TENXTIN 20

(**Teneligliptin 20mg Tablets)**

COMPOSITION:

Each film coated tablet contains:

Teneligliptin Hydrobromide Hydrate Eq. to Teneligliptin 20 mg

PHARMACOKINETICS:

Mechanism of action Glucagon-like peptide-1 (GLP-1) is secreted from the gastrointestinal tract in response to meal ingestion and regulates postprandial blood glucose level by stimulating insulin secretion from the pancreas and suppressing glucagon secretion. Teneligliptin inhibits the degradation of GLP-1 through the inhibition of dipeptidyl peptidase-4 (DPP-4) and reduces blood glucose levels by increasing blood concentration of active GLP-1. Inhibitory effect on DPP-4 and suppressive action on GLP-1 degradation 1) Teneligliptin inhibited the activity of DPP-4 in human plasma in a concentrationdependent manner, with IC50 of 1.75 nmol/L (in vitro). 2) Teneligliptin prevented the degradation of active GLP-1 in rat plasma in a concentrationdependent manner (in vitro). 3) In a glucose tolerance test in Zucker Fatty rats, a model of obesity with insulin resistance and impaired glucose tolerance, a single oral administration of Teneligliptin increased plasma active GLP-1 and plasma insulin levels. 4) In patients with type 2 diabetes mellitus, once-daily administration of Teneligliptin 20 mg inhibited plasma DPP-4 activity and increased the concentration of active GLP-1 in plasma. Improvement of glucose tolerance 1) In a glucose tolerance test in Zucker Fatty rats, a model of obesity with insulin resistance and impaired glucose tolerance, a single oral administration of Teneligliptin improved postloaded hyperglycemia. 2) In patients with type 2 diabetes mellitus, once-daily administration of Teneligliptin 20 mg improved blood glucose after breakfast, lunch and dinner and fasting blood glucose.

PHARMACODYNAMICS:

Pharmacotherapeutic group: Drugs used in diabetes, sodium-glucose co-transporter 2 (SGLT2) inhibitors,

ATC code: A10B K01

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INDICATIONS:

Monotherapy: TENELIGLIPTIN Tablets is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus. Combination therapy: TENELIGLIPTIN Tablets is indicated in patients with type 2 diabetes mellitus to improve glycemic control in combination with metformin, sulfonylureas, PPAR agonist (e.g., thiazolidinediones), rapid insulin secretagogues, alpha-glucosidase inhibitors, sodium glucose co-transporter 2 inhibitor, or insulin when the single agent alone, with diet and exercise, does not provide adequate glycemic control

CONTRAINDICATIONS:

TENELIGLIPTIN Tablets is contraindicated in the following patients. 1) Patients with a history of hypersensitivity to any of the ingredients of this product. 2) Patients with severe ketosis, diabetic coma or precoma, and type 1 diabetes mellitus [Treatment with this product is not appropriate because such patients require rapid correction of hyperglycaemia with transfusion and insulin.] 3) Patients with severe infection, pre- or post-operative patients, and patients with serious traumatic 2 injury [Treatment with this product is not appropriate because glycaemic control with insulin injection is desirable in such patients.]

POSOLOGY & ADMINISTRATIONS:

Posology

The usual adult dosage is 20 mg of Teneligliptin administered orally once daily. If efficacy is insufficient, the dose may be increased to 40 mg once daily with close monitoring of clinical course.

WARNINGS & PRECAUTIONS:

Careful Administration TENELIGLIPTIN Tablets should be administered with care in the following patients. Patients with severe hepatic impairment [There has been no clinical experience establishing its safety in such patients. Patients with cardiac failure (NYHA class III or IV) [There has been no clinical experience establishing its safety in such patients. Patients receiving sulfonylurea or insulin [The risk of hypoglycaemia may be increased. The following patients or conditions [Hypoglycaemia may occur.] Pituitary insufficiency or adrenal insufficiency , Malnutrition, starvation, irregular diet, insufficient food intake or hyposthenia Extreme muscle exercise Patients with excessive alcohol intake Patients with a history of abdominal operation or a history of intestinal obstruction [Intestinal obstruction may occur. Patients prone to QT interval prolongation (patients with current or a history of arrhythmia such as severe bradycardia, patients with cardiac disease such as congestive cardiac failure, patients with hypokalaemia, etc.) [QT interval prolongation may occur.] Important Precautions 1) Prior to the use of this product, patients should be instructed to recognize hypoglycemic symptoms and their management. In particular, when used in combination with sulfonylurea or insulin, this product may increase the risk of hypoglycaemia. In order to decrease the risk of hypoglycaemia associated with coadministration with sulfonylurea or insulin, a reduction in the dose of sulfonylurea or insulin should be considered when this product is coadministered with these drugs. 2) Use of this product should be considered only in patients with established diagnosis of diabetes mellitus. It should be noted that there are other diseases than diabetes mellitus that have symptoms similar to those of diabetes mellitus (renal glycosuria, abnormal thyroid function, etc.), such as impaired glucose tolerance and positive urine sugar. 3) Use of this product should be considered only when there is inadequate response to diet and exercise therapy, which are fundamental for treatment of diabetes mellitus, after adequate trial of the therapies. 4) During treatment with this product, blood glucose should be regularly monitored, and the effect of the drug should be checked. If the response to this product is inadequate after 3 months of treatment, a change to other treatment should be considered. 5) During continued treatment with this product, it may become unnecessary to administer the product or it may become necessary to reduce a dose of the product. In addition, there may be no or inadequate response to the product due to patient's failure to take care of themselves or a complication of infection, etc. Therefore, attention should be paid to the amount of food intake, blood glucose level and presence/absence of infection to judge continuation of treatment, doses and selection of drugs. 6) Adverse drug reactions such as prolonged QT may occur. Treatment with this product should preferably be avoided in patients with current or a history of QT interval prolongation (congenital long QT syndrome, etc.) or with a history of Torsades de pointes. 7] Both GLP-1 receptor agonists and this product have an antihyperglycaemic action mediated by GLP-1 receptor. No results of clinical trials studying a combined therapy with both drugs are available and the efficacy and safety of the coadministration have not been proved. 8) Acute pancreatitis may occur. Patients should be instructed to consult with a physician immediately 3 if initial symptoms including persistent and intense abdominal pain and/or vomiting occur. Use in the Elderly Since elderly patients often have reduced physiological function, this product should be administered carefully with close monitoring of the patient's condition. Paediatric Use The safety of this product in low-birth-weight infants, neonates, nursing infants, infants, or children has not been established (no clinical experience). Precaution concerning Use For drugs that are dispensed in a press-through package (PTP), instruct the patient to remove the drug from the PTP sheet prior to use. [It was reported that, if the PTP sheet is swallowed, the sharp corners of the sheet may puncture the esophageal mucosa, resulting in severe complications such as mediastinitis.] Other Precautions QT interval prolongation has been reported after administration of this product at a dose of 160 mg once daily. [The usual approved dosage of this product is 20 mg of Teneligliptin once daily, and the maximum dosage is 40 mg once daily

