TELMICLAR 80 Telmisartan Tablets USP 80 mg	
Module 1	Administrative Information and Product Information
Section 1.6	Product Information

1.6.3 Patient Information Leaflet (PIL)

Please find enclosed herewith Package Insert.

FRONT

3029687

TELMICLAR

TELMISARTAN TABLETS USP

COMPOSITION

Telmiclar 40 (Telmisartan Tablets USP 40 mg)
Each uncoated tablet contains:

Telmisartan USP	40 mg
Excipients	q.s.

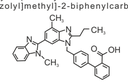
Telmiclar 80 (Telmisartan Tablets USP 80 mg)
Each uncoated tablet contains:

Telmisartan USP	80 mg
Excipients	q.s.

DOSAGE FORM
Oral Tablets

Distribution Category: Prescription Only Medicine or POM

DESCRIPTION
Chemically Telmisartan is [1,1'-Biphenyl]-2-carboxylic acid, 4'-[(1,4'-dimethyl-2'-propyl[2,6'-bi-1H-benzimidazol]-1'-yl)methyl-];4'-[[4-Methyl-6-(1-methyl-2-benzimidazolyl)-2-propyl 1benzimidazolyl]methyl]-2-biphenylcarboxylic acid



EXCIPIENT LIST
Telmiclar 40 (Telmisartan Tablets USP 40 mg)
Lactose Monohydrate (11SD) (Supertab), Crospovidone (Polyplasdone XL 10), Sodium Hydroxide, Meglumine, Povidone (Plasdone K-25), Magnesium Stearate and Purified Water.

Telmiclar 80 (Telmisartan Tablets USP 80 mg)
Lactose Monohydrate (11SD) (Supertab), Crospovidone (Polyplasdone XL 10), Sodium Hydroxide, Meglumine, Povidone (Plasdone K-25), Magnesium Stearate and Purified Water.

CLINICAL PARTICULARS
Therapeutic 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) or
- type 2 diabetes mellitus with documented target organ damage

Posology and method of administration
Posology
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. Alternatively, telmisartan may be used in combination with thiazide-type diuretics such as hydrochlorothiazide, which has been shown to have an additive blood pressure lowering effect with telmisartan. When considering raising the dose, 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. It is not known whether doses lower than 80 mg of telmisartan are effective in reducing cardiovascular morbidity.
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.
Method of administration
Telmisartan tablets are for once-daily oral administration and should be taken with liquid, with or without food.
Precautions to be taken before handling or administering the medicinal product.
Telmisartan should be kept in the sealed blister due to the hygroscopic property of the tablets. Tablets should be taken out of the blister shortly before administration

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 Tablets USP with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m^2).

Special warnings and precautions for use
Pregnancy
Angiotensin II receptor antagonists should not be initiated during pregnancy. Unless continued angiotensin II receptor antagonist therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in 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 Tablets USP is not to be given to patients with cholestasis, biliary obstructive disorders or severe hepatic impairment since telmisartan is mostly eliminated with the bile. These patients can be expected to have reduced hepatic clearance for telmisartan. Telmisartan Tablets USP 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 renin-angiotensin-aldosterone system.
Renal impairment and kidney transplantation
When Telmisartan Tablets USP 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 Tablets USP in patients with recent kidney transplantation.
Intravascular hypovolaemia
Symptomatic hypotension, especially after the first dose of Telmisartan Tablets USP, may occur in patients who are volume and/or sodium depleted by vigorous diuretic therapy, dietary salt restriction, diarrhoea, or vomiting. Such conditions should be corrected before the administration of Telmisartan Tablets USP. Volume and/or sodium depletion should be corrected prior to administration of Telmisartan Tablets USP.
Dual blockade of the renin-angiotensin-aldosterone system (RAAS)
There is evidence that the concomitant use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren increases the risk of hypotension, hyperkalaemia and decreased renal function (including acute renal failure). Dual blockade of RAAS through the combined use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren is therefore not recommended. 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 medicinal products that affect this system such as 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.
In the elderly, in patients with renal insufficiency, in diabetic patients, in patients concomitantly treated with other medicinal products that may increase potassium levels, and/or in patients with inter-current events, hyperkalaemia may be fatal.
Before considering the concomitant use of medicinal products that affect the renin-angiotensin-aldosterone system, the benefit risk ratio should be evaluated.
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. Medicinal products or therapeutic classes of medicinal products that may provoke hyperkalaemia are 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 (cyclosporine or tacrolimus), and trimethoprim.
- Inter current events, in particular dehydration, 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.

