

GLUCRETA M

To be sold by retail on the prescription of a R.M.P only

Abbreviated Prescribing information for GLUCRETA M (Dapagliflozin and Metformin Hydrochloride Extended-Release Tablets)

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Dapagliflozin is an inhibitor of Sodium-glucose cotransporter 2 (SGLT2), which is expressed in the proximal renal tubules, and is responsible for the majority of the reabsorption of filtered glucose from the tubular lumen, thus inhibiting SGLT2, reduces reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion. Metformin, a biguanides decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization.

DOSAGE AND ADMINISTRATION: One tablet once daily or as directed by physician.

CONTRAINDICATION: GLUCRETA M is contraindicated in patients with: Moderate to severe renal impairment which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia. Hypersensitivity to the active substance or to any of the excipients of the tablet; acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma.

WARNINGS & PRECAUTIONS: Lactic acidosis, ketoacidosis, acute kidney injury, urosepsis and pyelonephritis, hypoxic states, use in patients with renal impairment, hypotension, impaired hepatic function, alcohol intake, surgical procedures, radiologic studies with intravascular iodinated contrast materials, vitamin B12 concentrations, genital mycotic infections, necrotizing fasciitis of the perineum (Fournier's Gangrene), increases in low-density lipoprotein cholesterol (LDL-C) and bladder cancer.

DRUG INTERACTION: Dapagliflozin can interact with positive urine glucose test and interference with 1, 5-anhydroglucitol (1, 5-AG) assay. Metformin hydrochloride have potential to interact with cationic drugs (e.g., amiloride, cimetidine, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, or vancomycin), also along with medications like the thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs, and isoniazid.

ADVERSE REACTIONS: use in patients with renal impairment, hypotension use with medications known to cause hypoglycemia, vitamin B12 concentrations, genital mycotic infections, increases in low-density lipoprotein cholesterol (LDL-C), bladder cancer, male and female genital mycotic infections, nasopharyngitis, diarrhea, influenza, dyslipidemia, pharyngitis, discomfort with urination, urinary tract infections, constipation, back pain, pain in extremity, hypersensitivity reactions, increase in hematocrit and serum inorganic phosphorus.

MARKETED BY:

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IN/ GLUCRETA M 5+500, 5+1000, 10+500, 10+1000 /MAY-22/03/ABPI
(Additional information is available on request)