TELDAY

(USP Specifications)
Telmisartan
40mg **& 80**mg film coated tablets
(USP Specifications)

COMPOSITION
TELDAY 40mg tablets:
Each film coated tablet contains...40 mg Telmisartan (USP Specifications)
TELDAY 80mg tablets:
Each film coated tablet contains...80 mg Telmisartan (USP Specifications)

DESCRIPTION
TELDAY (Telmisartan) is non-peptide angiotensin II receptor blocker (ARB) antagonists.

MECHANISM OF ACTION
Angiotensin II is formed from angiotensin I in a reaction catalyzed by angiotensin-converting enzyme (ACE, kininase II). Angiotensin II is the principal pressor agent of the renin- angiotensin system, with effects that include vasoconstriction, stimulation of synthesis and release of aldosterone, cardiac stimulation, and renal reabsorption of sodium. Telmisartan blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT, receptor in many tissues, such as vascular smooth muscle and the adrenal gland. Its action is therefore independent of the pathways for angiotensin II synthesis. Telmisartan has much greater affinity (>3,000 fold) for the AT, receptor than for the AT, receptor. Blockade of the renin-angiotensin system with ACE inhibitors, which inhibit the biosynthesis of angiotensin II from angiotensin I, is widely used in the treatment of hypertension. ACE inhibitors also inhibit the degradation of bradykinin, a reaction also catalyzed by ACE. Because Telmisartan does not inhibit ACE (kininase II), it does not affect the response to bradykinin. Blockade of the angiotensin II receptor inhibits the negative regulatory feedback of angiotensin II on renin secretion, but the resulting increased plasma renin activity and angiotensin II circulating levels do not overcome the effect of Telmisartan on blood pressure.

PHARMACOKINETICS
Telmisartan is rapidly absorbed from the gastrointestinal tract. The absolute bioavailability is dose dependent and is about 42% after a 40mg dose and 58% after a 160 mg dose. Peak plasma concentration of Telmisartan reached about 0.5 to 1 hour after an oral dose. Telmisartan is over 99% bound to plasma proteins. It is excreted almost entirely in the faeces via bile, mainly as unchanged drug. The terminal elimination half-life is about 24 hours.

INDICATIONS AND USAGE
Telmisartan tablet is indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. It may be used alone or in combination with other antihypertensive agents. Telmisartan is indicated for reduction of the risk of myocardial infarction, stroke, or death from cardiovascular causes in patients 55 years of age or older at high risk of developing major cardiovascular events who are unable to take ACE inhibitors. It can be used in addition to other needed treatment (such as antihypertensive, antiplatelet or lipid-lowering therapy). Use of Telmisartan with an ACE inhibitor is not recommended.

DOSAGE AND ADMINISTRATION
Dosage must be individualized. In hypertension the usual starting dose of Telmisartan tablets is 40 mg once a day. Blood pressure response is dose-related over the range of 20mg to 80mg. Most of the antihypertensive effect is apparent within 2 weeks and maximal reduction is generally attained after 4 weeks. When additional blood pressure, reduction beyond that achieved with 80 mg Telmisartan is required, a calcium channel blocker or diuretic may be added. No initial dosage adjustment is necessary for elderly patients or patients with renal impairment, including those on hemodialysis. Patients on dialysis may develop orthostatic hypotension; their blood pressure should be closely monitored. It may be administered with other antihypertensive agents. It may be administered with or without food. In cardiovascular risk reduction, the recommended dose of Telmisartan tablets is 80 mg once a day and can be administered with or without food. When initiating Telmisartan therapy for cardiovascular risk reduction, monitoring of blood pressure is recommended, and if appropriate, adjustment of medications that lower blood pressure may be necessary.