Ethnic differences
As observed for angiotensin converting enzyme inhibitors, telmisartan and the other angiotensin II receptor antagonists are 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.
Sodium:
Each tablet contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Interaction with other medicinal products and other forms of interaction
Digoxin
When telmisartan was co-administered with digoxin, median increases in digoxin peak plasma concentration (49%) and in trough concentration (20%) were observed. When initiating, adjusting, and discontinuing telmisartan, monitor digoxin levels in order to maintain levels within the therapeutic range.
As with other medicinal products acting on the renin-angiotensin-aldosterone system, 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, immunosuppressive (cyclosporine or tacrolimus), and trimethoprim).
The occurrence of hyperkalaemia depends on associated risk factors. The risk is increased in case of the above-mentioned treatment combinations. The risk is particularly high in combination with potassium sparing-diuretics, and when combined with salt substitutes containing potassium. A combination with ACE inhibitors or NSAIDs, for example, presents a lesser risk provided that precautions for use are strictly followed.
Concomitant use not recommended.
Potassium sparing diuretics or potassium supplements
Angiotensin II receptor antagonists such as telmisartan, attenuate diuretic induced potassium loss. Potassium sparing diuretics e.g. spironolactone, eplerenone, triamterene, or amiloride, potassium supplements, or potassium-containing salt substitutes may lead to a significant increase in serum potassium. If concomitant use is indicated because of documented hypokalaemia, they should be used with caution and with frequent monitoring of serum potassium.
Lithium
Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with angiotensin converting enzyme inhibitors, and with angiotensin II receptor antagonists, including telmisartan. If use of the combination proves necessary, careful monitoring of serum lithium levels is recommended.
Concomitant use requiring caution.
Non-steroidal anti-inflammatory medicinal products
NSAIDs (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.
In some patients with compromised renal function (e.g. dehydrated patients or elderly patients with compromised renal function), the co-administration of angiotensin II receptor antagonists and agents that inhibit cyclo-oxygenase may result in further deterioration of renal function, including possible acute renal failure, which is usually reversible. 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.
In one study the co-administration of telmisartan and ramipril led to an increase of up to 2.5 fold in the $AUC_{0-\tau}$ and C_{max} of ramipril and ramiprilat. The clinical relevance of this observation is not known.
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.
Published Clinical trial data has shown that dual blockade of the renin-angiotensin-aldosterone-system (RAAS) through the combined use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren is associated with a higher frequency of adverse events such as hypotension, hyperkalaemia and decreased renal function (including acute renal failure) compared to the use of a single RAAS-acting agent.
Based on their pharmacological properties it can be expected that the following medicinal products may potentiate the hypotensive effects of all antihypertensive including telmisartan: Baclofen, amifostine. Furthermore, orthostatic hypotension may be aggravated by alcohol, barbiturates, narcotics, or antidepressants.
Corticosteroids (systemic route)
Reduction of the antihypertensive effect.

Pregnancy and Lactation
Pregnancy
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.
There are no adequate data from the use of Telmisartan Tablets USP in pregnant women. Studies in animals have shown reproductive toxicity.
Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive; however, a small increase in risk cannot be excluded. Whilst there is no controlled epidemiological data on the risk with angiotensin II receptor antagonists, similar risks may exist for this class of drugs. Unless continued angiotensin II receptor antagonist therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started.
Exposure to angiotensin II receptor antagonist therapy during the second and third trimesters is known to induce human fetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia).
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.
Breast-feeding
Because no information is available regarding the use of Telmisartan Tablets USP during breast-feeding, Telmisartan Tablets USP is not recommended and alternative treatments with better established safety profiles during breast-feeding are preferable, especially while nursing a new-born or preterm infant.

