

METRIDE

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for METRIDE [Metformin Hydrochloride Prolonged-Release and Glimpiride Tablets I.P.]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: *Metformin Hydrochloride*: Metformin may act via 3 mechanisms: **1.** reduction of hepatic glucose production by inhibiting gluconeogenesis and glycogenolysis. **2.** in muscle, by increasing insulin sensitivity, improving peripheral glucose uptake and utilisation and **3.** delay of intestinal glucose absorption. *Glimpiride*: The primary mechanism of action of glimepiride in lowering blood glucose appears to be dependent on stimulating the release of insulin from functioning pancreatic beta cells.

INDICATIONS: For the treatment of patients with type 2 diabetes mellitus when diet, exercise & the single agent does not result in adequate glycemic control.

DOSAGE AND ADMINISTRATION: As directed by the Physician.

CONTRAINDICATION: *Metformin Hydrochloride*: **1.** Hypersensitivity to metformin or to any of the excipients. **2.** Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis). **3.** Diabetic pre-coma. **4.** Severe renal failure (GFR <30mL/min). **5.** Acute conditions with the potential to alter renal function such as: dehydration, severe infection, shock. **6.** Disease which may cause tissue hypoxia (especially acute disease, or worsening of chronic disease) such as: decompensated heart failure, respiratory failure, recent myocardial infarction, shock. **7.** Hepatic insufficiency, acute alcohol intoxication, alcoholism. *Glimpiride I.P.*: METRIDE 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.

WARNINGS & PRECAUTIONS: *Metformin Hydrochloride*: *Lactic acidosis*: Metformin accumulation occurs at acute worsening of renal function and increases the risk of lactic acidosis. *Renal function*: Metformin is contraindicated in patients with GFR<30 mL/min and should be temporarily discontinued in the presence of conditions that alter renal function. *Cardiac function*: Patients with heart failure are more at risk of hypoxia and renal insufficiency. *Administration of iodinated contrast media*: Intravascular administration of iodinated contrast agents may lead to contrast induced nephropathy, resulting in metformin accumulation and an increased risk of lactic acidosis. *Surgery*: Metformin must be discontinued at the time of surgery with general, spinal or epidural anaesthesia. *Other precautions*: All patients should continue their diet with a regular distribution of carbohydrate intake during the day. Overweight patients should continue their energy-restricted diet. *Glimpiride*: **WARNING: SPECIAL WARNING ON INCREASED RISK OF CARDIOVASCULAR MORTALITY. PRECAUTIONS:** *General*: Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with METRIDE or any other anti-diabetic drug. **Information for Patients**: Patients should be informed of the potential risks and advantages of METRIDE and of alternative modes of therapy. **Laboratory Tests**: Fasting blood glucose should be monitored periodically to determine therapeutic response.

DRUG INTERACTIONS: *Metformin Hydrochloride*: Alcohol, Iodinated contrast agents, Combinations requiring precautions for use, Medicinal products with intrinsic hyperglycaemic activity (e.g. glucocorticoids (systemic and local routes) and sympathomimetics), Organic cation transporters (OCT), *Glimpiride*: CYP2C9 inducers (eg. rifampicin); inhibitors (e.g. fluconazole), phenylbutazone, azapropazone and oxyfenbutazone, insulin and oral antidiabetic products, salicylates and p-amino-salicylic acid, anabolic steroids and male sex hormones, chloramphenicol, certain long acting

sulfonamides, tetracyclines, quinolone antibiotics and clarithromycin, coumarin anticoagulants, fenfluramine, disopyramide, fibrates, ACE inhibitors, fluoxetine, MAO-inhibitors, allopurinol, probenecid, sulfinpyrazone, sympatholytics, cyclophosphamide, trophosphamide and iphosphamides, miconazole, fluconazole, pentoxifylline (high dose parenteral), tritoqualine, oestrogens and progestogens, saluretics, thiazide diuretics, thyroid stimulating agents, glucocorticoids, phenothiazine derivatives, chlorpromazine, adrenaline and sympathicomimetics, nicotinic acid (high dosages) and nicotinic acid derivatives, laxatives (long term use), phenytoin, diazoxide, glucagon, barbiturates and rifampicin, acetazolamide.

ADVERSE REACTIONS: Metformin Hydrochloride: Lactic Acidosis, Taste Disturbance, Nausea, Vomiting, Diarrhoea, Abdominal Pain, Loss of Appetite, Hepatitis, Skin Reactions e.g. Erythema, Pruritus, Urticaria. **Glimepiride:** Cholestasis, Jaundice, Morbilliform or Maculopapular Eruptions, Leukopenia, Agranulocytosis, Thrombocytopenia, Hemolytic Anemia, Aplastic Anemia, Pancytopenia, Hepatic Porphyrin Reactions, Disulfiram-like Reactions and Blurred Vision.

MARKETED BY:



Torrent Pharmaceuticals Limited.

IN/METRIDE (500 mg + 1 mg), (500 mg + 2 mg)/Feb-2025/01/ABPI

(Additional information is available on request)