

TORGLIP M SR

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.
Abbreviated Prescribing information for TORGLIP M SR (Metformin Hydrochloride (As Sustained Release) and Vildagliptin Tablets)

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: TORGLIP M SR contains vildagliptin and metformin. Vildagliptin acts primarily by inhibiting DPP-4, the enzyme responsible for the degradation of the incretin hormones GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulintropic polypeptide). 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: Administer orally with or just after food. Tablets should be swallowed whole with a glass of water and should not be chewed or crushed. Dosing must be individualized for patients with impaired renal function.

CONTRAINDICATION: Hypersensitivity to the active substances 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, intravascular administration of iodinated contrast agents. Acute or chronic disease, which may cause tissue hypoxia, such as: cardiac or respiratory failure, recent myocardial infarction, shock. Hepatic impairment, acute alcohol intoxication, alcoholism, Breast-feeding.

WARNINGS & PRECAUTIONS: 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.

DRUG INTERACTION: *Vildagliptin:* Combination with ACE inhibitors: Increased risk of angioedema in patients concomitantly taking ACE inhibitors. As with other oral antidiabetic medicinal products the hypoglycaemic effect of vildagliptin may be reduced by certain active substances, including thiazides, corticosteroids, thyroid products and sympathomimetics.
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 TORGLIP 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, tremor, headache, dizziness, chills, hyperhidrosis, fatigue, asthenia, nausea, diarrhoea, constipation, flatulence, abdominal pain, loss of appetite, metallic taste, gastro-oesophageal reflux disease, pancreatitis, upper respiratory tract infection, nasopharyngitis, oedema peripheral, arthralgia, myalgia, decrease of vitamin b absorption and 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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IN/TORGLIP M SR 500/ 1000, 50/APR-22/01/ABPI

(Additional information is available on request)