Use in specific populations
Elderly
No dose adjustment is necessary for elderly patients.
Renal impairment
Limited experience is available in patients with severe renal impairment or haemodialysis.
A lower starting dose of 20 mg is recommended in these patients. No posology adjustment is required for patients with mild to moderate renal impairment.
Hepatic impairment
Telmisartan Tablets 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.
Paediatric population
The safety and efficacy of Telmisartan Tablets in children and adolescents aged below 18 years have not been established.

Effects on ability to drive and use machines
When driving vehicles or operating machinery it should be taken into account that dizziness or drowsiness may occasionally occur when taking antihypertensive therapy such as Telmisartan Tablets.

Undesirable effects
Summary of the safety profile
Serious adverse drug reactions include anaphylactic reaction and angioedema which may occur rarely (≥1/10,000 to <1/1,000), and acute renal failure.
The overall incidence of adverse reactions reported with telmisartan was usually comparable to placebo (41.4 % vs 43.9 %) in controlled trials in patients treated for hypertension. The incidence of adverse reactions was not dose related and showed no correlation with gender, age or race of the patients. The safety profile of telmisartan in patients treated for the reduction of cardiovascular morbidity was consistent with that obtained in hypertensive patients.
The adverse reactions listed below have been accumulated from controlled clinical trials in patients treated for hypertension and from post-marketing reports. The listing also takes into account serious adverse reactions and adverse reactions leading to discontinuation reported in three clinical long-term studies including 21,642 patients treated with telmisartan for the reduction of cardiovascular morbidity for up to six years.
Tabulated list of adverse reactions
Adverse reactions have been ranked under headings of frequency using the following convention: 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).
Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Infections and infestations	
Uncommon: Rare:	Urinary tract infection including cystitis, upper respiratory tract infection including pharyngitis and sinusitis Sepsis including fatal outcome
Blood and the lymphatic system disorders	
Uncommon:	Anaemia
Rare:	Eosinophilia, thrombocytopenia
Immune system disorders	
Rare:	Anaphylactic reaction, hypersensitivity
Metabolism and nutrition disorders	
Uncommon: Rare:	Hyperkalaemia Hypoglycaemia (in diabetic patients)
Psychiatric disorders	
Uncommon:	Insomnia, depression
Rare:	Anxiety
Nervous system disorders	
Uncommon: Rare:	Syncope Somnolence
Eye disorders	
Rare:	Visual disturbance
Ear and labyrinth disorders	
Uncommon:	Vertigo
Cardiac disorders	
Uncommon:	Bradycardia
Rare:	Tachycardia
Vascular disorders	
Uncommon:	Hypotension, orthostatic hypotension
Respiratory, thoracic and mediastinal disorders	
Uncommon: Very rare:	Dyspnoea, cough Interstitial lung disease
Gastrointestinal disorders	
Uncommon: Rare:	Abdominal pain, diarrhoea, dyspepsia, flatulence, vomiting Dry mouth, stomach discomfort, dysgeusia
Hepato-biliary disorders	
Rare:	Hepatic function abnormal/liver disorder
Skin and subcutaneous tissue disorders	
Uncommon: Rare:	Pruritus, hyperhidrosis, rash Angioedema (also with fatal outcome), eczema, erythema, urticaria, drug eruption, toxic skin eruption
Muscoloskeletal and connective tissue disorders	
Uncommon: Rare:	Back pain (e.g. sciatica), muscle spasms, myalgia Arthralgia, pain in extremity, tendon pain (tendinitis like symptoms)
Renal and urinary disorders	
Uncommon:	Renal impairment including acute renal failure
General disorders and administration site conditions	
Uncommon: Rare:	Chest pain, asthenia (weakness) Influenza-like illness
Investigations	
Uncommon:	Blood creatinine increased
Rare:	Haemoglobin decreased, blood uric acid increased, hepatic enzyme increased, blood creatinine phosphokinase increased