ADVERSE REACTIONS
The reported adverse events of the Telmisartan are upper respiratory tract infection, back pain, sinusitis, diarrhea, pharyngitis, influenza-like symptoms, dyspepsia, myalgia, urinary tract infection, abdominal pain, headache, dizziness, pain, fatigue, hypertension, chest pain, nausea, cough, peripheral edema, impotence, increased sweating, flushing., allergy, fever, leg pain,malaise,palpitation, dependent edema,mangina pectoris, tachycardia, leg edema, abnormal ECG, insomnia, somnolence, migraine, vertigo, paraesthesia, involuntary muscle contractions, hypoesthesia, flatulence, constipation, gastritis, vomiting, dry mouth, haemorrhoids, gastroenteritis, enteritis, gastroesophageal reflux, toothache, nonspecific gastrointestinal disorders, gout, hypercholesterolemia, diabetes mellitus, arthritis, arthralgia, leg cramps, anxiety, depression, nervousness, infection, fungal infection, abscess, otitis media, asthma, bronchitis, rhinitis, dyspnea, epistaxis, dermatitis, rash, eczema, pruritus, micturition frequency, cystitis, cerebrovascular disorder, abnormal vision, conjunctivitis, tinnitus and earache. The additional reported events of Telmisartan are: asthenia, edema, face edema, lower limb edema, angioneurotic edema, urticaria, hypersensitivity, sweating increased, erythema, chest pain, atrial fibrillation, congestive heart failure, myocardial infarction, blood pressure increased, hypertension aggravated. hypotension (including postural hypotension), hyperkalemia, syncope, urinary tract infection, erectile dysfunction, muscle cramps, bradycardia, eosinophilia, thrombocytopenia, uric acid increased, abnormal hepatic function/liver disorder, renal impairment, including acute renal failure, anemia, and increased CPK, anaphylactic reaction, tendon pain (including tendonitis, tenosynovitis), drug eruption (e.g., toxic skin eruption mostly reported as toxic oedema, rash, and urticaria), hypoglycaemia (in diabetic patients), angioedema (with fatal outcome), decrease in hemoglobin, increase creatinine, intermittent claudication and skin ulcer. In rare cases of rhabdomyolysis have been reported in patients receiving angiotensin II receptor blockers, including Telmisartan and occasional elevations of liver chemistries occurred in patients treated with Telmisartan.