DRUG INTERACTIONS:

Drugs for diabetes mellitus Sulfonylurea Rapid-acting insulin secretagogues Alpha-glucosidase inhibitors Biguanides, Thiazolidines GLP-1 receptor agonists SGLT2 inhibitors Insulin, etc. When this product is coadministered, patients should be carefully observed since hypoglycemic symptoms may occur. In particular, when used in combination with sulfonylurea or insulin, the risk of hypoglycaemia may be increased. In order to decrease the risk of hypoglycaemia associated with coadministration with sulfonylurea or insulin, a reduction in the dose of sulfonylurea or insulin should be considered. When hypoglycemic symptoms appear, sucrose should normally be administered. When this product is coadministered with an alpha-glucosidase inhibitor, glucose should be administered. Drugs that intensify antihyperglycaemic action Beta-blockers Salicylic acid Monoamine oxidase inhibitors, etc. When this product is coadministered, blood glucose level and patient's other conditions should be carefully observed since blood glucose may further be decreased. Drugs that reduce antihyperglycaemic action Adrenalin Adrenocortical hormones Thyroid hormones, etc. When this product is coadministered, blood glucose level and patient's other conditions should be carefully observed since blood glucose may be increased. Drugs that are known to cause QT interval prolongation Class IA antiarrhythmic (quinidine sulfate hydrate, procainamide hydrochloride, etc.) Class III antiarrhythmic (amiodarone hydrochloride, sotalol hydrochloride, etc.) When this product is coadministered, QT interval prolongation, etc. may occur.

ADVERSE REACTIONS:

Inhibitory effect on DPP-4 and suppressive action on GLP-1 degradation 1) Teneligliptin inhibited the activity of DPP-4 in human plasma in a concentrationdependent manner, with IC50 of 1.75 nmol/L (in vitro). 2) Teneligliptin prevented the degradation of active GLP-1 in rat plasma in a concentrationdependent manner (in vitro). 3) In a glucose tolerance test in Zucker Fatty rats, a model of obesity with insulin resistance and impaired glucose tolerance, a single oral administration of Teneligliptin increased plasma active GLP-1 and plasma insulin levels. 4) In patients with type 2 diabetes mellitus, once-daily administration of Teneligliptin 20 mg inhibited plasma DPP-4 activity and increased the concentration of active GLP-1 in plasma. Improvement of glucose tolerance 1) In a glucose tolerance test in Zucker Fatty rats, a model of obesity with insulin resistance and impaired glucose tolerance, a single oral administration of Teneligliptin improved postloaded hyperglycemia. 2) In patients with type 2 diabetes mellitus, once-daily administration of Teneligliptin 20 mg improved blood glucose after breakfast, lunch and dinner and fasting blood glucose.

PREGNANCY & LACTATION:

Pregnancy This product should be used in pregnant women or women who may possibly be pregnant only if the expected therapeutic benefits outweigh the possible risks associated with treatment. [The safety of this product for use during pregnancy has not been established. An animal study (in rats) has reported that this product is transferred to the fetus.] Breast-feeding In lactating women, breast-feeding must be discontinued during treatment. [An animal study (in rats) has reported that this product is excreted in breast milk.]

OVERDOSE:

The maximum doses of Teneligliptin in clinical studies were 320 mg for a single dose in healthy adult subjects and 80 mg once daily for 7 days for repeated doses in healthy adult subjects. No serious adverse drug events and adverse drug events leading to discontinuation of the study treatment were reported after administration of Teneligliptin at the 2 doses. QT interval prolongation has been reported after administration of this product at a dose of 160 mg once daily

STORAGE: Store below 30°C. Protect from light and moisture.

SHELF LIFE: 36 months

PRESENTATION:

TENXTIN 20 : ALU-ALU Pack of 10×10 tablets.

MANUFACTURED BY:

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