Overdose
There is limited information available with regard to overdose in humans.
Symptoms
The most prominent manifestations of telmisartan overdose were hypotension and tachycardia; bradycardia dizziness, increase in serum creatinine, and acute renal failure have also been reported.
Management

BACK

Telmisartan is not removed by haemodialysis. The patient should be closely monitored, and the treatment should be symptomatic and supportive. Management depends on the time since ingestion and the severity of the symptoms. Suggested measures include induction of emesis and / or gastric lavage. Activated charcoal may be useful in the treatment of overdosage. Serum electrolytes and creatinine should be monitored frequently. If hypotension occurs, the patient should be placed in a supine position, with salt and volume replacement given quickly.

Pharmacological properties

Pharmacodynamic properties

Pharmacotherapeutic group: Angiotensin II Receptor Blocker (ARBs), Plain Antagonists, plain
ATC Code: C09CA07

Mechanism of action

Telmisartan is an orally active and specific angiotensin II receptor (type AT_1) antagonist. Telmisartan displaces angiotensin II with very high affinity from its binding site at the AT_1 receptor subtype, which is responsible for the known actions of angiotensin II. Telmisartan does not exhibit any partial agonist activity at the AT_1 receptor. Telmisartan selectively binds the AT_1 receptor. The binding is long-lasting. Telmisartan does not show affinity for other receptors, including AT_2 and other less characterised AT receptors. The functional role of these receptors is not known, nor is the effect of their possible overstimulation by angiotensin II, whose levels are increased by telmisartan. Plasma aldosterone levels are decreased by telmisartan. Telmisartan does not inhibit human plasma renin or block ion channels. Telmisartan does not inhibit angiotensin converting enzyme (kininase II), the enzyme which also degrades bradykinin. Therefore, it is not expected to potentiate bradykinin-mediated adverse effects.

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.

Pharmacokinetic properties

Absorption

Absorption of telmisartan is rapid although the amount absorbed varies. The mean absolute bioavailability for telmisartan is about 50 %. When telmisartan is taken with food, the reduction in the area under the plasma concentration-time curve ($AUC_{0-\infty}$) of telmisartan varies from approximately 6 % (40 mg dose) to approximately 19 % (160 mg dose). By 3 hours after administration, plasma concentrations are similar whether telmisartan is taken fasting or with food.

Linearity/non-linearity

The small reduction in AUC is not expected to cause a reduction in the therapeutic efficacy. There is no linear relationship between doses and plasma levels. C_{max} and to a lesser extent AUC increase disproportionately at doses above 40 mg.

Distribution

Telmisartan is largely bound to plasma protein (>99.5 %), mainly albumin and alpha-1 acid glycoprotein. The mean steady state apparent volume of distribution (V_{ss}) is approximately 500 l.

Biotransformation

Telmisartan is metabolised by conjugation to the glucuronide of the parent compound. No pharmacological activity has been shown for the conjugate.

Elimination

Telmisartan is characterised by biexponential decay pharmacokinetics with a terminal elimination half-life of >20 hours. The maximum plasma concentration (C_{max}) and, to a smaller extent, the area under the plasma concentration-time curve (AUC), increase disproportionately with dose. There is no evidence of clinically relevant accumulation of telmisartan taken at the recommended dose. Plasma concentrations were higher in females than in males, without relevant influence on efficacy.

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 (Cl_{tot}) is high (approximately 1,000 ml/min) compared with hepatic blood flow (about 1,500 ml/min).

