

METRIDE DS

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only
Abbreviated Prescribing information for **METRIDE DS** [Metformin Hydrochloride Prolonged-Release and Glimepiride Tablets I.P.]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: *Metformin:* Metformin may act via 3 mechanisms: • reduction of hepatic glucose production by inhibiting gluconeogenesis and glycogenolysis • in muscle, by increasing insulin sensitivity, improving peripheral glucose uptake and utilization • and delay of intestinal glucose absorption. Metformin stimulates intracellular glycogen synthesis by acting on glycogen synthase. Metformin increases the transport capacity of all types of membrane glucose transporters (GLUT). *Glimepiride:* Glimepiride acts mainly by stimulating insulin release from pancreatic beta cells. As with other sulfonylureas this effect is based on an increase of responsiveness of the pancreatic beta cells to the physiological glucose stimulus. In addition, glimepiride seems to have pronounced extra pancreatic effects also postulated for other sulfonylureas.

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

DOSAGE AND ADMINISTRATION: As directed by Physician. Swallow whole tablet do not crush or chew.

CONTRAINDICATION: • Hypersensitivity to metformin or to any of the excipients • Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis) • Diabetic pre-coma • Severe renal failure (GFR <30mL/min) • Acute conditions with the potential to alter renal function such as: - dehydration, - severe infection, - shock • 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 • Hepatic insufficiency, acute alcohol intoxication, alcoholism. Glimepiride 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 carries a rare but life-threatening risk of lactic acidosis, especially with renal impairment, dehydration, hypoxia, sepsis, heart failure, excessive alcohol use, or contrast exposure, so renal function must be checked regularly, and metformin temporarily stopped during acute illness, surgery, or iodinated contrast procedures. It is contraindicated in severe renal impairment (GFR <30 mL/min) and acute or unstable heart failure, while stable heart failure requires close monitoring. Glimepiride (as part of combination therapy) is associated with an increased risk of hypoglycaemia—particularly in the elderly, malnourished, renally impaired, or stressed patients—and sulfonylureas as a class have been linked to increased cardiovascular mortality compared with diet alone. Careful dose selection, patient education, monitoring for hypoglycaemia, and consideration of insulin during stress or secondary treatment failure are essential, with caution advised in G6PD deficiency due to risk of hemolytic anaemia.

DRUG INTERACTIONS: Metformin should not be used with alcohol or around iodinated contrast procedures due to increased lactic acidosis risk and requires close renal monitoring when combined with drugs that impair kidney function (e.g. NSAIDs, ACE inhibitors, ARBs, loop diuretics) or raise blood glucose (e.g. glucocorticoids,

sympathomimetics). Its efficacy and plasma levels can be altered by drugs affecting OCT1 and OCT2 transporters, potentially requiring dose adjustment, especially in renal impairment. Glimepiride shows no evidence of carcinogenicity, mutagenicity, or impaired fertility in animal studies, though high-dose mouse studies showed benign pancreatic adenomas, with no relevance at therapeutic human doses.

ADVERSE REACTIONS: Lactic acidosis, decrease of vitamin B12 absorption, taste disturbance, nausea, vomiting, diarrhea, abdominal pain, loss of appetite, Isolated reports of liver function tests abnormalities or hepatitis resolving upon metformin Discontinuation, erythema, pruritus, urticaria, dizziness, asthenia, headache, Leukopenia, agranulocytosis, thrombocytopenia, hemolytic anemia, aplastic anemia, and pancytopenia.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

IN/ METRIDE DS 1, 2,3 4, and 1000 mg/Feb-21/01/ABPI

(Additional information is available on request)