DRUG INTERACTIONS
Aliskiren:
Do not co-administer aliskiren with Telmisartan in patients with diabetes. Avoid use of aliskiren with Telmisartan in patients with renal impairment (GFR < 60 ml/min).
Digoxin:
Monitor digoxin levels when initiating, adjusting, and discontinuing Telmisartan for the purpose of keeping the digoxin level within the therapeutic range.
Lithium:
Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with angiotensin II receptor antagonists including Telmisartan. Therefore, monitor serum lithium levels during concomitant use.
Non-Steroidal Anti-inflammatory Agents including Selective
Cyclooxygenase-2 Inhibitors (COX-2 Inhibitors): In patients who are elderly, volume-depleted (including those on diuretic therapy), or with compromised renal function, co-administration of NSAIDs, including selective COX-2 inhibitors, with angiotensin II receptor antagonists, including Telmisartan, may result in deterioration of renal function, including possible acute renal failure. These effects are usually reversible. Monitor renal function periodically in patients receiving Telmisartan and NSAID therapy. The antihypertensive effect of angiotensin II receptor antagonists, including Telmisartan may be attenuated by NSAIDS including selective COX-2 inhibitors.
Ramipril and Ramiprilat:
Co-administration of telmisartan and ramipril is not recommended. When co-administering telmisartan and ramipril, the response may be greater because of the possibly additive pharmacodynamic effects of the combined drugs, and also because of the increased exposure to ramipril and ramiprilat in the presence of telmisartan.
Other Drugs:
Co-administration of telmisartan did not result in a clinically significant interaction with acetaminophen, amlodipine, glyburide, simvastatin, hydrochlorothiazide, warfarin, or ibuprofen. Telmisartan is not metabolized by the cytochrome P450 system and had no effects in vitro on cytochrome P450 enzymes, except for some inhibition of CYP2C19. Telmisartan is not expected to interact with drugs that inhibit cytochrome P450 enzymes; it is also not expected to interact with drugs metabolized by cytochrome P450 enzymes, except for possible inhibition of the metabolism of drugs metabolized by CYP2C19.
Drug Interactions with Amlodipine
Amlodipine has been safely administered with thiazide diuretics, beta- blockers, enzyme inhibitors, long-acting nitrates, angiotensin-converting sublingual nitro-glycerine, digoxin, warfarin, non-steroidal anti- inflammatory drugs, antibiotics, and oral hypoglycemic drugs.
Simvastatin:
Limit the dose of simvastatin in patients on amlodipine to 20 mg daily.
Immunosuppressants:
Amlodipine may increase the systemic sure of cyclosporine or tacrolimus when co-administered. Frequent exposure monitoring of trough blood levels of cyclosporine and tacrolimus s recommended and adjust the dose when appropriate. The following have no clinically relevant effects on the pharmacokinetics of amlodipine: cimetidine, grapefruit juice, magnesium and aluminium hydroxide antacid, sildenafil. Hydroxide Amlodipine has no clinically relevant effects on the pharmacokinetics or pharmacodynamics of the following: atorvastatin, digoxin, warfarin.
CYP3A4 inhibitors:
Strong inhibitors of CYP3A4 (e.g., ketoconazole,
Anti-Viral:
itraconazole, ritonavir) may increase the plasma concentrations of amlodipine to a greater extent. Monitor for symptoms of hypotension and edema when amlodipine is co-administered with CYP3A4 inhibitors.
CYP3A4 Inducers:
Patients should be monitored for adequate clinical effect when amlodipine is co-administered with CYP3A4 inducers.

CONTRAINDICATIONS
It is contraindicated in patients with known hypersensitivity (e.g... anaphylaxis or angioedema) to Telmisartan, or any other component of this product.

USE IN SPECIFIC POPULATIONS
Pregnancy
Pregnancy Category D
Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. Resulting oligohydramnios can be associated with fetal lung hypoplasia and skeletal deformations. Potential neonatal adverse effects include skull hypoplasia, anuria, hypotension, renal failure, and death. When pregnancy is detected, discontinue Telmisartan as soon as possible. These adverse outcomes are usually associated with use of these drugs in the second and third trimester of pregnancy. In the unusual case that there is no appropriate alternative to therapy with drugs affecting the renin-angiotensin system for a particular patient, apprise the mother of the potential risk to the fetus. Perform serial ultrasound examinations to assess the intra-amniotic environment. If oligohydramnios is observed, discontinue Telmisartan, unless it is considered lifesaving for the mother. Fetal testing may be appropriate, based on the week of pregnancy. Patients and physicians should be aware, however, that oligohydramnios may not appear until after the fetus has sustained irreversible injury. Closely observe infants with histories of in utero exposure to Telmisartan for hypotension, oliguria, and hyperkalemia.
Nursing Mothers
Because of the potential for adverse effects on the nursing infant, decide whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother. It is not known whether Telmisartan is excreted in human milk.
Pediatric Use
Safety and effectiveness of Telmisartan in pediatric patients have not been established. If oliguria or hypotension occurs, direct attention toward support of blood pressure and renal perfusion. Exchange transfusions or dialysis may be required as a means of reversing hypotension and/or substituting for disordered renal function.
Geriatric Use
In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.
Hepatic Insufficiency
Monitor carefully and up-titrate slowly in patients with biliary obstructive disorders or hepatic insufficiency since patients with hepatic impairment have decreased clearance of amlodipine.

WARNINGS AND PRECAUTIONS
Fetal Toxicity
Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. Resulting oligohydramnios can be associated with fetal lung

anuria, hypotension, renal failure, and death. When pregnancy is detected discontinue Telmisartan as soon as possible.