Preclinical safety data

In preclinical safety studies, doses producing exposure comparable to that in the clinical therapeutic range caused reduced red cell parameters (erythrocytes, haemoglobin, haematocrit), changes in renal haemodynamics (increased blood urea nitrogen and creatinine), as well as increased serum potassium in normotensive animals. In dogs, renal tubular dilation and atrophy were observed. Gastric mucosal injury (erosion, ulcers or inflammation) also was noted in rats and dogs. These pharmacologically-mediated undesirable effects, known from preclinical studies with both angiotensin converting enzyme inhibitors and angiotensin II receptor antagonists, were prevented by oral saline supplementation.

In both species, increased plasma renin activity and hypertrophy/hyperplasia of the renal juxtaglomerular cells were observed. These changes, also a class effect of angiotensin converting enzyme inhibitors and other angiotensin II receptor antagonists, do not appear to have clinical significance.

No clear evidence of a teratogenic effect was observed, however at toxic dose levels of telmisartan an effect on the postnatal development of the off-springs such as lower body weight and delayed eye opening was observed.

There was no evidence of mutagenicity and relevant clastogenic activity *in vitro* studies and no evidence of carcinogenicity in rats and mice.

PHARMACEUTICAL PARTICULARS

Incompatibilities

Not applicable.

Shelf life

24 months

Storage Condition

Store below 30ºC. Protect from moisture.

Name and Contents of Container
10 tablets in Alu-Alu Blister pack, 3 such blisters in a printed carton along with pack Insert.

Ver: 00

Last Revision Date: Oct 25, 2021

Manufacturing Authorization Holder	Manufacturer
Ajanta Pharma Limited Ajanta House, Charkop Kandivli (West) Mumbai - 400 067, India. Tel : 022-6913 2111/2112 Fax : 022-6913 2070 Email : info@ajantapharma.com	Ajanta Pharma Limited Mirza-Palashbari Road, Village Kokjhar, Kamrup (R), Guwahati, Assam - 781128, India.

TELMICLAR

TELMISARTAN TABLETS USP

PATIENT INFORMATION LEAFLET
Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side, effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Distribution Category: Prescription Only Medicine or POM

What is in this leaflet:

1. What Telmiclar is and what it is used for

Telmiclar contains Telmisartan that belongs to a class of medicines known as angiotensin II receptor antagonists. Angiotensin II is a substance produced in your body, which causes your blood vessels to narrow, thus increasing your blood pressure. Telmiclar blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

Telmiclar is used to treat essential hypertension (high blood pressure) in adults. "Essential" means that the high blood pressure is not caused by any other condition.

High blood pressure, if not treated, can damage blood vessels in several organs, which could lead sometimes to heart attack, heart or kidney failure, stroke, or blindness. There are usually no symptoms of high blood pressure before damage occurs. Thus, it is important to regularly measure blood pressure to verify if it is within the normal range.

Telmiclar is also used to reduce cardiovascular events (i.e. heart attack or stroke) in adults who are at risk because they have a reduced or blocked blood supply to the heart or legs, or have had a stroke or have high risk diabetes. Your doctor can tell you if you are at high risk for such events.

2. What you need to know before you take Telmiclar
Do not take Telmiclar:

- If you are allergic to telmisartan or any of the other ingredients of this medicine
- If you are more than 3 months pregnant. (it is also better to avoid Telmiclar in early pregnancy
- If you have severe liver problems such as cholestasis or biliary obstruction (problems with the drainage of the bile from the liver and gall bladder) or any other severe liver disease.
- If you have diabetes or impaired kidney, function and you are treated with a blood pressure lowering medicine containing aliskiren.
  If any of the above applies to you, tell your doctor or pharmacist before taking Telmiclar.

Warnings and precautions
Talk to your doctor before taking Telmiclar if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Kidney disease or kidney transplant.
- Renal artery stenosis (narrowing of the blood vessels to one or both kidneys).
- Liver disease.
- Heart trouble.
- Raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals).
- Low blood pressure (hypotension), likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy ('water tablets'), low-salt diet, diarrhoea, or vomiting.
- Elevated potassium levels in your blood.
- Diabetes.

