TIAPRID TABLETS

Glimepiride 2 mg, 3 mg & 4 mg

COMPOSITION

Each Tiaprid tablet contains Glimepiride 2 mg, 3 mg or 4 mg, as stated on the pack. Excipients: q.s. according to the approved formulation.

PHARMACOLOGICAL CLASS

Oral antidiabetic agent; third-generation sulfonylurea.

PHARMACOLOGY

Glimepiride lowers blood glucose primarily by stimulating insulin release from functioning pancreatic beta cells. Its action requires endogenous insulin production. It may also improve peripheral insulin sensitivity.

PHARMACOKINETICS

Glimepiride is absorbed after oral administration. Peak concentrations generally occur in approximately 2-3 hours. It is extensively protein bound and is metabolized in the liver, principally by CYP2C9. Metabolites are eliminated in urine and faeces.

INDICATIONS

Adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus. It is not indicated for type 1 diabetes mellitus or diabetic ketoacidosis.

DOSAGE AND ADMINISTRATION

For adults, the usual initial dose is 1 mg or 2 mg once daily with breakfast or the first main meal. Patients at increased risk of hypoglycaemia, including older adults or those with renal impairment, should generally start at 1 mg once daily; a 1 mg product may be required. Titrate by 1 mg or 2 mg at intervals of at least 1-2 weeks according to blood glucose response. Maximum recommended dose is 8 mg once daily. The 3 mg strength may be used when clinically appropriate during individual titration. Swallow with water; do not skip meals after taking a dose. Use only as prescribed.

MONITORING

Monitor fasting and postprandial blood glucose and HbA1c as advised. Renal and hepatic function and risk of hypoglycaemia should be assessed during treatment.

CONTRAINDICATIONS

Known hypersensitivity to glimepiride, formulation ingredients or sulfonamide derivatives. Do not use for diabetic ketoacidosis or type 1 diabetes.

IMPORTANT WARNING: HYPOGLYCAEMIA

Glimepiride can cause severe or prolonged low blood glucose, sometimes resulting in unconsciousness or seizures. Risk rises with missed meals, reduced calorie intake, exercise without adequate food, alcohol, renal impairment and combination with other antidiabetic drugs. Symptoms include sweating, hunger, tremor, palpitations, confusion and dizziness; some patients may have few warning symptoms. Treat promptly with fast-acting glucose if conscious and able to swallow; severe episodes require emergency medical attention. Do not give food or drink to an unconscious person.

WARNINGS AND PRECAUTIONS

Use caution in elderly, debilitated or malnourished patients and those with renal or hepatic impairment. Stress, fever, trauma, infection or surgery may require temporary insulin therapy. Severe allergic reactions, including anaphylaxis, angioedema and serious skin reactions, have been reported. Sulfonylureas may cause haemolytic anaemia in patients with G6PD deficiency; consider alternatives. Driving or machinery operation may be unsafe during hypo- or hyperglycaemia.

DRUG INTERACTIONS

Other glucose-lowering drugs, ACE inhibitors, fluconazole and some other medicines may increase hypoglycaemia risk. Corticosteroids, thiazide diuretics, sympathomimetics and thyroid hormones may reduce glucose-lowering effect. Beta-blockers can mask warning signs of hypoglycaemia. Alcohol can alter glucose control. Rifampicin and CYP2C9 inhibitors/inducers may affect exposure. Give glimepiride at least 4 hours before colesevelam. Review all concurrent medicines.

PREGNANCY AND LACTATION

Glimepiride is generally not recommended during pregnancy; insulin is commonly preferred to maintain glycaemic control. Neonatal hypoglycaemia may occur following maternal exposure. Breastfeeding is not recommended during glimepiride therapy because of potential hypoglycaemia in the infant. Seek medical advice before treatment changes.

CHILDREN AND ADOLESCENTS

Not recommended for paediatric use due to concerns including hypoglycaemia and weight gain; follow locally approved prescribing information.

UNDESIRABLE EFFECTS

Hypoglycaemia, dizziness, headache, nausea and weight gain may occur. Less commonly, rash, itching, liver enzyme changes or blood-cell abnormalities may develop. Serious events include severe hypoglycaemia, severe hypersensitivity reactions, serious skin reactions and haemolytic anaemia. Seek urgent help for severe symptoms.

OVERDOSAGE

Overdose may produce severe, recurrent or prolonged hypoglycaemia. Obtain emergency medical care immediately. Treatment includes glucose administration and prolonged blood-glucose monitoring; intravenous dextrose may be needed. Monitor for recurrence.

MISSED DOSE

Take the missed dose when remembered if it is appropriate to take it with a meal and not near the next scheduled dose. Otherwise skip it. Never double a dose. Ask the prescriber for individualized advice.

STORAGE

Store according to the approved product label. Protect from moisture and excessive heat. Keep out of reach of children.

PRESENTATION

Tiaprid Tablets: Glimepiride 2 mg, 3 mg and 4 mg. Pack size: 10 tablets for each strength.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.