

1.6.3 Patient Information Leaflet (PIL)

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<div style="text-align: center;"> <h1 style="margin: 0;">T-SAR</h1> <h2 style="margin: 0;">Telmisartan Tablet</h2> </div> <p>COMPOSITION: T-SAR Tablet 20mg: Each tablet contains: Telmisartan EP 20 mg (CCL Pharmaceuticals Specifications)</p> <p>T-SAR Tablet 40mg: Each tablet contains: Telmisartan EP 40 mg (CCL Pharmaceuticals Specifications)</p> <p>T-SAR Tablet 80mg: Each tablet contains: Telmisartan EP 80 mg (CCL Pharmaceuticals Specifications)</p> <p>DRUG DESCRIPTION AND MECHANISM OF ACTION: Telmisartan is a member of a family of drugs called angiotensin receptor blockers (ARBs), which includes losartan, valsartan, eprosartan, and candesartan. ARBs block the ability of the chemical angiotensin II to constrict or squeeze arteries and veins. As a result, the arteries and veins enlarge and blood pressure falls. The reduced pressure in the arteries also makes it easier for the heart to pump blood.</p> <p>Pharmacokinetics: Following oral administration, peak concentrations (C_{max}) of Telmisartan are reached in 0.5-1 hour after dosing. Food slightly reduces the bioavailability of Telmisartan. The absolute bioavailability of Telmisartan is dose dependent. The pharmacokinetics of orally administered Telmisartan are nonlinear over the dose range 20-160 mg, with greater than proportional increases of plasma concentrations (C_{max} and AUC) with increasing doses. Telmisartan shows bi-exponential decay kinetics with a terminal elimination half-life of approximately 24 hours.</p> <p>Distribution: Telmisartan is highly bound to plasma proteins (> 99.5%), mainly albumin and α₁-acid glycoprotein. Plasma protein binding is constant over the concentration range achieved with recommended doses. The volume of distribution for Telmisartan is approximately 500 liters indicating additional tissue binding.</p> <p>Metabolism and excretion: Most of the administered dose (> 87%) was eliminated unchanged in urine via biliary excretion, only minute amounts were found in the urine (0.31% and 0.49% of administered dose, respectively). Telmisartan is metabolized by conjugation to form a pharmacologically inactive acyl glucuronide; the glucuronide of the parent compound is the only metabolite that has been identified in human plasma and urine. After a single dose, the glucuronide represents approximately 11% of the measured radioactivity in plasma. The cytochrome P450 isoenzymes are not involved in the metabolism of Telmisartan.</p> <p>Total plasma clearance of Telmisartan is > 800 ml/min. Terminal half-life and total clearance appears to be independent of dose.</p> <p>Special Populations: Renal Insufficiency: No dosage adjustment is necessary in patients with decreased renal function. Telmisartan is not removed from blood by hemodialysis. Hepatic Insufficiency: In patients with hepatic insufficiency, plasma concentrations of Telmisartan is increased, and absolute bioavailability approaches 100%. Gender: Plasma concentrations of Telmisartan are generally 2-3 times higher in females than in males. No dosage adjustment is necessary. Geriatric Patients: The pharmacokinetics of Telmisartan do not differ between the elderly and those younger than 65 years. Pediatric Patients: Telmisartan pharmacokinetics have not been investigated in patients < 18 years of age.</p> <p>INDICATIONS: Telmisartan is used for the treatment of hypertension (high blood pressure). It also is used for reducing the risk of heart attack, 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.</p> <p>DOSEAGE: Hypertension: Dosage must be individualized. The usual starting dose of Telmisartan is 40 mg once a day. Blood pressure response is dose related over the range of 20-80 mg. 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 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. T-SAR tablets may be administered with other antihypertensive agents. T-SAR tablets may be administered with or without food.</p> <p>Cardiovascular Risk Reduction: The recommended dose of Telmisartan is 80 mg once a day and can be administered with or without food. It is not known whether doses lower than 80 mg of Telmisartan are effective in reducing the risk of cardiovascular morbidity and mortality. 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.</p> <p>CONTRAINDICATIONS: None.</p>	<p>SIDE EFFECTS: Like other angiotensin-receptor blockers, Telmisartan generally is well tolerated. The most common side effects have been headache, light-headedness, blurred vision, dizziness, back pain, fatigue, and diarrhea, fainting, decreased sexual ability, muscle pain/tenderness/weakness, unusual tiredness, change in the amount of urine, easy bruising/bleeding, yellowing eyes/skin, dark urine, persistent nausea/vomiting. An allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of an allergic reaction include rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. The incidence of adverse events was not dose related and did not correlate with gender, age, or race of patients.