30XXXX

TENELIGLIPTIN PIOGLITAZONE

TENELIZONE®

20 mg / 15 mg Film-Coated Tablet
20 mg / 30 mg Film-Coated Tablet
Blood Glucose Lowering Drugs
(Dipeptidyl Peptidase 4 [DPP-4] Inhibitor/Thiazolidinedione)

℞

FORMULATION
Each film-coated tablet contains:
Teneligliptin (as hydrobromide hydrate)..... 20mg
Pioglitazone (as hydrochloride), USP 15mg
Teneligliptin (as hydrobromide hydrate)..... 20mg
Pioglitazone (as hydrochloride), USP 30mg

DESCRIPTION
Tenelizone® 20mg/15mg - Light Yellowish brown to Yellowish brown colored, circular, biconvex film coated tablets, plain on both sides.
Tenelizone® 20mg/30mg - Light Blue to Blue colored, circular, biconvex film coated tablets, plain on both sides.

INDICATIONS
Indicated as an adjunct to diet and exercise, to improve glycemic control in patients with type II diabetes inadequately controlled on Pioglitazone monotherapy.

CONTRAINDICATIONS
Teneligliptin plus Pioglitazone tablet is contraindicated in patients with hypersensitivity to the active substances or to any of the excipients. The combination tablet is also contraindicated in patients with diabetic ketoacidosis, diabetic pre-coma; moderate and severe renal impairment (creatinine clearance < 60 mL/min); acute conditions with the potential to alter renal function such as dehydration, severe infection, shock, intravascular administration of iodinated contrast agents, current bladder cancer or a history of bladder cancer and uninvestigated macroscopic hematuria. Administration of combination is not suitable for severe infection, before and after surgery, glycemic control by insulin injection.
The combination is also contraindicated in 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 and during pregnancy and lactation.

DOSAGE AND ADMINISTRATION
The recommended dose of Teneligliptin plus Pioglitazone combination is one tablet once daily. Or as prescribed by the physician.

CLINICAL PHARMACOLOGY
PHARMACODYNAMICS
Teneligliptin is a novel highly selective DPP-4 (dipeptidyl peptidase-4) inhibitor. It shows a unique chemical structure which is characterized by five consecutive rings (J-shaped), thereby potentially producing unique characteristics including its glucose lowering efficacy and half-life. Incretin hormones, namely glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP), are released from enteroendocrine cells and enhance insulin secretion. Incretins are rapidly inactivated by the enzyme dipeptidyl peptidase-4 (DPP-4), and as a result have a very short half-life ($t_{1/2}$). DPP-4 inhibitors increase the levels of active GLP-1 and GIP by inhibiting DPP-4 enzymatic activity; thus, in patients with diabetes, these inhibitors improve hyperglycemia in a glucose-dependent manner by increasing serum insulin levels and decreasing serum glucagon levels. Glycemic efficacy of Teneligliptin is obtained through activating beta-cell function as well as decreasing insulin resistance.
Pioglitazone effects may be mediated by a reduction of insulin resistance. Pioglitazone appears to act via activation of specific nuclear receptors (peroxisome proliferator activated receptor gamma) leading to increased insulin sensitivity of liver, fat and skeletal muscle cells in animals. Treatment with Pioglitazone has been shown to reduce hepatic glucose output and to increase peripheral glucose disposal in the case of insulin resistance.
Fasting and postprandial glycemic control is improved in patients with type 2 diabetes mellitus. The improved glycemic control is associated with a reduction in both fasting and postprandial plasma insulin concentrations.

