For the use of only a Registered Medical Practitioner or a Hospital or a Laboratory

Not to be sold by retail without the prescription of a Registered Medical Practitioner

Prescribing Information

1. Generic Name

Cilnidipine & Telmisartan Tablets
(Brand Name: CILNIBLU®-T Tablets)

2. Qualitative and Quantitative Composition

Each film coated tablet contains:
Cilnidipine IP …… 10 mg.
Telmisartan IP …….……..... 40 mg.
Excipients ……. q.s.
Colours: Titanium Dioxide IP

3. Dosage Form and Strength

Dosage Form: Tablets.
Dosage Strength: Cilnidipine 10 mg with Telmisartan 40 mg per tablet.

4. Clinical Particulars

4.1 Therapeutic Indication

CILNIBLU-T Tablets are indicated for the treatment of essential hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and non-fatal cardiovascular events, primarily stroke and myocardial infarction (MI).
CILNIBLU-T Tablets are usually administered in patients whose blood pressure is not adequately controlled by monotherapy with either telmisartan or cilnidipine.
CILNIBLU-T Tablets may be used alone or in combination with other antihypertensive drugs.

4.2Posology and Method of Administration

For oral administration in adults.
The usual dose is 1 tablet of CILNIBLU-T to be administered once daily. Adjust dosage according to blood pressure goals. If adequate response is not achieved after 2 to 4 weeks of therapy, dose may be increased to 2 tablets once daily. The dosage, however, must be individualized.
Dosage of individual agents should not exceed the recommended maximum daily doses.

- Cilnidipine is effective over the range of 5 to 20 mg once daily; maximum recommended daily dose is 20 mg.
- Telmisartan efficacy is dose-related over the range of 20 to 80 mg per day; maximum recommended daily dose is 80 mg.

If blood pressure remains uncontrolled, consider a change to more appropriate treatment.
CILNIBLU-T Tablets can be administered regardless of meal. The tablet should be swallowed whole with water.
Or, as prescribed by the physician.

4.3Contraindications

CILNIBLU-T Tablets are contraindicated in the following conditions:

- Hypersensitivity to cilnidipine or to telmisartan or to any component of the formulation.
- Cardiogenic shock.
- Severe aortic stenosis.
- Recent history of unstable angina or acute myocardial infarction, heart failure, hypotension.
- Second and third trimesters of pregnancy.
- Severe hepatic impairment and biliary obstructive disorders.
- 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 m^2).

4.4Special Warnings and Precautions for Use

Cilnidipine

Cardiovascular Disorders: Cilnidipine should be used with caution in patients with hypotension, heart failure, and poor cardiac reserve. Cilnidipine should be discontinued immediately in patients who feel chest pain following the administration of the drug.
Abrupt Cessation of Therapy: In case of angina, cilnidipine should not be discontinued abruptly to avoid withdrawal symptoms.
Grapefruit Juice: Grapefruit juice may intensify the effect of cilnidipine. Thus, avoid drinking grapefruit juice as much as possible while on cilnidipine therapy.
Laboratory Test: Cilnidipine therapy may interfere with the results of vanillyl mandelic acid test which is used to detect tumors such as pheochromocytoma and neuroblastoma. Therefore, cilnidipine should be avoided for 72 hours before sample collection, but the patient should be monitored intensively in a clinical setting.

Telmisartan

Fetal Toxicity: Use of drugs that act on the RAAS 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. Thus, when pregnancy is detected, discontinue telmisartan as soon as possible.
Hypotension: In patients with an activated RAAS, 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. Either correct this condition prior to administration of telmisartan, or start treatment under close medical supervision with a reduced dose.

Hyperkalemia: Hyperkalemia may occur in patients on angiotensin receptor blockers/antagonists (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.

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 drugs that affect the RAAS.

