250 x 180 mm

Food effect
Cmax decreased after a single dose of 20 mg of teneligliptin given post meal to the healthy adults as compared to empty stomach and tmax prolonged from 1:1 hr; however, no difference observed in AUC.

Pharmacokinetic parameters at the time of fasting and after food intake in healthy adults

	C_{max}(ng/mL)	$AUC_{0\text{-}24}$hr(ng.hr/mL)	$AUC_{0\text{-}inf}$(ng.hr/mL)	t_{max} (hr)	$t_{1/2}$ (hr)
Empty stomach	232.2(236.2±43.77)	1855.5(1861.1±148.1)	2090.3(2094.6±138.5)	1.1±0.4	26.5(27.8±9.3)
Post Meal	184.9(187.5±33.55)	1806(1814.6±183.3)	2044.0(2056.1±230.9)	2.6±1.1	26.9(28.3±9.5)

Geometric mean (Arithmetic mean value ± standard Deviation)
t_{max}, Arithmetic mean value ± Standard Deviation

Rate of protein binding
The protein binding ratio was 77.6 to 82.2% when the (14C) label teneligliptin (20, 100 and 500 ng/mL) was added to the human plasma (in vitro).

Metabolism
Following a single oral administration of 20 mg (^{14}C) label teneligliptin to the healthy adults, the unaltered substance and the metabolism M1, M2, M3, M4 and M5 were observed in the blood plasma. furthermore the ratio of $AUC_{0\text{-}\infty}$ of teneligliptin, M1,M2,M3,M4 and M5 with respect to $AUC_{0\text{-}\infty}$ calculated from the plasma radioactive concentration up to 72 hours after administration was 71.1%,14.7%,1.3%,1.3%,0.3% and 1.1%.
Mainly CYP3A4, a cytochrome P450 isozyme and flavin-containing monooxygenases (FMO1 and FMO3) participate in the metabolism of teneligliptin. In vitro, teneligliptin exhibits a weak inhibitory effect for CYP2D6, CYP3A4, and FMO(IC50 value: 489.4,1); however, it demonstrates no inhibitory effect for CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C8/9, CYP2C19, and CYP2E1. In addition, teneligliptin does not induce the expression of CYP1A2 or CYP3A4.

Excretion
When a single oral administration of 20 mg teneleglipti was given to the healthy adults on empty stomach , about 21.0 to 22.1% of dose was excreated as unaltered substance in urine, and the renal clearance was 37 to 39 mL/hr/kg. When a single oral administration of 20 mg (^{14} C) label teneleglipti to the healthy adults, 45.4% of dosage radioactive was excreated in urine and 46.5% was excreated in faces up to 216 hours after administration. furthermore, with respect to the dosage up to 120 hours after administration, the accumulated urinary excretion rate of unaltered substance, M1,M2,M3,M4 and M5 was17.7%, 1.4% and 1.9% respectively and the accumulated feces excretion rate of unaltered substance M1,M2,M3,M4 and M5 was 26.1%,4.0%, 1.6%, 0.3%, and 1.3%, respectively. Teneligliptin is a substrate of P-glycoprotein that inhibited the transportation of digoxin up to 42.5% through P-glycoprotein in the concentration of 99 µmol/L. furthermore Teneligliptin showed a weak inhibitory action towards the organic transporter OAT3 appeared in kidney,(IC50 value: 99.2 µmol/L); however, it did not show inhibitor action towards OAT1 and organic cation transporter OCT2 (in vitro)

Renal dysfunction
When a single oral dose of 20 mg teneligliptin was given to the renal dysfunction patients, no remarkable change was observed in Cmax and t1/2 of teneligliptin depending on the the extent/degree of renal dysfunction. on the other hand in the mild renal dysfunction patients (Ccr ⩾ 50 to ⩾ 80 ml/min), moderate renal dysfunction patient (Ccr ⩾ 30 to ⩾ 50 ml/min) and sever renal dysfunction patient (Ccr< 30 ml/min), $AUC_{0\text{-}\infty}$ was found to be about 1.25 times, 1.68 times and 1.49 times respectively as compared to the healthy adults. Further 15.6% of teneligliptin dose was removed due to hemodialysis.