PHARMACOKINETICS
The plasma concentrations of Teneligliptin after the administration of Teneligliptin at dosages of 10 or 20 mg once daily for 4 weeks revealed a median time to maximum concentration (C_{max}) of 1.0 hour in both groups and a mean half-life of 20.8 and 18.9 hours, respectively. The AUC_{0-2h} values for the active GLP-1 concentration after breakfast, lunch, and dinner were 8.0, 8.4, and 7.8 pmol • h/L, respectively, in the 10 mg Teneligliptin group, and 8.3, 7.9, and 8.6 pmol •h/L, respectively, in the 20 mg Teneligliptin group. About 34.4% of Teneligliptin is excreted unchanged via the kidney and the remaining 65.6% Teneligliptin is metabolized and eliminated via renal and hepatic excretion. Following oral administration, Pioglitazone is rapidly absorbed, and peak plasma concentrations of unchanged Pioglitazone are usually achieved 2 hours after administration. Proportional increases of the plasma concentration were observed for doses from 2-60 mg. Steady state is achieved after 4-7 days of dosing. Repeated dosing does not result in accumulation of the compound or metabolites. Absorption is not influenced by food intake. Absolute bioavailability is greater than 80%. The estimated volume of distribution in humans is 0.25 L/kg. Pioglitazone and all active metabolites are extensively bound to plasma protein (> 99%). Pioglitazone undergoes extensive hepatic metabolism by hydroxylation of aliphatic methylene groups. Following oral administration of radio labelled Pioglitazone to man, recovered label was mainly in feces (55%) and a lesser amount in urine (45%). The mean plasma elimination half-life of unchanged Pioglitazone in man is 5 to 6 hours and for its total active metabolites 16 to 23 hours.

SPECIAL WARNINGS AND PRECAUTIONS
Safety is not established in severe hepatic impairment and NYHA (classification III ~ IV) heart failure patients. There is a risk of hypoglycemia if administered along with insulin formulations or sulfonylurea drugs.
There is a risk of hypoglycemia [state or patient listed below]:
- Adrenal insufficiency or pituitary gland dysfunction
- Debilitating condition malnourishment, starvation, irregular dietary intake, or lack of dietary intake
- Intense muscular exercise
- Alcohol intake by excessive