Talk to your doctor before taking Telmiclar:

- if you are taking any of the following medicines used to treat high blood pressure:
  - An ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
  - Aliskiren.

  Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.
  If you are taking digoxin.

You must tell your doctor if you think you are (or might become) pregnant. Telmiclar is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage.
In case of surgery or anaesthesia, you should tell your doctor that you are taking Telmiclar.
Telmiclar may be less effective in lowering the blood pressure in black patients.

Children and adolescents
The use of Telmiclar in children and adolescents up to the age of 18 years is not recommended.

Other medicines and Telmiclar
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor may need to change the dose of these other medications or take other precautions. In some cases, you may have to stop taking one of the medicines. This applies especially to the medicines listed below taken at the same time with Telmiclar:

- Lithium containing medicines to treat some types of depression.
- Medicines that may increase blood potassium levels such as salt substitutes containing potassium, potassium-sparing diuretics (certain 'water tablets'), ACE inhibitors, angiotensin II receptor antagonists, NSAIDs (non-steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen), heparin, immunosuppressive (e.g. cyclosporine or tacrolimus), and the antibiotic trimethoprim.
- Diuretics ('water tablets'), especially if taken in high doses together with Telmiclar, may lead to excessive loss of body water and low blood pressure (hypotension).
- If you are taking an ACE-inhibitor or aliskiren
- Digoxin.

The effect of Telmiclar may be reduced when you take NSAIDs (non-steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids.
Telmiclar may increase the blood pressure lowering effect of other medicines used to treat high blood pressure or of medicines with blood pressure lowering potential (e.g. baclofen, amifostine).
Furthermore, low blood pressure may be aggravated by alcohol, barbiturates, narcotics or antidepressants. You may notice this as dizziness when standing up. You should consult with your doctor if you need to adjust the dose of your other medicine while taking Telmiclar.

Pregnancy and breast-feeding
Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Telmiclar before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Telmiclar. Telmiclar is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Telmiclar is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines
Some people feel dizzy or tired when taking Telmiclar. If you feel dizzy or tired, do not drive or operate machinery.

3. How to take Telmiclar
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
The recommended dose is one tablet a day. Try to take the tablet at the same time each day.
You can take Telmiclar with or without food. The tablets should be swallowed with some water or other non-alcoholic drink. It is important that you take Telmiclar every day until your doctor tells you otherwise. If you have the impression that the effect of Telmiclar is too strong or too weak, talk to your doctor or pharmacist.
For treatment of high blood pressure, the usual dose of Telmiclar for most patients is one 40 mg tablet once a day to control blood pressure over the 24-hour period. Your doctor has recommended a lower dose of one 20 mg tablet daily. Telmiclar may also be used in combination with diuretics ('water tablets') such as hydrochlorothiazide, which has been shown to have an additive blood pressure lowering effect with Telmiclar.
For reduction of cardiovascular events, the usual dose of Telmiclar is one 80 mg tablet once a day. At the beginning of the preventive therapy with Telmiclar 80 mg, blood pressure should be frequently monitored.
If your liver is not working properly, the usual dose should not exceed 40 mg once daily.

If you take more Telmiclar than you should
If you accidentally take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately.

If you forget to take Telmiclar
If you forget to take a dose, do not worry. Take it as soon as you remember then carry on as before. If you do not take your tablet on one day, take your normal dose on the next day. Do not take a double dose to make up for forgotten individual doses.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.
Some side effects can be serious and need immediate medical attention
You should see your doctor immediately if you experience any of the following symptoms:
Sepsis* (often called "blood poisoning", is a severe infection with whole-body inflammatory response), rapid swelling of the skin and mucosa (angioedema); these side effects are rare (may affect up to 1 in 1,000 people) but are extremely serious and patients should stop taking the medicine and see their doctor immediately. If these effects are not treated, they could be fatal.

