TENEPURE

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

Abbreviated Prescribing information for TENEPURE (Teneligliptin Tablets IP 20 mg)

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

PHARMACOLOGICAL PROPERTIES: The glucagon-like peptide-1 (GLP-1) is secreted from alimentary canal in response to meal that promotes insulin secretion from pancreas and regulates blood sugar post meal by controlling glucagon secretion. 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.

INDICATION: It is indicated for the treatment of type 2 Diabetes Mellitus as a monotherapy adjunct to diet and exercise.

DOSAGE AND ADMINISTRATION: The usual adult dose for oral use is 20 mg of Teneligliptin once daily. In case of insufficient effect, dosage can be increased to 40 mg once time daily while closely monitoring the clinical progress.

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.

WARNINGS & PRECAUTIONS: *Careful administration recommended in:*Patient with severe hepatic, heart failure (NYHA class III~IV), under sulfonyl urea medication or Insulin formulations, Hypoglycemia may occur in patients with: Adrenal insufficiency, Malnutrition, starved state, irregular dietary intake, insufficient dietary intake or hyposthenia , Vigorous muscular movement, Patient with excessive alcohol consumption. *Important Precautions:* hypoglycaemia and its coping strategy consider decreasing the dose of sulfonylurea or insulin formulation when given in combination with teneligliptin, its use only to the patient diagnosed with Type 2 diabetes mellitus (T2DM), regularly check the blood sugar; check the effect of the drug., possibility that adverse reactions, such as QT prolongation, might occur. It is desirable to avoid the medication in the patients having QT prolongation, This drug and GLP-1 receptor agonist both have GLP-1 receptor mediated antihyperglycemic effect.*Other Precautions:* The usual dosage is 20 mg of teneligliptin once daily and the maximum dose is 40 mg once daily).

DRUG INTERACTION: Medicines for diabetic disease: Sulfonylurea, Fast-acting insulin secretagogue α- glucosidase inhibitor, Biguanides drugs, Thiazolidine drug, GLP-1 analogue preparation**. SGLT2 inhibitor insulin preparation, Drugs increasing hypoglycaemic action**: β-blocking agents, Salicylic acid drugs, Monoamine oxidase inhibitor, **Drugs decreasing hypoglycaemic action:** Adrenaline, Adrenocortical hormone, Thyroid hormone, **Drugs known to cause QT prolongation:** Class IA antiarrhythmic drug: Quinidine Sulphate Hydrate, Procainamide Hydrochloride, III antiarrhythmic drugs: Amiodarone Hydrochloride, Sotalol Hydrochloride.

ADVERSE REACTIONS: Hypoglycemia, dizziness, headache, constipation, diarrhoea and pyrexia, Hypoglycemia, Intestinal Obstruction (0.1%), Liver dysfunction (unknown frequency), Interstitial pneumonia (frequency unknown). **Significant adverse reactions:** Hypoglycemia, Intestinal Obstruction (0.1%), Liver dysfunction (unknown frequency, Interstitial pneumonia (frequency unknown. Other Adverse reactions: Digestive system: Constipation, abdominal swelling, abdominal discomfort, nausea, stomach ache, flatulence, stomatitis, gastric polyp, colon polyp, duodenal ulcer, reflux esophagitis, diarrhea, anorexia, increased amylase, increased lipase, acute pancreatitis. **Liver:** Increased AST (GOT), increased ALT (GPT), and increased γ-GTP and rise in Al-P. **Kidney and urinary system:**

Albuminuria, positive ketone body in urine. **Skin:** Eczema, Wet rash, pruritus, allergic dermatitis. **Others**: Increased CK (CPK), increased serum potassium, fatigue, allergic, rhinitis, and increased serum uric acid.

MARKETED BY

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(Additional information is available on request)