There is a risk of intestinal obstruction in patients with a history of bowel obstruction or a history of abdominal surgery.
There is a possibility that adverse reactions, such as QT prolongation, might occur. Caution in patients prone to QT prolongation (patients with heart disease such as congestive heart failure, patients having hypokalemia, patients with or with a history of arrhythmia such as severe bradycardia).
Acute pancreatitis
Use of DPP-4 inhibitors has been associated with a risk of developing acute pancreatitis. Patients should be informed of the characteristic symptom of acute pancreatitis (persistent, severe abdominal pain). Resolution of pancreatitis has been observed after discontinuation of DPP-4 inhibitors (with or without supportive treatment), but very rare cases of necrotizing or hemorrhagic pancreatitis and/or death have been reported. If pancreatitis is suspected, the Teneligliptin plus Pioglitazone tablet and other potentially suspect medicinal products should be discontinued. Caution should be exercised in patients with a history of pancreatitis.
Hypoglycemia
Patients receiving Teneligliptin plus Pioglitazone tablet in combination with a sulphonylurea or with insulin may be at risk for hypoglycemia. Therefore, a reduction in the dose of the sulphonylurea or insulin may be necessary.
Hypersensitivity reactions
Serious hypersensitivity reactions have been reported in patients treated with other DPP-4 inhibitors. These reactions include anaphylaxis, angioedema, and exfoliative skin conditions including Stevens-Johnson syndrome. If a hypersensitivity reaction is suspected, the medication should be discontinued, other potential causes of the event should be assessed, and alternative treatment for diabetes should be instituted.
Change in clinical status of patients with previously controlled type 2 diabetes
A patient with type 2 diabetes previously well controlled on Teneligliptin plus Pioglitazone combination that develops laboratory abnormalities or clinical illness (especially vague and poorly defined illness) should be evaluated promptly for evidence of ketoacidosis or lactic acidosis. Evaluation should include serum electrolytes and ketones, blood glucose and if indicated, blood pH, lactate, pyruvate levels. If acidosis of either form occurs, Teneligliptin plus Pioglitazone tablet must be stopped immediately and other appropriate corrective measures initiated.
QT prolongation
QT prolongation has been observed with very high doses of Teneligliptin (160 mg). Special caution is required in the administration of Teneligliptin to patients who are prone to QT prolongation. In addition, the coadministration of Teneligliptin with drugs known to cause QT prolongation on their own, such as class IA or class III antiarrhythmic drugs should be performed with caution.
Fluid retention and cardiac failure
Pioglitazone can cause fluid retention, which may exacerbate or precipitate heart failure. When treating patients who have at least one risk factor for development of congestive heart failure (e.g. prior myocardial infarction or symptomatic coronary artery disease or the elderly), physicians should start with the lowest available dose and increase the dose gradually. Patients should be observed for signs and symptoms of heart failure, weight gain or edema; particularly those with reduced cardiac reserve. Since insulin and Pioglitazone are both associated with fluid retention, concomitant administration of insulin may increase the risk of edema. Therapy should be discontinued if any deterioration in cardiac status occurs.
Elderly
Combination use with insulin should be considered with caution in the elderly because of increased risk of serious heart failure. In light of age-related risks (especially bladder cancer, fractures and heart failure), the balance of benefits and risks should be considered carefully both before and during treatment in the elderly.
Bladder cancer
Cases of bladder cancer were reported more frequently in clinical trials with Pioglitazone. A possible risk after short-term treatment cannot be excluded. Risk factors for bladder cancer should be assessed before initiating Pioglitazone treatment (risks include age, smoking history, exposure to some occupational or chemotherapy agents e.g. cyclophosphamide or prior radiation treatment in the pelvic region). Any macroscopic hematuria should be investigated before starting Pioglitazone therapy.
Patients should be advised to promptly seek the attention of their physician if macroscopic hematuria or other symptoms such as dysuria or urinary urgency develop during treatment.
Monitoring of liver function
There have been rare reports of elevated liver enzymes and hepatocellular dysfunction during post-marketing experience with Pioglitazone. It is recommended, therefore, that patients treated with Teneligliptin plus Pioglitazone tablet undergo periodic monitoring of liver enzymes. Liver enzymes should be checked prior to the initiation of therapy in all patients. Therapy should not be initiated in patients with increased baseline liver enzyme levels (ALT > 2.5 times upper limit of normal) or with any other evidence of liver disease.
Following initiation of therapy, it is recommended that liver enzymes be monitored periodically according to clinical judgement. If ALT levels are increased to 3 times upper limit of normal during therapy, therapy should be discontinued. If any patient develops symptoms suggesting hepatic dysfunction, which may include unexplained nausea, vomiting, abdominal pain, fatigue, anorexia and/or dark urine, liver enzymes should be checked. The decision whether to continue the patient on therapy with Teneligliptin plus Pioglitazone tablet should be guided by clinical judgement pending laboratory evaluations. If jaundice is observed, the medicinal product should be discontinued.
Weight gain
In clinical trials with Pioglitazone there was evidence of dose related weight gain, which may be due to fat accumulation and in some cases associated with fluid retention. In some cases weight increase may be a symptom of cardiac failure, therefore weight should be closely monitored.
Hematology
There was a small reduction in mean hemoglobin (4% relative reduction) and hematocrit (4.1% relative reduction) during therapy with Pioglitazone, consistent with hemodilution.
Hypoglycemia
Patients receiving Pioglitazone with a sulphonylurea may be at risk for dose-related hypoglycemia, and a reduction in the dose of the sulphonylurea may be necessary.
Eye disorders
Post-marketing reports of new-onset or worsening diabetic macular edema with decreased visual acuity have been reported with thiazolidinediones, including Pioglitazone. Many of these patients reported concurrent peripheral edema. It is unclear whether or not there is a direct association between Pioglitazone and macular edema but prescribers should be alert to the possibility of macular edema if patients report disturbances in visual acuity; an appropriate ophthalmological referral should be considered.
Polycystic ovarian syndrome
As a consequence of enhancing insulin action, Pioglitazone treatment in patients with polycystic ovarian syndrome may result in resumption of ovulation. These patients may be at risk of pregnancy. Patients should be aware of the risk of pregnancy and if a patient wishes to become pregnant or if pregnancy occurs, the treatment should be discontinued.
Others
An increased incidence in bone fractures in women was seen in clinical trials with Pioglitazone. The risk of fractures should be considered in the long term care of patients treated with Pioglitazone.
Pioglitazone should be used with caution during concomitant administration of cytochrome P450 2C8 inhibitors (e.g. gemfibrozil) or inducers (e.g. rifampicin). Glycemic control should be monitored closely. Pioglitazone dose adjustment within the recommended posology or changes in diabetic treatment should be considered.