</p> <p>WARNINGS: This drug can cause serious (possibly fatal) harm to an unborn baby if used during pregnancy. Therefore, it is important to prevent pregnancy while taking this medication. Consult your doctor for more details and to discuss the use of reliable forms of birth control while taking this medication. If you are planning pregnancy, become pregnant, or think you may be pregnant, contact your doctor immediately.</p> <p>Pregnancy: Medications which interfere with the angiotensin converting enzyme system, such as Telmisartan, have been found to cause fetal and neonatal toxicity and death when taken by pregnant women. Pregnant women should discontinue use of Telmisartan as soon as they know they are pregnant.</p> <p>Nursing mother: It is not known if Telmisartan is excreted into breast milk. Since most medicines are secreted into breast milk, potential risks and benefits need to be addressed in women who are nursing to determine if breast feeding or Telmisartan needs to be discontinued.</p> <p>HOW TO USE: Take this medication by mouth, usually once daily or as directed by your doctor. You may take this drug with or without food. Use this medication regularly in order to get the most benefit from it. To help you remember, use it at the same time each day. Do not take potassium supplements or salt substitutes containing potassium without talking to your doctor or pharmacist first. This medicine can raise your potassium levels, which rarely can cause serious side effects such as muscle weakness or very slow heartbeats. Tell your doctor immediately if these effects occur. The dosage is based on your medical condition and response to therapy. For the treatment of high blood pressure, it may take 4 weeks before the full benefit of this drug occurs. It is important to continue taking this medication even if you feel well. Most people with high blood pressure do not feel sick.</p> <p>DRUG INTERACTIONS: Your healthcare professional (e.g., doctor or pharmacist) may already be aware of any possible drug interactions and may be monitoring you for it. Do not start, stop or change the dosage of any medicine before checking with them first. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially all diuretics, nitrates, potassium-sparing "water pills" (diuretics such as amiloride, spironolactone, triamterene). Check the labels on all your medicines (e.g., cough and cold products, diet aids, nonsteroidal anti-inflammatory drugs - NSAIDs such as ibuprofen and naproxen for pain/fever reduction) because they may contain ingredients that could increase your blood pressure. Ask your pharmacist about the safe use of these products. Low-dose aspirin, as prescribed by your doctor for specific medical reasons such as heart attack or stroke prevention (usually at dosages of 81-325mg per day), should be continued. Consult your doctor or pharmacist for more details.</p> <p>OVERDOSAGE: If over-dose is suspected, contact your local poison control center or emergency room immediately. Note: Do not share this medication with others. Lifestyle changes such as stress reduction programmes, exercise and dietary changes may increase the effectiveness of this medicine. Talk to your doctor or pharmacist about lifestyle changes that might benefit you. Laboratory and/or medical tests (e.g., kidney function, potassium blood level) should be performed periodically to monitor your progress or check for side effects. Consult your doctor for more details. Have your blood pressure checked regularly while taking this medication. Learn how to monitor your own blood pressure at home. Discuss this with your doctor.</p> <p>Missed Dose: If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.</p> <p>INSTRUCTIONS: - Store below 30°C. - Protect from heat, sunlight & moisture. - Keep out of the reach of children. - To be sold on the prescription of a registered medical practitioner only.</p> <p>PRESENTATION:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">T-SAR Tablet 20 mg</td> <td style="width: 50%;">Pack of 1x10 tablets</td> </tr> <tr> <td>T-SAR Tablet 20 mg</td> <td>Pack of 3x10 tablets</td> </tr> <tr> <td>T-SAR Tablet 40 mg</td> <td>Pack of 10x10 tablets</td> </tr> <tr> <td>T-SAR Tablet 40 mg</td> <td>Pack of 1x10 tablets</td> </tr> <tr> <td>T-SAR Tablet 40 mg</td> <td>Pack of 3x10 tablets</td> </tr> <tr> <td>T-SAR Tablet 40 mg</td> <td>Pack of 10x10 tablets</td> </tr> <tr> <td>T-SAR Tablet 80 mg</td> <td>Pack of 1x10 tablets</td> </tr> <tr> <td>T-SAR Tablet 80 mg</td> <td>Pack of 3x10 tablets</td> </tr> <tr> <td>T-SAR Tablet 80 mg</td> <td>Pack of 10x10 tablets</td> </tr> </table> <p>For further information please contact:</p> <div style="display: flex; align-items: center;"> <div style="font-size: 8px;"> Manufactured by: CCL Pharmaceuticals (Pvt.) Ltd. 62 Industrial Estate, 4th Lakhpat, Lahore, Pakistan. </div> <div style="margin-left: 20px; text-align: right; font-size: 8px;"> 2020 32007 0010 661 0000-0000 </div> </div>	T-SAR Tablet 20 mg	Pack of 1x10 tablets	T-SAR Tablet 20 mg	Pack of 3x10 tablets	T-SAR Tablet 40 mg	Pack of 10x10 tablets	T-SAR Tablet 40 mg	Pack of 1x10 tablets	T-SAR Tablet 40 mg	Pack of 3x10 tablets	T-SAR Tablet 40 mg	Pack of 10x10 tablets	T-SAR Tablet 80 mg	Pack of 1x10 tablets	T-SAR Tablet 80 mg	Pack of 3x10 tablets	T-SAR Tablet 80 mg	Pack of 10x10 tablets
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