Possible side effects of Telmiclar
Common side effects (may affect up to 1 in 10 people):
Low blood pressure (hypotension) in users treated for reduction of cardiovascular events.

Uncommon side effects (may affect up to 1 in 100 people):
Urinary tract infections, upper respiratory tract infections (e.g. sore throat, inflamed sinuses, common cold), deficiency in red blood cells (anaemia), high potassium levels, difficulty falling asleep, feeling sad (depression), fainting (syncope), feeling of spinning (vertigo), slow heart rate (bradycardia), low blood pressure (hypotension) in users treated for high blood pressure, dizziness on standing up (orthostatic hypotension), shortness of breath, cough, abdominal pain, diarrhoea, discomfort in the abdomen, bloating, vomiting, itching, increased sweating, drug rash, back pain, muscle cramps, muscle pain (myalgia), kidney impairment including acute kidney failure, pain in the chest, feeling of weakness, and increased level of creatinine in the blood.
Rare side effects (may affect up to 1 in 1,000 people):
Sepsis* (often called "blood poisoning", is a severe infection with whole-body inflammatory response which can lead to death), increase in certain white blood cells (eosinophilia), low platelet count (thrombocytopenia), severe allergic reaction (anaphylactic reaction), allergic reaction (e.g. rash, itching, difficulty breathing, wheezing, swelling of the face or low blood pressure), low blood sugar levels (in diabetic patients), feeling anxious, somnolence, impaired vision, fast heart beat (tachycardia), dry mouth, upset stomach, taste disturbance (dysgeusia), abnormal liver function, rapid swelling of the skin and mucosa which can also lead to death (angioedema also with fatal outcome), eczema (a skin disorder), redness of skin, hives (urticaria), severe drug rash, joint pain (arthralgia), pain in extremity, tendon pain, flu-like-illness, decreased haemoglobin (a blood protein), increased levels of uric acid, increased hepatic enzymes or creatinine phosphokinase in the blood.
Very rare side effects (may affect up to 1 in 10,000 people):
Progressive scarring of lung tissue (interstitial lung disease) **
* The event may have happened by chance or could be related to a mechanism currently not known.
** Cases of progressive scarring of lung tissue have been reported during intake of telmisartan.
However, it is not known whether telmisartan was the cause.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Telmiclar

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the carton after "EXP". The expiry date refers to the last day of that month.
- This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from moisture. Remove your Telmiclar tablet from the blister only directly prior to intake.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Telmiclar contains:
The active ingredient is
Telmiclar 40 (Telmisartan Tablets USP 40 mg)
Each uncoated tablet contains:

Telmisartan USP	40 mg
Excipients	q.s.

Telmiclar 80 (Telmisartan Tablets USP 80 mg)
Each uncoated tablet contains:

Telmisartan USP	80 mg
Excipients	q.s.

List of Excipients:
Telmiclar 40 (Telmisartan Tablets USP 40 mg)
Lactose Monohydrate (115D) (Supertab), Crospovidone (Polyplasdone XL 10), Sodium Hydroxide, Meglumine, Povidone (Plasdone K-25), Magnesium Stearate and Purified Water.

Telmiclar 80 (Telmisartan Tablets USP 80 mg)
Lactose Monohydrate (115D) (Supertab), Crospovidone (Polyplasdone XL 10), Sodium Hydroxide, Meglumine, Povidone (Plasdone K-25), Magnesium Stearate and Purified Water.

What Telmiclar looks like and contents of the pack
Telmiclar 40 (Telmisartan Tablets USP 40 mg)
White to off white coloured, oval shaped, biconvex, uncoated tablets, plain on both the sides.

Telmiclar 80 (Telmisartan Tablets USP 80 mg)
White to off white coloured, oval shaped, biconvex, uncoated tablets, plain on both the sides.

For any information about this medicinal product, please contact Manufacturing Authorization Holder.

DATE OF PUBLICATION OR REVISION
Oct 25, 2021

Manufacturing Authorization Holder	Manufacturer
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