Liver dysfunction
When a single oral dose of 20 mg teneligliptin was given to the hepatic dysfunction patients, the C_{max} of teneligliptin was found to be about 1.25 times and1.38 times and AUC 0-∞ was found to be about 1.46 times and 1.59 times respectively. in the mild hepatic dysfunction patients (total score 5-6 by Child –Pugh classification), and moderate hepatic dysfunction patient (total score 7-9 by Child –Pugh classification) as compared to the healthy adults. There is no clinical experience in high degree hepatic dysfunction patients (total score more than 9 by Child –Pugh classification)

Pharmacokinetic in elderly patients
When a single oral dose of 20 mg teneligliptin was given to the healthy patients (⩾ 65 years old ⩽ 75 years old, 12 patients) and non-elderly patients (⩾45 years old ⩽ 65 years old, 12 patients) on empty stomach, the ratio (90% confidence interval) of geometric minimum mean –square value of elderly patients with Cmax, AUC0-∞ and t1/2 of non-elderly patients was almost similar, 1,006(0.871-1.163),1.090(0.975-1.218), and 1.054(0.911-1.219), respectively.

INCOMPATIBILITIES
None

SHELF LIFE
24 months from the date of manufacturing

PACKAGING INFORMATION
Blister pack of 10 tablets.

STORAGE AND HANDLING INSTRUCTIONS
Store below 25°C away from direct sunlight, heat and moisture.
Keep the medicine out of reach of children.

PPIT080

For more information and details contact :
Panacea Biotec Ltd.
B-1Extn./A-27, Mohan Co-op. Indl. Estate,
Mathura Road, New Delhi - 110 044.

Last updated December 2015

Panacea Biotec
Innovation in support of life

For the Use of Registered Medical Practitioner or a Hospital or a Laboratory

Teneligliptin Tablets 20 mg

TENEPAN

DESCRIPTION
Teneligliptin is a Dipeptidyl peptidase-4 (DPP-4) inhibitorsfor the treatment of type 2 diabetes mellitus. it is Chemically known as {(2S,4S)-4-[4-(3-Methyl-1-phenyl-1H-pyrazol-5-yl) piperazin-1-yl] pyrrolidin-2-yl} (1,3-thiazolidin-3-yl) methanone hemipentahydrobromide hydrate. It has the Molecular formula: $C_{22}H_{30}N_6OS.2\ 1/2HBr.xH_2O$. it is a white color powder. It is readily soluble in water, sparingly soluble in methanol, slightly insoluble in ethanol (99.5) and insoluble in acetonitrile. Its molecular weight is 628.86.

COMPOSITION
Each film coated tablet contains:
Teneligliptin Hydrobromide Hydrate equivalent to Teneligliptin 20 mg
Colours: Titanium Dioxide, Ferric Oxide (Red) and Ferric Oxide (Black)

INDICATIONS
Teneligliptin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).

DOSAGE AND METHOD OF ADMINISTRATION
The usual adult dosage is 20mg of Teneligliptin administered orally once daily. If efficacy is insufficient, the dose may be increased up to 40 mg once daily while closely monitoring the clinical course. Teneligliptin tablets are to be administered orally without regard to meal. Do not crush or chew tablets.

USE IN SPECIAL POPULATION
Pediatric Population
Pediatric use the safety of this product in low birth weight baby, newborn baby, infant, or little child has not been established.
Geriatric Population
In general elderly patients often have physiological hypofunction; and therefore, teneligliptin should be administered carefully.
Renal impairment
As determined from the pharmacokinetic characteristics of teneligliptin the extent of increase in the exposure level of teneligliptin in patients with renal impairment will not pose any significant safety risk. Thus no dose adjustment is proposed in renal impaired patients.
Hepatic impairment
As determined from the pharmacokinetic characteristics of teneligliptin the extent of increase in the exposure level of teneligliptin in patients with mild to moderate hepatic impairment will not pose any significant safety risk. Thus no dose adjustment is proposed in mild to moderate hepatic impairment patients. There was no clinical experience in severe degree hepatic dysfunction patients

Pregnancy and Lactation
The safety of this product in pregnant women has not been established, Teneligliptin should be used in pregnant women or in women who may possibly be pregnant only if the expected therapeutic benefits outweigh the possible risks associated with treatment. (The safety of this product in pregnant women has not been established. Furthermore, the transfer to embryo in animal studies (rats) has been reported.)

CONTRAINDICATIONS
- 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 of hyperglycemias with infusion and insulin.
- Severe trauma, before and after surgery and when the blood glucose level is controlled with insulin injection.

