ZUCATOR M 500

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

Abbreviated Prescribing information for ZUCATOR M 500 [Remogliflozin Etabonate 100 mg and Metformin Hydrochloride 500 mg Tablets]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:
MECHANISM OF ACTION: Consistent with inhibition of SGLT2, a dose-dependent increase in urine glucose excretion has been observed with a plateau of- 400 mmols/day in healthy subjects (equating to 72 g/day or 288 kcal/day). The maximal filtered glucose excreted in the urine is- 45%.Metformin is a biguanide with antihyperglycemic effects, lowering both basal and postprandial plasma glucose. It does not stimulate insulin secretion and therefore does not produce hypoglycaemia. Metformin may activate 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.

INDICATIONS: Indicated in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control: In Patients insufficiently controlled on their maximally tolerated dose of metformin alone. In Patients already being treated with the combination of remogliflozin and metformin as separate tablets.

DOSAGE AND ADMINISTRATION: Adults with normal renal function (GFR ≥90 ml/min):The recommended dose is one tablet twice dailyFor the different doses of metformin, ZUCATOR M is available in strengths of 100 mg remogliflozin etabonate plus 500 mg metformin hydrochloride and 100 mg remogliflozin etabonate plus 1000 mg metformin hydrochloride. Remogliflozin 100 mg, and Metformin 500 mg and 1000 mg in the combination are present in immediate release forms. ZUCATOR M should be taken twice daily with meals to reduce the gastrointestinal adverse reactions associated with metformin. All patients should continue their diet with an adequate distribution of carbohydrate intake during the day. Overweight patients should continue their energy restricted diet. It a dose is missed; it should be taken as soon as the patient remembers. However, a double dose should not be taken on the same time. In that case, the missed dose should be skipped. No sex or age-related effect was identified in glucose lowering effect of remogliflozin etabonate.

CONTRAINDICATION: Hypersensitivity to the active substance 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 <30 ml/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 impairment, acute alcohol intoxication, alcoholism.

WARNINGS & PRECAUTIONS: Remogliflozin and Metformin is contraindicated in patients with GFR<45 ml/min and should be temporarily discontinued in the presence of conditions that alter renal function. Intravascular administration of iodinated contrast agents may lead to contrast induced nephropathy, resulting in metformin accumulation and an increased risk of lactic acidosis. Metformin should be discontinued prior to or at the time of the imaging procedure and not restarted until at least 48 hours after, provided that renal function has been re-evaluated and found to be stable. An increase in cases of lower limb amputation (pr1manly of the toe) has been observed in ongoing long-term, clinical studies with another SGLT2 inhibitor. The effect of remogliflozin on urinary glucose excretion is associated with osmotic diuresis, which could affect the hydration status

DRUG INTERACTIONS: Alcohol intoxication is associated with an increased risk of lactic acidosis, particularly in case of fasting, malnutrition or hepatic impairment**.** Insulin and insulin secretagogues,

such as sulphonylureas, may increase the risk of hypoglycaemia. Therefore, a lower dose of insulin or an insulin secretagogue may be required to reduce the risk of hypoglycaemia when used in combination with metformin.

ADVERSE REACTIONS: Anemia, vertigo, abdominal pain, constipation, diarrhea, gastritis, asthma, fatigue, pyrexia, urinary tract infection, Bacteriuria, Genital infection fungal, Vulvovaginal candidiasis, Vulvovaginitis, Blood bicarbonate abnormal, Blood creatinine increased, Blood/acne acid increased, Glomerular filtration rale decreased, Diabeticketoacidos1s, Dyslipidaemia, Hypercholesterolaemia, Hyperlacticaemia, Hypertriglyceridemia, Hypoglycaemia, Lactic acidosis, Polydipsia, Weight decreased, pain in extremities, dizziness, headache, dysuria, ketonuria, pollakiuria, Polyuria, Renal failure, Pruritus genital, Vaginal discharge, Vulvovaginal pruritus, Hyperhidrosis, lntertrigo, Urticaria, Orthostatic hypotension, Lactic acidosis,

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

IN/ZUCATOR M 500 /May 2026/03/ABPI

(Additional information is available on request)