MEDIOCARD TABLETS

CHEMICAL COMPOSITION: Each tablet contains 80 mg telmisartan.
Excipients: Magnesium stearate, Sorbitol ,Sodium hydroxide,Microcrystalline cellulose(MCC),Cross carmellose sodium, Povidon ,Starch .

Warnings box:
The use of angiotensin II receptor antagonists is not recommended during the first trimester of pregnancy .
The use of angiotensin II receptor antagonists is contraindicated during the second and third trimesters of pregnancy (see sections: Warnings and Pregnancy).

PHARMACOLOGICAL CLASSIFICATION : Antihypertensive drugs.
PHARMACODYNAMIC EFFECTS:
Mechanism of action:
Telmisartan is an orally active and specific angiotensin II receptor (type AT1) antagonist. Telmisartan displaces angiotensin II with very high affinity from its binding site at the AT1 receptor subtype, which is responsible for the known actions of angiotensin II.
In human, an 80 mg dose of telmisartan almost completely inhibits the angiotensin II evoked blood pressure increase. The inhibitory effect is maintained over 24 hours and still measurable up to 48 hours.
PHARMACOKINETICS:
Absorption: Absorption of telmisartan is rapid although the amount absorbed varies. The mean absolute bioavailability for telmisartan is about 50 %.
Distribution: Telmisartan is largely bound to plasma protein (>99.5 %)
Metabolism: Telmisartan is metabolised by conjugation to the glucuronide of the parent compound.
Elimination: terminal elimination half-life of >20 hours. After oral (and intravenous) administration telmisartan is nearly exclusively excreted with the faeces, mainly as unchanged compound. Cumulative urinary excretion is <1 % of dose. Total plasma clearance (Cltot) is high (approximately 1,000 ml/min) compared with hepatic blood flow (about 1,500 ml/min).
Special populations:
Gender: Differences in plasma concentrations were observed, with Cmax and AUC being approximately 3- and 2-fold higher, respectively, in females compared to males.
Elderly: The pharmacokinetics of telmisartan do not differ between the elderly and those younger than 65 years.
Renal impairment: In patients with mild to moderate and severe renal impairment, doubling of plasma concentrations was observed. However, lower plasma concentrations were observed in patients with renal insufficiency undergoing dialysis. Telmisartan is highly bound to plasma protein in renal-insufficient patients and cannot be removed by dialysis. The elimination half-life is not changed in patients with renal impairment.
Hepatic impairment: Pharmacokinetic studies in patients with hepatic impairment showed an increase in absolute bioavailability up to nearly 100 %.
INDICATIONS:
Hypertension: Treatment of essential hypertension in adults.
Cardiovascular prevention: Reduction of cardiovascular morbidity in adults with:
• manifest atherothrombotic cardiovascular disease (history of coronary heart disease, stroke, or peripheral arterial disease)
• type 2 diabetes mellitus with documented target organ damage.
CONTRAINDICATIONS:
• Hypersensitivity to the active substance or to any of the excipients.
• Second and third trimesters of pregnancy .
• Biliary obstructive disorders
• Severe hepatic impairment
The concomitant use of Telmisartan with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m2).
ADVERSE EFFECTS:
Uncommon: Urinary tract infection including cystitis, upper respiratory tract infection including pharyngitis and sinusitis, Anaemia, Hyperkalaemia, Insomnia, depression, Syncope, Vertigo, Bradycardia, Hypotension , orthostatic hypotension, Dyspnoea, cough, Abdominal pain, diarrhoea, dyspepsia, flatulence, vomiting, Pruritus, hyperhidrosis, rash, Back pain (e.g. sciatica), muscle spasms, myalgia, Renal impairment including acute renal failure, Chest pain, asthenia (weakness), Blood creatinine increased.
EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
It should be taken into account that dizziness or drowsiness may occasionally occur when taking Telmisartan .
WARNINGS AND PRECAUTIONS:
Pregnancy:
Angiotensin II receptor antagonists should not be initiated during pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started
Hepatic impairment:
Telmisartan is not to be given to patients with cholestasis, biliary obstructive disorders or severe hepatic impairment. Telmisartan should be used only with caution in patients with mild to moderate hepatic impairment.
Renovascular hypertension:
There is an increased risk of severe hypotension and renal insufficiency when patients with bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney are treated with medicinal products that affect the reninangiotensin-aldosterone system.
Renal impairment and kidney transplantation:
When Telmisartan is used in patients with impaired renal function, periodic monitoring of potassium and creatinine serum levels is recommended. There is no experience regarding the administration of Telmisartan in patients with recent kidney transplantation.
Intravascular hypovolaemia:
Symptomatic hypotension, especially after the first dose of Telmisartan , may occur in patients who are volume and/or sodium depleted by vigorous diuretic therapy, dietary salt restriction, diarrhoea, or vomiting. Volume and/or sodium depletion should be corrected prior to administration of Telmisartan .
Dual blockade of the renin-angiotensin-aldosterone system (RAAS):
The concomitant use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren is not recommended because it increases the risk of hypotension, hyperkalaemia and decreased renal function (including acute renal failure). If dual blockade therapy is considered absolutely necessary, this should only occur under specialist supervision and subject to frequent close monitoring of renal function, electrolytes and blood pressure.
ACE-inhibitors and angiotensin II receptor blockers should not be used concomitantly in patients with diabetic nephropathy.
Other conditions with stimulation of the renin-angiotensin-aldosterone system:
In patients whose vascular tone and renal function depend predominantly on the activity of the renin-angiotensin aldosterone system (e.g. patients with severe congestive heart failure or underlying renal disease, including renal artery stenosis), treatment with telmisartan has been associated with acute hypotension, hyperazotaemia, oliguria, or rarely acute renal failure.
Primary aldosteronism:
Patients with primary aldosteronism generally will not respond to antihypertensive medicinal products acting through inhibition of the renin-angiotensin system. Therefore, the use of telmisartan is not recommended.
Aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy:
As with other vasodilators, special caution is indicated in patients suffering from aortic or mitral stenosis, or obstructive hypertrophic cardiomyopathy.
Diabetic patients treated with insulin or antidiabetics:
In these patients hypoglycaemia may occur under telmisartan treatment. Therefore, in these patients an appropriate blood glucose monitoring should be considered; a dose adjustment of insulin or antidiabetics may be required, when indicated.
Hyperkalaemia:
The use of medicinal products that affect the renin-angiotensin-aldosterone system may cause hyperkalaemia.
The main risk factors for hyperkalaemia to be considered are:
- Diabetes mellitus, renal impairment, age (>70 years)
- Combination with one or more other medicinal products that affect the renin-angiotensin-aldosterone system and/or potassium supplements.
- Intercurrent events, in particular dehydratation, acute cardiac decompensation, metabolic acidosis, worsening of renal function, sudden worsening of the renal condition (e.g. infectious diseases), cellular lysis (e.g. acute limb ischemia, rhabdomyolysis, extend trauma).
Close monitoring of serum potassium in at risk patients is recommended.
Sorbitol:
This medicinal product contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take it .
Ethnic differences:
Telmisartan is apparently less effective in lowering blood pressure in black people than in non-blacks, possibly because of higher prevalence of low-renin states in the black hypertensive population.
Other:
As with any antihypertensive agent, excessive reduction of blood pressure in patients with ischaemic cardiopathy or ischaemic cardiovascular disease could result in a myocardial infarction or stroke.
DRUG INTERACTIONS:
Digoxin
When telmisartan was co-administered with digoxin, median increases in digoxin peak plasma concentration and in trough concentration were observed. When initiating, adjusting, and discontinuing telmisartan, monitor digoxin levels in order to maintain levels within the therapeutic range.
Medicinal products that may also provoke hyperkalaemia: Telmisartan may provoke hyperkalaemia. The risk may increase in case of treatment combination with other medicinal products that may also provoke hyperkalaemia (salt substitutes containing potassium, potassium-sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, non steroidal anti-inflammatory medicinal products (NSAIDs, including selective COX-2 inhibitors), heparin, immunosuppressives (cyclosporin or tacrolimus), and trimethoprim).
Concomitant use not recommended:
Potassium sparing diuretics or potassium supplements : such as spirinolactone, eplerenone, triamterene, or amiloride, potassium supplements, or potassium-containing salt substitutes may lead to a significant increase in serum potassium.
Lithium
Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with Telmisartan.
Concomitant use requiring caution:
Non-steroidal anti-inflammatory medicinal products: (i.e. acetylsalicylic acid at anti-inflammatory dosage regimens, COX-2 inhibitors and non-selective NSAIDs) may reduce the antihypertensive effect of angiotensin II receptor antagonists. Therefore, the combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy and periodically thereafter.
Ramipril: the co-administration of telmisartan and ramipril led to an increase the AUC and Cmax of ramipril and ramiprilat.
Diuretics (thiazide or loop diuretics):
Prior treatment with high dose diuretics such as furosemide (loop diuretic) and hydrochlorothiazide (thiazide diuretic) may result in volume depletion and in a risk of hypotension when initiating therapy with telmisartan.
To be taken into account with concomitant use:
Other antihypertensive agents:
The blood pressure lowering effect of telmisartan can be increased by concomitant use of other antihypertensive medicinal products. Furthermore, orthostatic hypotension may be aggravated by alcohol, barbiturates, narcotics or antidepressants.
Corticosteroids (systemic route): Reduction of the antihypertensive effect.
PREGNANCY AND LACTATION:
Pregnancy:
Pregnancy category: 1st trimester : C, 2nd and 3rd trimesters : D.
The use of angiotensin II receptor antagonists is not recommended during the first trimester of pregnancy .
The use of angiotensin II receptor antagonists is contraindicated during the second and third trimesters of pregnancy.
When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started.
Should exposure to angiotensin II receptor antagonists have occurred from the second trimester of pregnancy, ultrasound check of renal function and skull is recommended.
Infants whose mothers have taken angiotensin II receptor antagonists should be closely observed for hypotension.
Lactation:
Telmisartan is not recommended and alternative treatments with better established safety profiles during breast-feeding are preferable, especially while nursing a newborn or preterm infant.
DOSAGE AND ADMINISTRATION:
Method of administration:
Telmisartan tablets are for once-daily oral administration and should be taken with liquid, with or without food.
Tablets should be taken out of the blister shortly before administration due to the hygroscopic property of the tablets.
Treatment of essential hypertension:
The usually effective dose is 40 mg once daily. Some patients may already benefit at a daily dose of 20 mg. In cases where the target blood pressure is not achieved, the dose of telmisartan can be increased to a maximum of 80 mg once daily. It must be borne in mind that the maximum antihypertensive effect is generally attained four to eight weeks after the start of treatment
Cardiovascular prevention:
The recommended dose is 80 mg once daily. When initiating telmisartan therapy for the reduction of cardiovascular morbidity, close monitoring of blood pressure is recommended, and if appropriate adjustment of medications that lower blood pressure may be necessary.
Patients with renal impairment:
A lower starting dose of 20 mg is recommended in patients with severe renal impairment or haemodialysis. No posology adjustment is required for patients with mild to moderate renal impairment.
Patients with hepatic impairment:
Telmisartan is contraindicated in patients with severe hepatic impairment . In patients with mild to moderate hepatic impairment, the posology should not exceed 40 mg once daily.
Elderly patients:
No dose adjustment is necessary for elderly patients.
Pediatric populations:
The safety and efficacy of Telmisartan in children and adolescents aged below 18 years have not been established.
OVERDOSAGE:
Symptoms: Hypotension and tachycardia; bradycardia, dizziness, increase in serum creatinine, and acute renal failure have been reported.
Treatment: Telmisartan is not removed by haemodialysis. The patient should be closely monitored, and the treatment should be symptomatic and supportive. Suggested measures include induction of emesis and / or gastric lavage. Activated charcoal may be useful in the treatment of overdosage.
STORAGE: "Keep at temperature below 25 °c.
"Protect from moisture"
PACKAGE: Carton box contains 3 blisters each one contains 10 tablets .

*** THIS IS A MEDICAMENT ***

- Keep out of reach of children.
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly doctor's prescriptions, the method of use and instructions of the pharmacist who sold the medicament.
- The doctor and pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

(Council of Arab Ministers) **(Union of Arab Pharmacists)**

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