WARNING AND PRECAUTION
Careful administration (this medicine should be carefully administered in the following patients)
1. Patient with severe hepatic dysfunction (as there no usage experience and safety has not been established).
2. Acute pancreatitis has been observed in studies and since acute pancreatitis is also reported with similar molecules, it should not be used in patients with history of acute pancreatitis. In case a patient develops acute pancreatitis the drug should be withdrawn and immediately physician consultation should be done.
3. Patient with heart failure (NYHA class III-IV) as there is no usage experience and safety has not been established)
4. Co- administration of sulfonylurea medication or insulin formulation (Risk of hypoglycemia may increase).
5. 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
6. Patient with history of abdominal surgery or intestinal obstruction (intestinal obstruction might occur)
7. 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 patients having hypokalemia

Important Precautions
1. The point regarding hypoglycemia and its coping strategy should be sufficiently explained to the patient when using this product. Particularly, when co-administrated with sulfonylurea or insulin formulation, there is a possibility of higher risk of hypoglycemia. In order to reduce the risk of hypoglycemia caused sulfonylurea or insulin formulation, consider decreasing the dose of sulfonylurea or insulin formulation when given in combination with teneligliptin.
2. Consider its application only to the patient diagnosed with Type 2 diabetes mellitus (T2DM). In addition to T2DM, pay attention to disease having symptoms (such as renal glycosuria, thyroid dysfunction) similar to diabetes, such as abnormal glucose tolerance/positive urine sugar.
3. Consider the application of this product: in patients who have not sufficiently responded to diet and exercise therapy, which is a basic treatment for diabetes.
4. During administration of this product, regularly check the blood sugar; check the effect of the drug. In case the drug effect is insufficient even after taking this product for 3 months, then change to the other treatment.
5. During continuous administration, there are cases that do not need medication, cases where dose has to be reduced, and cases where there is no effect or inadequate response due to complication of patients infestation and infection; and therefore, pay attention to dietary intake, blood sugar level, and presence of infection, as well as, always take care of selection of drugs, dosage, and whether to continue the drug.
6. Since there is a possibility that adverse reaction, such as QT prolongation, might occur, it desirable to avoid the medication in the patients having QT prolongation or its history (such as hereditary QT prolongation syndrome) or the patients having history of Torsade s de pointes.
7. Since there is a risk of hypoglycemia, attention should be paid while administration of this drug to the patients who are engaged in car driving or working at height.
8. In regard to the co-administration of this drug and insulin formulation, the efficacy and the safety have not been studied.
9. This drug and GLP-1 receptor agonist both have GLP-1 mediated anti-hyperglycemia effect. No clinical trial results are available regarding concomitant use of both drugs; also, effectiveness and safety have not been confirmed.

Marketing (Mr. Ankesh Jain (dated 31.12.2015), Mr. Gurinder Pal Singh (01.01.2016) and Mr. Subhasis Dasgupta(30.12.2015) has already approved

Product Name	**Tenepan**	**Change Control No.: BCC151-15**
Item Code	PPIT080	**Colours: Black**
Size	250x180 mm	
Market	Domestic	**Revision No:** 01 - As per comments from FRD, RA and CRD

Other Precautions
In clinical trials, QT prolongation has been reported when 160 mg of this product was administered once daily.(Approved dose of this product: The usual dosage is 20 mg of teneligliptin once daily, and the maximum dose is 40 mg once daily). When a repeated oral dose of 40 mg or 160 mg teneligliptin once daily to the healthy adults for four days, the maximum mean value (90% confidence interval upper limit) of placebo- corrected QTcI(QTc corrected per individual) interval change was 3.9(7.6) msec at 3 hours after dosing completion in 40 mg group and 9.3 (13.0) msec at 1.5 hours after dosing completion in 160 mg group). In a 52-week repeated oral administration toxicity test using cynomolgus monkey, the cutaneous symptoms, such as superficial abrasion, scab, or ulcer, were observed on the trial, extremities, and auricles with the dose of 75 mg/kg/day. $AUC_{0\text{-}24hr}$ in this case reached to around 45 times when 40 mg/day was administrated to humans. Note that the same toxicity findings have not been reported in other animal species (rats, mice, and rabbit) and human.