Dual Blockade of the RAAS: There is evidence that the concomitant use of angiotensin-converting enzyme (ACE) inhibitors, ARBs or aliskiren increases the risk of hypotension, hyperkalemia, and decreased renal function (including acute renal failure). Dual blockade of RAAS through combined use of ACE-inhibitors, ARBs or aliskiren is therefore not recommended. If dual blockade therapy is considered absolutely necessary, this should only occur under specialist supervision and be subject to close monitoring of renal function, electrolytes and blood pressure. ACE-inhibitors and ARBs should not be used concomitantly in patients with diabetic nephropathy. Do not co-administer aliskiren with telmisartan in patients with diabetes or renal impairment.

Other Body Functions Depends on the Activation of RAAS: As a consequence of inhibiting the RAAS, changes in renal function in susceptible individuals may be anticipated. In patients whose vascular tone and renal function depend predominantly on the activity of the RAAS (e.g., patients with severe congestive heart failure or underlying renal disease, including renal artery stenosis), treatment with drugs which affect this system such as telmisartan has been associated with acute hypotension, azotemia, oliguria, or rarely acute renal failure.

Primary Aldosteronism: Patients with primary aldosteronism generally will not respond to antihypertensive drugs acting through inhibition of the RAAS. Therefore, 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 Antidiabetic Drugs: Hypoglycaemia may occur when telmisartan is co-administered with these drugs. Therefore, in these patients appropriate blood glucose monitoring should be considered; a dose adjustment of insulin or antidiabetics may be required, when indicated.

Other Precautions: As with any antihypertensive agent, excessive reduction of blood pressure in patients with ischemic cardiovascular disease could result in a myocardial infarction or stroke.

4.5Drug Interactions

Cilnidipine

Antipsychotic Drugs: Co-administration of antipsychotic drugs with cilnidipine may result in low blood pressure. Thus, caution should be exercised while concomitant use of these drugs with cilnidipine.

Antidiabetic Drugs: Co-administration of cilnidipine with antidiabetic drugs may result in changes in glucose levels, thus, monitoring of blood glucose levels may be required.

Other Drugs: Antiepileptic drugs (such as phenytoin and carbamazepine), rifampin, quinidine, erythromycin, other anti-hypertensive drugs, and aldesleukin should also be used with caution along with cilnidipine.

Telmisartan

Telmisartan is not metabolized by the cytochrome P450 enzymes and had no effects *in vitro* on cytochrome P450 enzymes, except for some inhibition of CYP2C19. Thus, telmisartan is not expected to interact with drugs that inhibit or are metabolised by cytochrome P450 enzymes.

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/1.73 m^2).

Digoxin: When telmisartan was co-administered with digoxin, median increases in digoxin peak plasma concentration (49%) and in trough concentration (20%) were observed. Therefore, monitor digoxin levels when initiating, adjusting, and discontinuing telmisartan for the purpose of keeping digoxin level within the therapeutic range.

Lithium: Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with ARBs, including telmisartan. Therefore, monitor serum lithium levels during concomitant use.

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Including Selective Cyclooxygenase-2 (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 ARBs, 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 ARBs (including telmisartan) may be attenuated by NSAIDs, including selective COX-2 inhibitors.

Potassium Sparing Diuretics or Potassium Supplements: Telmisartan attenuates 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.

Other Drugs: Co-administration of telmisartan did not result in a clinically significant interaction with acetaminophen, amlodipine, glyburide, simvastatin, hydrochlorothiazide, warfarin, or ibuprofen.

4.6Use in Special Populations

Pregnant Women

Hypertension in pregnancy increases the maternal risk for pre-eclampsia, gestational diabetes, premature delivery, and delivery complications (e.g., need for cesarean section, post-partum hemorrhage). Hypertension increases the fetal risk for intrauterine growth restriction and intrauterine death. Thus, pregnant women with hypertension should be carefully monitored and managed accordingly.