DRUG INTERACTIONS
Teneligliptin is metabolized by (FMO3 and FMO1) flavin-containing monooxygenase and CYP3A4 primarily; this drug was 14.8 to 22.1% is urinary excretion of unchanged drug:

Diabetes drugs, sulfonylurea drugs, rapid acting insulin secretagogue, a-glucosidase inhibitor, biguanides, thiazolidinediones drug, GLP-1 analog formulation insulin preparations etc.	Since there is possibility that hypoglycemia occurs, be administered while observing well the patient's condition. In particular, when used in combination with insulin formulation or sulfonylurea drugs, there is a possibility that the risk of hypoglycemia is increased. In order to reduce the risk of hypoglycemia with insulin formulation, may want to consider weight loss of the insulin formulation or sulfonylurea drugs (see "careful administration", "important precautions" and "serious side effects"). In the case of low blood sugar symptoms are observed, was administered, usually sucrose, and the combination with the a-glucosidase inhibitor be administered glucose at times.	Blood glucose lowering effect is enhanced
Drug to enhance thehypoglycemic effect β-blocker agent salicylic acid monoamine oxidase inhibitor such as	Because it can result in reduced blood glucose further be administered while observing well the condition of the patient other blood sugar.	Blood glucose lowering effect is enhanced
Drug to attenuate the hypoglycemic action adrenaline adrenal cortical hormone, etc.	Because there is a possibility that the blood glucose rises, be administered while observing well the patient's condition and other blood sugar.	Blood glucose lowering effect is attenuated
Drug may cause QT prolongation is known class IA antiarrhythmic drug quinidine sulfate hydrate, procainamide hydrochloride, such as class III antiarrhythmic agent Amiodarone hydrochloride, sotalol hydrochloride etc.	There is possibility that QT prolongation etc. occur.	QT prolongation has been observed in monotherapy with these agents.

Co-administration of Pioglitazone with gemfibrozil (an inhibitor of cytochrome P450 2C8) is reported to result in a 3-fold increase in AUC of Pioglitazone. Since there is a potential for an increase in dose-related adverse events, a decrease in the dose of Pioglitazone may be needed when gemfibrozil is concomitantly administered. Close monitoring of glycemic control should be considered.
Co-administration of Pioglitazone with rifampicin (an inducer of cytochrome P450 2C8) is reported to result in a 54% decrease in AUC of Pioglitazone. The Pioglitazone dose may need to be increased when rifampicin is concomitantly administered. Close monitoring of glycemic control should be considered.

PREGNANCY AND LACTATION

Pregnancy

There are no adequate data from the use of Teneligliptin plus Pioglitazone combination tablet in pregnant women. Studies in animals have shown reproductive toxicity at high doses of DPP-4 inhibitors.

Teneligliptin plus Pioglitazone tablet should not be used during pregnancy. If a patient wishes to become pregnant or if a pregnancy occurs, treatment should be discontinued and switched to insulin treatment as soon as possible.

Lactation

In studies performed with the individual active substances, DPP-4 inhibitors and Pioglitazone are excreted in the milk of lactating rats. Teneligliptin plus Pioglitazone tablet must therefore not be used in women who are breast-feeding.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

When driving or using machines, it should be taken into account that dizziness and somnolence has been reported with DPP-4 inhibitors. In addition, patients should be alerted to the risk of hypoglycemia when Teneligliptin plus Pioglitazone tablet is used in combination with a sulphonylurea or with insulin.

ADVERSE EFFECTS

Teneligliptin is well tolerated in various clinical trials. Data from 1,183 patients reported that 118 (10%) patients experienced AEs, and the most common AEs were hypoglycemia (3%) and constipation (0.9%). Hypoglycemia can occur when other antidiabetic drugs are coadministered. Intestinal obstruction may occur with Teneligliptin and must be administered cautiously in patients with a history of intestinal obstruction or surgery. This may be because of reduced gastrointestinal motility due to enhanced activity of incretins. Cases of intestinal obstruction are also reported with other gliptins.