DRUG INTERACTIONS
Precaution for administration with certain drug

Drug name and other details	Clinical symptoms and treatment methods	Mechanism and risk factor
Medicines for diabetic disease: - Drug for diabetes sulfonylurea fast- acting insulin secretagogue α-glucosidase inhibitor Biguanide drug thaizolidine drug GLP- 1 analog preparation SGLT2 inhibitor insulin preparation	Since hypoglycemia might occur, these drugs should be administrated while carefully monitoring the patient condition. Particularly, when co- administrated with sulfonylurea or insulin formulation, there is a possibility of higher risk of hypoglycemia caused by sulfonylurea or insulin formulation consider decreasing the quantity of sulfonylurea or insulin formulation when hypoglycemia is observed usually , cane sugar should be given, and when co administrated with glycosidase inhibitor, glucose should be given	Hypoglycemic action is increased
Drug increasing hypoglycemic action B-Blocking agent salicylic acid drug monoamine oxidase inhibitor	Since the blood sugar may further decrease, these drugs should be administrated while carefully observing the patient's condition in additional blood sugar level.	Hypoglycemic action is increased
Drug decreasing hypoglycemic action Adrenaline adrenocortical hormone thyroid hormone	Since the blood sugar may increase, these drugs should be administrated while carefully observing the patient's condition in additional blood sugar level.	Hypoglycemic action is decreased
Drug known to cause QT prolongation Class IA anti arrhythmic drug Quinidine sulfate hydrate, procainamide hydrochloride Class III anti arrhythmic drug amiodarone hydrochloride, sotalol hydrochloride.	QT prolongation might occur.	QT prolongation is seen with single administration of these drugs.

Glimepiride combination
When a repeated dose of 1 mg glimepiride for four day and a single combined dose (2 day of glimepiride administration) of 40 mg teneligliptin were administration to the healthy adult (16), the ratio (90% confidence interval) of C_{max} of teneligliptin and $AUC_{0\text{-}\infty}$ geometric mean value was 0.971 (0.866-1.088) and 0.926 (0.894-0.959) with respect to single- dose administration of teneligliptin alone. Furthermore , when a repeated –dose of 40 mg teneligliptin for seven days and single combined dose (7th day of teneligliptin administration) of 1 mg glimepiride were administered to the healthy adults , the ratio (90% confidence interval) of C_{max} of glimepiride an d $AUC_{0\text{-}\infty}$ geometric mean value was 1.016 (0.932- 1.106) and1.023 (0.978-1.071) with respect to single-dose administration of glimepiride alone).
Pioglitazone combination
When a reported dose of 30 mg pioglitazone for nine days and single combined dose (2 day of glimepiride administration) of 40 mg teneligliptin were administration to the healthy adult(16), the ratio (90% confidence interval) of C_{max} of teneligliptin and $AUC_{0\text{-}\infty}$ geometric mean value was 0.971 (0.866-1.088) and 0.926 (0.894-0.959) with respect to single- dose administration of teneligliptin alone. And the C_{max} of teneligliptin increased 11.7% due to co-administration. Furthermore, when a repeated –dose of 40 mg teneligliptin for seven days and single combined dose (7th day of teneligliptin administration) of 1 mg glimepiride were administered to the healthy adults , the ratio (90% confidence interval) of C_{max} of pioglitazone an d $AUC_{0\text{-}\infty}$ geometric mean value was 1.004 (0.917- 1.100) and1.134 (1.060-1.213) with respect to single- dose administration of administration of pioglitazone alone). Similarly , the ratio (90% confidence interval) of C_{max} of active metabolites (M-III and M IV) of pioglitazone and $AUC_{0\text{-}\infty}$ geometric mean value was 1.041(m0.975-1.113) and 1.116 (1.056-1.180) 9n M III and 1.028 (.963- 1.096) and 1.088 (1.032- 1.147) on M –IV).
Metformin combination
When a repeated dose of 40 mg teneligliptin once a daily for eight days and repeated combined dose (6th and 8th day of teneligliptin administration) of 850 mg metformin twice daily were administrated to the healthy adults, the ratio (90% confidence interval) of C_{max} of teneligliptin and $AUC_{0\text{-}24hr}$ geometric minimum mean square value was 0.907(0.853-0.965) and 1.042(0.997- 1.089) with respect to repeated dose administration of teneligiptin only. Furthermore , when repeated combined dose (4th to 8th day of metformin administration) of 850 mg metformin twice daily for eight days and 40 mg teneligliptin once daily was administrated to the healthy adult, the ratio (90% confidence interval) of C_{max} to metformin and $AUC_{0\text{-}12hr}$ geometric minimum mean – secure value was 1.057) 0.974- 1.148) and 1.209(1.143-1.278) with repeated – dose administration of metformin only , and the $AUC_{0\text{-}12hr}$ of metformin increased 20.9% due to co administration).
Ketoconazole combination
When a repeated dose of 400 mg ketoconazole for Six days and single combined dose (4th day of ketoconazole administration) of 420mg teneligliptin were administration to the healthy adult(14), the ratio (90% confidence interval) of C_{max} of teneligliptin and $AUC_{0\text{-}\infty}$ geometric mean value was 1.37 (1.25- 1.50) and 1.49 (1.39 -1.60) with respect to single- dose administration of teneligliptin alone, and increased to 37% and 49% due to co administration.

