (Glimepiride Tablets USP) is 1 to 4 mg once daily. The maximum recommended dose is 8 mg once daily. If patients do not respond adequately to the maximal dose of Limoride (Glimepiride Tablets USP) monotherapy, addition of metformin may be considered. Combination therapy with insulin may also be used in secondary failure patients. The fasting glucose level for instituting combination therapy is in the range of >150 mg/dl in plasma or serum depending on the patient.

CONTRAINDICATIONS:
Limoride (Glimepiride Tablets USP) 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.

SIDE-EFFECTS:
Other than hypoglycemia, there are few side effects e.g., vomiting, gastrointestinal pain, and diarrhea, allergic skin reactions, e.g., pruritus, erythema, urticaria, and morbilliform or maculopapular eruptions, occur in less than 1% of treated patients. Leukopenia, agranulocytosis, thrombocytopenia, hemolytic anemia, aplastic anemia, and pancytopenia have been reported with sulfonylureas, including Limoride (Glimepiride Tablets USP) Hepatic porphyria reactions and disulfiram-like reactions have been reported with sulfonylureas, including Limoride (Glimepiride Tablets USP). Changes in accommodation and/or blurred vision may also occur.

DRUG INTERACTIONS:
The hypoglycemic action of sulfonylureas e.g. Limoride (Glimepiride Tablets USP) 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, beta adrenergic blocking agents, disopyramide, fluoxetine, quinolones, oral miconazole and clarithromycin. Certain drugs tend to produce hyperglycemia and may lead to loss of control. These drugs include the thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics and isoniazid.

PRECAUTIONS:
In elderly, debilitated, or malnourished patients, or in patients with renal and hepatic insufficiency, the initial dosing, dose increments, and maintenance dosage should be conservative based upon blood glucose levels prior to and after initiation of treatment to avoid hypoglycemic reactions.

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 Limoride (Glimepiride Tablets USP). A starting dose of 1 mg once daily followed by appropriate dose titration is recommended in those patients.

LOSS OF CONTROL OF BLOOD GLUCOSE:
When a patient stabilized on any diabetic regimen is exposed to stress such as fever, trauma, infection, or surgery, a loss of control may occur.

PREGNANCY & LACTATION:
Pregnancy Category C. Limoride (Glimepiride Tablets USP) is not recommended for use in pregnancy or nursing mothers.

STORAGE:
Store at temperature between 15 to 30 ºC away from light & moisture.

PRESENTATION:
Limoride (Glimepiride Tablets USP) 1mg tablets is available in blister pack of 20 Tablets
Limoride (Glimepiride Tablets USP) 2mg tablets is available in blister pack of 20 Tablets
Limoride (Glimepiride Tablets USP) 3mg tablets is available in blister pack of 20 Tablets
Limoride (Glimepiride Tablets USP) 4mg tablets is available in blister pack of 20 Tablets

خوراک اور طریقہ استعمال:
لیموراٹڈ کا طریقہ استعمال مستقل خوراک کی صورت میں نہیں ہے۔ خوراک کا تعین مریض کے نہار منہ ذیابطیس کے
تناسب اور HbA1c کے ٹیسٹ کی بنیاد پر کیا جاتا ہے۔
عمومی خوراک لیموراٹڈ 1 یا 2 ملی گرام روزانہ ناشتے سے قبل موثر ہے۔ لیموراٹڈ 2 سے 4 ملی گرام بطور
Maintenence خوراک دن میں ایک مرتبہ۔ اگر ذیابطیس کا تناسب صرف لیموراٹڈ سے معمول پر نہ ہو تو ایسی
صورت میں لیموراٹڈ کے ساتھ دیگر ادویات جیسا کہ Metfomin اور Insulin کا استعمال ڈاکٹر کے مشورے
کے بعد کیا جا سکتا ہے۔

اسٹوریج:
15 سے 30 ڈگری سینٹی گریڈ پر روشنی اور نمی سے بچا کر رکھیں۔

brookes

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ISO 9001
ISO14001
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BUREAU VERITAS
Certification