Reported evidence suggests that no QT prolongations were noted with Teneligliptin 40mg daily dose. Nevertheless, mild and transient QTc prolongation can be seen at a supradinical dose of 160mg/day given for a prolonged period of time in patients who are prone or have comorbid arrhythmia/ischemic heart disease and along with medications known for QT prolongation.

Intestinal obstruction (0.1%)

Because bowel obstruction may occur, should be carefully observed, abdominal pain severe constipation, abdominal distension, persist, administration of this drug should be discontinued when an abnormality of vomiting etc. are observed, and appropriate measures should be taken.

Other Side Effects

	0.1-1% less than	Less than 0.1%
Digestive Organ	Constipation, abdominal bloating, abdominal discomfort, nausea, abdominal pain, flatulence, stomatitis, gastric polyps, colon polyps, duodenal ulcer, reflux esophagitis, diarrhea, loss of appetite, increased amylase, lipase increased, acute pancreatitis [Note])	
Liver	AST (GOT) increased, ALT (GPT) rise, Y-GTP rise	Al-P rise
Kidney, Urinary System	Proteinuria, urine ketone-positive, a man who had	
Skin	Eczema, rash, itching, allergic dermatitis	
Other	CK (CPK) increased, serum potassium increased, malaise, allergic rhinitis, elevation of serum uric acid	

Pioglitazone

Tabulated list of adverse reactions

Adverse reactions reported in excess (> 0.5%) of placebo and as more than an isolated case in patients receiving Pioglitazone in double-blind studies are listed below as MedDRA preferred term by system organ class and absolute frequency. Frequencies are defined as: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to< 1/1,000); very rare (< 1/10,000); not known (cannot be estimated from the available data). Within each system organ class, adverse reactions are presented in order of decreasing incidence followed by decreasing seriousness.

Adverse reaction	Frequency of adverse reactions of Pioglitazone by treatment regimen				
	Mono therapy	Combination			
		with Metformin	with Sulphonyl urea	with Metformin and Sulphonyl urea	with Insulin
Infections and infestations					
upper respiratory tract infection	common	common	common	common	common
bronchitis					common
sinusitis	uncommon	uncommon	uncommon	uncommon	uncommon
Neoplasms benign, malignant and unspecified (including cysts and polyps)					
bladder cancer	uncommon	uncommon	uncommon	uncommon	uncommon
Blood and lymphatic system disorders					
anemia		common			
Immune System Disorders					
hypersensitivity and allergic reactions	not known	not known	not known	not known	not known
Metabolism and nutrition disorders					
hypoglycemia			uncommon	very common	common
appetite increased			uncommon		
Nervous system disorders					
hypo-aesthesia	common	common	common	common	common
headache		common	uncommon		
dizziness			common		
insomnia	uncommon	uncommon	uncommon	uncommon	uncommon
Eye disorders					
visual disturbance	common	common	uncommon		
macular edema	not known	not known	not known	not known	not known
Ear and labyrinth disorders					
vertigo			uncommon		
Cardiac disorders					
heart failure					common
Respiratory, thoracic and mediastinal disorders					
dyspnea					common
Gastrointestinal disorders					
flatulence		uncommon	common		
Skin and subcutaneous tissue disorders					
sweating			uncommon		
Musculoskeletal and connective tissue disorders					
fracture bone	common	common	common	common	common
arthralgia		common		common	common
back pain					common
Renal and urinary disorders					
hematuria		common			
glycosuria			uncommon		
proteinuria			uncommon		
Reproductive system and breast disorders					
erectile dysfunction		common			
General disorders and administration site conditions					
edema					very common
fatigue			uncommon		
Investigations					
weight increased	common	common	common	common	common
blood creatine phosphokinase increased				common	
increased lactic dehydrogenase			uncommon		
alanine aminotransferase increased	not known	not known	not known	not known	not known

Description of selected adverse reactions

Post-marketing reports of hypersensitivity reactions in patients treated with Pioglitazone have been reported. These reactions include anaphylaxis, angioedema, and urticaria.