UNDESIRABLE EFFECTS
The following adverse drug reactions have been identified in the clinical trials on Teneligliptin.
In clinical trials conducted in japan, 232 adverse reactions to this drug (including abnormal laboratory tests) were reported in 156 patients (9.5%) of total 1645 patients.
The most frequently observed adverse reactions were hypoglycemia in 43 patients (2.6%) and constipation in 14 patients (0.9%).
Patients with inadequate Glycemic Control on Diet and Exercise Alone.
In a clinical study conducted in 237 Indian patients with Type 2 diabetes mellitus inadequately controlled on diet and exercise alone.
A total of 158 patients were exposed to Teneligliptin Tablets for a mean duration of 106.7 days. Adverse events considered to be related to study medication were reported for 6/158 (3.8%) of patients in the Teneligliptin group. The most frequent individual adverse event was dizziness in Teneligliptin group (5/158) 3.2%, followed by headache in (5/158) 3.2%, diarrhea in (4/158)2.5% and pyrexia in (4/158) 2.5%. An AE (cancer right pyriform fossa) leading to early termination from the study was reported for 1/158(0.6%) of patients in the Teneligliptin group, this was unrelated to study drug. No SAE related to the study drug was reported during the study. Most of the adverse events were mild in severity.
Significance adverse reaction
Hypoglycemia: Hypoglycemia may occur when co-administered with other drugs for diabetes (in combination with glimepiride: 8.9%, in combination with pioglitazone: 1.5%, in combination with glinides :3.8%,in combination with biguanide:1.1%, and in combination with α-glucosidase inhibiter: 1.3%). Particularly, a severe hypoglycemia is noted when co-administerd with other DPP-4 inhibitor, sulfonylurea, and also the cases with loss of consciousness are reported; and therefore, consider decreasing the quantity of sulfonylurea when co-administered with sulfonylurea.
Furthermore, hypoglycemia (1.1%) is also reported when not co-administered with other drugs for diabetes. In case hypoglycemia is observed, appropriate measures must be taken such as intake of carbohydrate containing food.
Intestinal Obstruction (0.1%): Intestinal obstruction may occur; and therefore, the patient should be carefully monitored. If any abnormal findings such severe constipation, abdominal swelling, continuous abdominal pain, and vomiting, are observed, administration should be discontinued and appropriate measures must be taken.
Liver dysfunction (unknown frequency): Liver dysfunction occurs with increase in AST (SGOT). ALT (SGPT); and therefore, appropriate measures such as performing sufficient monitoring of these parameters should be taken. Discontinue teneligliptin if abnormalities are observed.
Interstitial pneumonia (frequency unknown): Interstitial pneumonia may occur. If coughing, breathing difficulty, onset of fever, and abnormal chest sounds (crepitation) are noticed, the examinations such as chest X-ray, chest CT, and serum maker should carried out. In case interstitial pneumonia is suspected, the appropriate measures like discontinuation of administration and administration of adrenocortical hormone should be taken.
Other adverse reactions/side effects
If adverse reactions are observed, the drug administration should be discontinued and appropriate measures should be taken.
Other Adverse reactions

Incidence/Type	0.1% ~ 1%	<0.1%
Digestive system	Constipation, abdominal swelling, abdominal discomfort, nausea, stomachache, flatulence, stomatitis, gastric polyp, duodenal ulcer, colon polyp, reflux esophagitis, diarrhea, anorexia, increased amylase, increased lipase, acute pancreatitis.	
Liver	Increased AST (GOT), increased A L T (GP T), and increased ϒ-GTP	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, fatigue, allergic rhinitis, and increased serum uric acid	

