

ZUCATOR 100

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

Abbreviated Prescribing information for ZUCATOR 100 [Remogliflozin Etabonate Tablets 100 mg I.P.]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: As an active ingredient, ZUCATOR contains Remogliflozin etabonate (RE). It is the prodrug of Remogliflozin, an inhibitor of Sodium-Glucose Co-Transporter 2 (SGLT2), enabling Urinary Glucose Excretion to reduce hyperglycemia for the treatment of Type 2 Diabetes.

INDICATIONS: Remogliflozin etabonate is indicated in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as: (a) Monotherapy when diet and exercise alone do not provide adequate glycaemic control. (b) Add on therapy with metformin, together with diet and exercise, when these do not provide adequate glycaemic control.

DOSAGE AND ADMINISTRATION: *Dose:* The recommended dose is Remogliflozin etabonate 100 mg twice daily for monotherapy and add-on therapy with metformin. As observed with other SGLT2 inhibitors, when Remogliflozin etabonate is used in addition to insulin or an insulin secretagogue, such as a sulphonylureas, a lower dose of insulin or insulin secretagogue may be considered to reduce the risk of hypoglycaemia. *Method of administration:* There was no clinically relevant impact of food on the PK of Remogliflozin etabonate. Remogliflozin etabonate can be taken orally twice daily with or without food. Tablets are to be swallowed whole. 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.

WARNINGS & PRECAUTIONS: Do not take ZUCATOR: if you have liver diseases, diabetic ketoacidosis. Talk to your doctor immediately: if you develop a combination of symptoms of rare but serious or even life-threatening infection, called necrotising fasciitis of the perineum or Fournier's gangrene, which destroys the tissue under the skin. Talk to your doctor, pharmacist, or nurse before taking ZUCATOR: If you have, type 1 diabetes, kidney problem, liver problem, taking anti-hypertensive and have a history of low blood pressure (hypotension), A very high levels of sugar in your blood leading to dehydration, nausea and vomiting.

DRUG INTERACTIONS: *Other medicines and ZUCATOR:* Tell your doctor, pharmacist, or nurse if you are taking, have recently taken or might take any other medicines. Especially tell your doctor: If you are taking a medicine used to remove water from the body (diuretic). Your doctor may ask you to reduce the dose of diuretic. If you have type 2 diabetes and are taking other medicines that lower the amount of sugar in your blood such as insulin or a "sulphonyl urea" medicine. Your doctor may want to lower the dose of these other medicines, to prevent you from getting low blood sugar levels (hypoglycaemia). As the effectiveness of oral contraceptives may be negatively impacted. Inform your doctor if you are taking any oral contraceptives.

ADVERSE REACTIONS: *Common:* Constipation, Diarrhoea, Asthenia, Pyrexia, Bacteriuria, Urinary tract infection, Viral upper respiratory tract infection, Glomerular filtration rate decreased, Dyslipidaemia, Hypoglycaemia, Headache, Ketonuria, Cough, Orthostatic hypotension, *Uncommon:* Anaemia, Eosinophilia, Vertigo, Eye pain, Lacrimation increased, Abdominal discomfort, Abdominal pain, Fatigue, Pain, Hyperbilirubinaemia, Gastroenteritis, Genital infection fungal, Decreased appetite, Diabetic ketoacidosis, Arthralgia Back pain, Costochondritis, Dizziness, Hypoaesthesia, Anxiety, Insomnia, Balanoposthitis, Pruritus genital, Oropharyngeal pain, Rhinitis allergic, Rash, Skin lesion, Hypertension.

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(Additional information is available on request)