Limpet-M2
Tablet

DRUG INTERNATIONAL LTD.

Composition : **Limpet-M 2 :** Each Film Coated Tablet Contains Glimepiride USP 2 mg and Metformin Hydrochloride USP 500 mg as extended release.

Pharmacology : Limpet-M is a combination of 2 oral anti-hyperglycemic drugs with complimentary mechanism of action to improve glycemic control in patients with type-2 diabetes mellitus: Glimepiride, a Sulfonylurea and Metformin, a member of the biguanide class. The primary mechanism of action of Glimepiride, is to stimulate the release of insulin from functioning pancreatic beta cells. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization.

Indication : This combination is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both Glimepiride and Metformin is appropriate or in cases where Glimepiride/Metformin mono-therapy does not result in adequate glycemic control.

Dosage & administration : The initial recommended dose of Glimepiride and Metformin combination tablet once daily with breakfast or first main meal of the day. Starting dose for patients inadequately controlled on Glimepiride or Metformin monotherapy is Limpet-M 1 once daily, and gradually titrated after assessing the therapeutic response. Titration: The daily dose must be titrated in increments of 1 tablet. The maximum recommended dose per day is 8 mg Glimepiride and 2000 mg Metformin. When switching from combination therapy of Glimepiride plus Metformin to separate tablets, Glimepiride and Metformin should be administered separately on the basis of dosage currently being taken. When Glimepiride and Metformin combination tablet is used in combination or with insulin, a lower dose of the Glimepiride or insulin may be required to reduce the risk of hypoglycemia. Or, as directed by the registered physician.

Contraindications : It is contraindicated in patients having serious hypersensitivity reaction to the any other components of this product. It is also contraindicated to Renal disease or renal dysfunction, Acute or chronic metabolic acidosis, including diabetic ketoacidosis, Hepatic impairment.

Precautions : Metformin: Lactic acidosis is a rare, complication of Metformin accumulation which can be fatal. Patients should be cautioned about prolonged fasting and excessive alcohol intake. It is not recommended in hepatic/renal impairment or hypoxic states. Glimepiride: In exceptional stress situations (e.g. trauma, surgery, febrile infections), blood glucose regulation may deteriorate and a temporary change to insulin may be necessary to maintain good metabolic control.

Side effects : The most common side effect is hypoglycemia. At the start of treatment, there may be temporary visual impairment due to the change in blood glucose level. Occasionally, gastrointestinal symptoms e.g. nausea, vomiting, sensations of pressure or fullness in the epigastrium, loss of appetite, abdominal pain and diarrhea may occur. Metallic taste is common. A decrease of vitamin B_{12} absorption with decrease of serum levels has been observed in patients treated long-term with Metformin. Lactic acidosis is very rare.

Use in pregnancy and lactation : The use of this combination is not recommended in pregnancy & lactation.

Use in Child : Safety and effectiveness of Glimepiride+Metformin combination in peadiatric patients have not been established.

Drug interactions : Based on experience with Glimepiride and known interactions for other sulfonylureas, the following interactions must be considered. In addition to insulin and other oral antidiabetic agents, drugs which may potentiate the hypoglycaemic action of Glimepiride include: ACE inhibitors, aminosalicylic acid, anabolic steroids and male sex hormones, azapropazone, chloramphenicol, colfibrate, coumarin dervatives, cyclophosphamide, disopyramide, fenfluramin, fenyramidol, fibrates, oxyphenbutazone, para-aminosalicylic acid, phenylbutazone, probenecid, quinolones, salicylates, sulphinpyrazone, sulfonamide antibiotics, tetracyclines, tritoqualine, trofosfamide. Drugs which may attenuate the hypoglycaemic action of Glimepiride include: acetazolamide, barbiturates, calcium channel blockers, corticosteroids, diazoxide, diuretics, glucagon, insoniazid, laxatives, nicotinic acid (high doses), oestrogens, phenothiazines, phenytoin, progestogens, rifamicin, sympathomimetic agents, thyroid hormones. H2 receptor antagonists, beta-blockers, clonidine and reserpine may lead to either potentiation or weakening of the blood-glucose-lowering effect. Concomitant treatment with a beta-receptor blocker, clonidine, guanethidine or reserpine may mask the warning symptoms of hypoglycemic attack. Acute and chronic alcohol intake may either potentiate or attenuate the activity of Glimepiride in an unpredictable fashion. Metformin: Increase risk of lactic acidosis in acute alcohol intoxication, particularly in case of fasting or malnutrition and hepatic insufficiency. Avoid consumption of alcohol and alcohol-containing medications. Intravascular administration of iodinated contrast agents may lead to renal failure, resulting in metformin accmulation and a risk of lactic acidosis.

Overdose : Overdosage of sulfonylureas, Including Glimepiride, can produce hypoglycaemia. Mid hypoglycaemic symptoms without loss of consciousness or neurologic findings should be treated aggressively with oral glucose and adjustments in drug dosage or meal patterns. Close monitoring should continue nutil the physician is assured that the patient is out of danger. Overdose of Metformin may lead to lactic acidosis. Remove Metformin by haemodialysis.

Storage : Store below 30°C in a dry place.

Packing : **Limpet-M 2 :** Each box contains 3 x 7's tablets in blister pack.