The safety of cilnidipine in human pregnancy has not been established. Telmisartan causes fetal harm when administered to a pregnant woman. Use of drugs that act on the renin-angiotensin aldosterone system (RAAS) during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. Thus, CILNIBLU-T Tablets are contraindicated during the second and third trimesters of pregnancy. When pregnancy is detected or planned, CILNIBLU-T Tablets should be discontinued immediately and appropriate alternative therapy should be initiated.

Lactating Women

It is not known whether cilnidipine is secreted in breast milk. There is no information regarding the presence of telmisartan in human milk, the effects on the breastfed infant, or the effects on milk production. Telmisartan is present in the milk of lactating rats. Telmisartan has potential for serious adverse reactions including hypotension, hyperkalemia, and renal impairment in the breastfed infant. Thus, it is advisable that nursing mothers not breastfeed their children while on CILNIBLU-T therapy. Accordingly, a decision should be made whether to discontinue nursing or discontinue drug therapy, taking into account the importance of the drug to the mother.

Paediatric Patients

The safety and efficacy of this combination therapy in children and adolescents below 18 years of age have not been established. Thus, CILNIBLU-T Tablets are not recommended for use in paediatric population.

Geriatric Patients

With telmisartan, no overall differences in effectiveness and safety were observed in elderly patients compared to younger patients, but greater sensitivity of some older individuals cannot be ruled out. In general, a lower starting dose is recommended in elderly patients given their greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease and/or other drug therapy. Dosage up-titration, if required, should be done with caution.

4.7Effect on Ability to Drive and Use Machines

For cilnidipine and telmisartan combination therapy, studies have not been performed on effects on the ability to drive and use machines. It is advised not to operate machinery or

drive a vehicle if patient experience side effects such as drowsiness, dizziness, fatigue, headache, or hypotension while taking antihypertensive drug therapy.

4.8Undesirable Effects

Cilnidipine

General: Edema (face, limb, etc.), facial flush, thickening of gums, heat sensation, lethargy, generalized fatigue, frequent urination, impotence, liver dysfunction, jaundice, thrombocytopenia (nose/gum bleeding), allergic reaction, etc.
Gastrointestinal: Nausea, vomiting, anorexia, stomach ache, gastrointestinal reflux disease (GERD).
Eye: Transient blindness, eye pain.
Musculoskeletal: Muscle ache, tremors.
Cardiovascular System: Hypotension, palpitations, ischemic chest pain.
Central Nervous System: Dizziness, headache, depression, cerebral ischemia.
Dermatological: Rashes, itching, photosensitivity.

Telmisartan

Clinical Trials Experience

Adverse events occurred at an incidence of ≥ 1% in patients treated with telmisartan and at a greater rate than in patients treated with placebo were upper respiratory tract infections (URTIs), sinusitis, pharyngitis, back pain, and diarrhea.
In addition, the adverse events occurred at a rate of ≥ 1%, but at least as frequent in the placebo group were influenza-like symptoms, dyspepsia, myalgia, urinary tract infection, abdominal pain, headache, dizziness, pain, fatigue, coughing, hypertension, chest pain, nausea, and peripheral edema. The incidence of adverse reactions was not dose-related and showed no correlation with gender, age or race of the patients.
Adverse events that occurred in more than 0.3% patients treated with telmisartan monotherapy in controlled or open trials are as follows. It cannot be determined whether these events were causally related to telmisartan therapy.
Autonomic Nervous System: Impotence, increased sweating, flushing.
Body as a Whole: Allergy, fever, leg pain, malaise.
Cardiovascular: Palpitation, edema, angina pectoris, tachycardia, abnormal ECG.
Central Nervous System: Insomnia, somnolence, migraine, vertigo, paresthesia, involuntary muscle contractions, hypoesthesia.
Gastrointestinal: Flatulence, constipation, gastritis, vomiting, dry mouth, hemorrhoids, gastroenteritis, gastroesophageal reflux, nonspecific gastrointestinal disorders, toothache.
Metabolic: Gout, hypercholesterolemia, diabetes mellitus.
Musculoskeletal: Arthritis, arthralgia, leg cramps.
Psychiatric: Anxiety, depression, nervousness.
Infections: Fungal infection, abscess, otitis media.
Respiratory: Asthma, bronchitis, rhinitis, dyspnea, epistaxis.
Skin: Dermatitis, rash, eczema, pruritus.
Urinary: Increased micturition frequency, cystitis.