OVERDOSE
In the event of an overdose, it is reasonable to employ the usual supportive measure, e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring (including obtaining an electrocardiogram), and institute supportive therapy if required.
PHARMACOLOGICAL PROPERTIES
Mechanism of Action
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 activity from GLP-1.
DPP-4 inhibitory action and GLP-1 degradation inhibitory action
- Teneligliptin inhibits concentration-dependent human plasma DPP-4 activity and its IC50 value(95% Confidence interval) was1.75 (1.62–1.89) nmol/L(in vitro)
- Teneligliptin concentration-dependently suppressed the degradation of GLP-1 in rat plasma, with IC50 value and 95% Confidence interval being 2.92nM(2.21,3.87)(in vitro)
- In the glucose tolerance test using Zucker Faty rat, an obesity model showing insulin resistance and abnormal glucose tolerance, teneligliptin increased plasma active from GLP-1 concentration and plasma insulin concentration by its single dose administration.
- In patients having type 2 diabetes mellitus the administration of 20 mg teneligliptin once daily inhibited the plasma DPP-4 activity and increased the plasma active from GLP-1 concentration.

Glucose Tolerance Improvement action
- In the glucose Tolerance test using Zucker Fatty rat, an obesity model showing insulin resistance and abnormal glucose Tolerance teneligliptin controlled an increase in the blood sugar level by its single dose administration
- In patients having type 2 diabetes mellitus the administration of 20 mg teneligliptin once daily improved the blood sugar after breakfast, lunch and dinner and the fasting blood sugar.

Clinical study
In a double-blind, randomized, comparative study of 16 week treatment duration Teneligliptin was compared with placebo in the treatment of patients with type 2 diabetes mellitus inadequately controlled on diet and exercise alone. A total of 237 subjects (age of 48.9-49.6 years) were enrolled in the study and randomized to treatment with 158 patients in the Teneligliptin group, and 79 patients placebo group. All subjects were Asian (Indian) and 60.8% were male and 39.2% were female. There was a statistically significant difference ($P < 0.05$) for the primary end point, mean change in HbA1c from baseline to end of treatment in both ITT (change in HbA1c: 0.555) and PP (change in HbA1c: 0.642) population. There was also statistical significant difference ($P<0.005$) for proportion of patients with HbA1c below 7% between Teneligliptin and placebo in both PP(43.6%) and ITT (43.4%) population.
Pharmacokinetic
Single –dose administration
The plasma concentration changes and the pharmacokinetic parameters of teneligliptin after single oral dose of 20 mg and 40 mg of teneligliptin given empty stomach to the healthy adults are shown below.
Pharmacokinetic parameters at the time of single-dose oral drug administration in healthy adults

Strengths	C_{max} (ng/mL)	$AUC_{0\text{-}\infty}$(ng.hr/mL)	t_{max} (hr)	$t_{1/2}$ (hr)
20 mg 40 mg	187.20±44.70 382.40±89.83	2028.9 ±459.5 3705.0±787.0	1.8(1.0-2.0) 1.0(0.5-3.0)	24.2±5.0 20.8±3.2

Repeated dose administration
The pharmacokinetic parameters of teneligliptin after repeated dose of 20 mg of teneligliptin once daily for seven days given 30 minutes before breakfast to the healthy adults are shown below. it was thought that the state of equilibrium will be attained within seven days.
Pharmacokinetic parameters at the time of repeated dose oral drug administration in healthy adults

	C_{max}(ng/mL)	$AUC_{0\text{-}24hr}$(ng.hr/mL)	$AUC_{0\text{-}\tau ss}$(ng.hr/mL)	t_{max} (hr)	$t_{1/2}$ (hr)
After first dose 7 days after administration	160.60±47.26 220.14±59.86	1057.2±283.9 1514.6±370.5	1627.9±427.8 2641.4±594.7	1.0(0.4-2.0) 1.0(1.0-1.0)	25.8±4.9 30.2±6.9

t_{max}= central value (minimum value – maximum value)

Marketing (Mr. Ankesh Jain (dated 31.12.2015), Mr. Gurinder Pal Singh (01.01.2016) and Mr. Subhasis Dasgupta(30.12.2015) has already approved

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