Hypotension

In patients with an activated renin-angiotensin system, such as volume- or salt-depleted patients (e.g., those being treated with high doses of diuretics), symptomatic hypotension may occur after initiation of therapy with Telmisartan tablets. Either correct this condition prior to administration of Telmisartan, or start treatment under close medical supervision with a reduced dose. If hypotension does occur, the patient should be placed in the supine position and, if necessary, given an intravenous infusion of normal saline. A transient hypotensive response is not a contraindication to further treatment, which usually can be continued without difficulty once the blood pressure has stabilized.

Hyperkalemia

Hyperkalemia may occur in patients on ARBS, particularly in patients with advanced renal impairment, heart failure, on renal replacement therapy, or on potassium supplements, potassium- sparing diuretics, potassium-containing salt substitutes or other drugs that increase potassium levels. Consider periodic determinations of serum electrolytes to detect possible electrolyte imbalances, particularly in patients at risk.

Impaired Hepatic Function

Caution should be exercised in hepatic impairment patients. Titrate slowly in hepatic impairment patients. As the majority of Telmisartan is eliminated by biliary excretion, patients with biliary obstructive disorders or hepatic insufficiency can be expected to have reduced clearance.

Impaired Renal Function

Caution should be exercised in renal impairment patients. As a consequence of inhibiting the renin-angiotensin-aldosteron system, anticipate changes in renal function in susceptible individuals. In patients whose renal function may depend on the. activity of the renin-angiotensin-aldosterone system (e.g., patients with severe congestive heart failure or renal dysfunction), treatment with angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor antagonists has been associated with oliguria and/or progressive azotaemia and (rarely) with acute renal failure and/or death.

Dual Blockade of the Renin-Angiotensin-Aldosterone System

Dual blockade of the RAS with angiotensin-receptor blockers, ACE inhibitors, or aliskiren is associated with increased risks of hypotension, hyperkalemia, and changes in renal function (including acute renal failure) compared to monotherapy. In general, avoid combined use of RAS inhibitors. Closely monitor blood pressure, renal function and electrolytes in patients on Telmisartan and other agents that affect the RAS.

Diabetics

Do not co-administer aliskiren with Telmisartan in patients with diabetes. Do not co-administer aliskiren with Telmisartan in patients with diabetes. Avoid concomitant use of aliskiren with Telmisartan in patients with renal impairment (GFR < 60 ml/min/1.73 m^2).

OVERDOSAGE

The most likely manifestations of overdosage with Telmisartan tablets would be hypotension, dizziness, and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation. If symptomatic hypotension should occur, supportive treatment should be instituted. Telmisartan is not removed by hemodialysis.

DOSAGE & INSTRUCTIONS:

Use as directed by the physician. For details, see enclosed leaflet.To be sold on the prescription of a registered medical practitioner only. Keep all medicines out of the reach of children. Store at 20°C-25°C. Protect from light and moisture.
(excursions permitted to 15°C-30°C).

PACK SIZE

TELDAY 40mg film coated tablets: Alu. Alu. blister Pack of 14's & 28's
TELDAY 80mg film coated tablets: Alu. Alu. blister Pack of 14's & 28's

Lactose & Gluten Free

NEXT PHARMACEUTICAL
Manufactured by:
NEXT Pharmaceutical Products (Pvt.) Ltd.
Plot no. 44-A&B, Sunder Industrial Estate Lahore-Pakistan

ٹیل ڈے

(ٹیلمیسارٹن)

40 ملی گرام اور 80 ملی گرام فلم کوٹڈ گولیاں

خوراک و ہدایات:

ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت کی جائے۔

تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

دوا کو 25°C-20°C درجہ حرارت پر نمی اور روشنی سے محفوظ رکھیں۔

(درجہ حرارت کی حد 15°C سے 30°C ہے۔)