Visual disturbance has been reported mainly early in treatment and is related to changes in blood glucose due to temporary alteration in the turgidity and refractive index of the lens as seen with other hypoglycemic treatments.

Edema was reported in 6–9% of patients treated with Pioglitazone over one year in controlled clinical trials. The edema rates for comparator groups (sulphonylurea, metformin) were 2–5%. The reports of edema were generally mild to moderate and usually did not require discontinuation of treatment.

In controlled clinical trials the incidence of reports of heart failure with Pioglitazone treatment was the same as in placebo, metformin and sulphonylurea treatment groups, but was increased when used in combination therapy with insulin. In an outcome study of patients with pre-existing major macrovascular disease, the incidence of serious heart failure was 1.6% higher with Pioglitazone than with placebo, when added to therapy that included insulin. However, this did not lead to an increase in mortality in this study. In this study in patients receiving Pioglitazone and insulin, a higher percentage of patients with heart failure were observed in patients aged ≥65 years compared with those less than 65 years (9.7% compared to 4.0%). In patients on insulin with no Pioglitazone the incidence of heart failure was 8.2% in those ≥65 years compared to 4.0% in patients less than 65 years. Heart failure has been reported with marketing use of Pioglitazone, and more frequently when Pioglitazone was used in combination with insulin or in patients with a history of cardiac failure.

A pooled analysis was conducted of adverse reactions of bone fractures from randomized, comparator controlled, double blind clinical trials in over 8100 patients in the Pioglitazone-treated groups and 7400 in the comparator-treated groups of up to 3.5 years duration. A higher rate of fractures was observed in women taking Pioglitazone (2.6%) versus comparator (1.7%). No increase in fracture rates was observed in men treated with Pioglitazone (1.3%) versus comparator (1.5%).

In the 3.5 year PROactive study, 44/870 (5.1%) of Pioglitazone-treated female patients experienced fractures compared to 23/905 (2.5%) of female patients treated with comparator. No increase in fracture rates was observed in men treated with Pioglitazone (1.7%) versus comparator (2.1%).

In active comparator controlled trials mean weight increase with Pioglitazone given as monotherapy was 2–3 kg over one year. This is similar to that seen in a sulphonylurea active comparator group. In combination trials Pioglitazone added to metformin resulted in mean weight increase over one year of 1.5 kg and added to a sulphonylurea of 2.8 kg. In comparator groups addition of sulphonylurea to metformin resulted in a mean weight gain of 1.3 kg and addition of metformin to a sulphonylurea a mean weight loss of 1.0 kg.

[7] In clinical trials with Pioglitazone the incidence of elevations of ALT greater than three times the upper limit of normal was equal to placebo but less than that seen in metformin or sulphonylurea comparator groups. Mean levels of liver enzymes decreased with treatment with Pioglitazone. Rare cases of elevated liver enzymes and hepatocellular dysfunction have occurred in post-marketing experience. Although in very rare cases fatal outcome has been reported, causal relationship has not been established

OVERDOSE AND TREATMENT

No data are available with regard to overdose of the combination.

In clinical studies, patients have taken Pioglitazone at higher than the recommended highest dose of 45 mg daily. The maximum reported dose of 120 mg/day for four days, then 180 mg/day for seven days was not associated with any symptoms. Hypoglycemia may occur in combination with sulphonylureas or insulin. Symptomatic and general supportive measures should be taken in case of overdose.

CAUTION

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without a prescription.

STORE AT TEMPERATURES NOT EXCEEDING 30°C

AVAILABILITY

Teneligliptin + Pioglitazone hydrochloride (TENELIZONE®) 20mg/15mg Film-Coated Tablet X 30 tablets / box / Alu-alu blister pack

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FOR SUSPECTED ADVERSE DRUG REACTION, REPORT TO THE FDA: www.fda.gov.ph

Seek medical attention immediately at the first sign of any adverse drug reaction.

TENELIZONE® is a registered trademark of Ajanta Pharma Philippines, Inc.

REGISTRATION NUMBER

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Tenelizone® 20mg/15mg: DR-XY47500

DATE OF FIRST AUTHORIZATION

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DATE OF REVISION OF PACKAGE INSERT

Tenelizone®: 0

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