TENEPURE- M

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for TENEPURE- M (Teneligliptin AND Metformin Hydrochloride (As Extended Release)**)**

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: TENEPURE- M contains Teneligliptin and metformin. Teneligliptin exhibits a hypoglycemic effect by controlling the decomposition of GLP-1 by inhibiting dipeptidyl peptidase-4 (DPP-4) activity and thereby increasing blood concentration of active GLP-1. Metformin exerts its glucose-lowering effect by reduction of hepatic glucose production through inhibition of gluconeogenesis and glycogenolysis; by modestly increasing insulin sensitivity, improving peripheral glucose uptake and utilisation; and by delaying intestinal glucose absorption.

DOSAGE AND ADMINISTRATION: TENEPURE- M tablets should be administered orally as directed by the Physician. Tablets should be swallowed whole with a glass of water and should not be chewed or crushed.

CONTRAINDICATION: Hypersensitivity to the drug or any of its components. Severe ketosis, diabetic coma or pre-coma and also for immediate remedy in type 1 Diabetes (since a prompt correction of hyperglycaemias is required) with infusion and insulin. Severe trauma before and after surgery and when the blood glucose level is controlled with insulin injection. Severe renal failure (GFR < 30 mL/min). Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis). 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

WARNINGS & PRECAUTIONS: Careful administration recommended in severe hepatic dysfunction and patient with heart failure (NYHA class III~IV). QT prolongation may occur in patients having arrhythmia such as severe bradycardia or having its history, patient having heart disease such as congestive heart failure and patient having hypokalaemia. Lactic acidosis (especially in patients with impaired renal function), administration of iodinated contrast agents, patients with underlying hepatic impairment and/or hepatic dysfunction, skin disorder, acute pancreatitis and hypoglycaemia. Patients with heart failure are more at risk of hypoxia and renal insufficiency.

DRUG INTERACTION: ***Teneligliptin*****:** Drugs increasing hypoglycaemic action like β-blocking agents, Salicylic acid drugs, Monoamine oxidase inhibitor should be administered carefully since the blood sugar may further decrease. Drugs decreasing hypoglycaemic action like adrenaline, adrenocortical hormone, thyroid hormones should be administered carefully since the blood sugar may further increase. QT prolongation is seen with single administration of these Class IA anti-arrhythmic drugs Quinidine Sulphate Hydrate and Procainamide Hydrochloride and Class III antiarrhythmic drugs Amiodarone Hydrochloride and Sotalol Hydrochloride.

***Metformin*:** Combinations not recommended: Alcohol, Iodinated contrast agents, Cationic active substances. Combinations requiring precautions for use: Some medicinal products can adversely affect renal function, which may increase the risk of lactic acidosis, e.g. NSAIDs, including selective cyclo-oxygenase (COX) II inhibitors, ACE inhibitors, angiotensin II receptor antagonists and diuretics, especially loop diuretics. When starting or using such products in combination with metformin, close monitoring of renal function is necessary. Glucocorticoids, beta-2-agonists, and diuretics have intrinsic hyperglycaemic activity. The patient should be informed and more frequent blood glucose monitoring performed, especially at the beginning of treatment. If necessary, the dosage of ENCELIN M SR may need to be adjusted during concomitant therapy and on its discontinuation. Angiotensin converting enzyme (ACE) inhibitors may decrease the blood glucose levels. If necessary, the dosage of the antihyperglycaemic medicinal product should be adjusted during therapy with the other medicinal product and on its discontinuation.

ADVERSE REACTIONS: Hypoglycaemia, dizziness, headache, constipation, diarrhoea and pyrexia, liver dysfunction, interstitial pneumonia, lactic acidosis, liver function test abnormalities or hepatitis, skin reactions such as erythema, pruritus, urticaria, exfoliative and bullous skin lesions, including bullous pemphigoid.

Marketed BY:
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(Additional information is available on request)