Vascular: Cerebrovascular disorder.
Special Senses: Abnormal vision, conjunctivitis, tinnitus, earache.
Laboratory Tests: Decrease in hemoglobin, increase in creatinine, elevations of liver enzymes may occur in patients treated with telmisartan.

Post-Marketing Experience
The most frequent spontaneously reported events included headache, dizziness, asthenia, coughing, nausea, fatigue, weakness, edema, angioneurotic edema, urticaria, hypersensitivity, increased sweating, erythema, chest pain, atrial fibrillation, congestive heart failure, myocardial infarction, increased blood pressure, aggravated hypertension, hypotension (including postural hypotension), hyperkalemia, syncope, dyspepsia, diarrhea, pain, urinary tract infection, erectile dysfunction, back pain, abdominal pain, muscle cramps (including leg cramps), myalgia, bradycardia, eosinophilia, thrombocytopenia, increased uric acid, abnormal hepatic function/liver disorder, renal impairment including acute renal failure, anemia, increased creatine phosphokinase (CPK), anaphylactic reaction, tendon pain (including tendonitis, tenosynovitis), drug eruption (mostly reported as toxicoderma, rash, and urticaria), hypoglycemia (in diabetic patients), and angioedema (with fatal outcome). Rare cases of rhabdomyolysis have been reported in patients receiving ARBs, including telmisartan.

4.9Overdose

Cilnidipine
In humans, experience with cilnidipine overdose is limited. Overdose symptoms include confusion, dizziness, headache, fatigue, and sedation. If overdose occurs, it might cause excessive peripheral vasodilation with marked hypotension.
If overdose should occur, initiate active cardiac and respiratory monitoring. Frequent blood pressure measurements are essential. Should hypotension occur, provide cardiovascular support including elevation of the extremities and the judicious administration of fluids. If hypotension remains unresponsive to these conservative measures, consider administration of vasopressors (such as phenylephrine) with attention to circulating volume and urine output.

Telmisartan
Limited data are available with regard to overdose in humans. The most likely manifestation of overdose with telmisartan would be hypotension, dizziness and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation.
If symptomatic hypotension occurs, supportive treatment should be instituted. Telmisartan is not removed by hemodialysis. Management of overdose depends on the time since ingestion and the severity of symptoms. Suggested measures include induction of emesis and/or gastric lavage. Activated charcoal may be useful in the treatment of overdose. 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.

5. Pharmacological Properties

5.1 Mechanism of Action

Cilnidipine

Cilnidipine is a novel dihydropyridine class of calcium-channel blocker (CCB)/antagonist used for the management of hypertension. Cilnidipine inhibits the transmembrane influx of calcium ions (Ca^{++}) into cardiac and vascular smooth muscle. However, it has greater selectivity for vascular smooth muscle. Antihypertensive action of cilnidipine is due to a direct relaxant effect on vascular smooth muscle. Cilnidipine has little or no action at the SA or AV nodes and negative inotropic activity is rarely seen at therapeutic doses. Like most of the other CCBs, cilnidipine acts on the L-type of calcium channels present on blood vessels. Cilnidipine blocks entry of calcium ions and thus, suppresses contraction of blood vessels, thereby reducing blood pressure.

Cilnidipine possesses both, L- and N-type calcium channel blocking activity. Since N-type calcium channels are distributed along the sympathetic nerve endings and in the brain, cilnidipine exerts specific antisympathetic effect i.e., it inhibits the release of norepinephrine, a sympathomimetic hormone. Thus, cilnidipine reduces blood pressure which is associated with sympathetic overactivity.

Telmisartan

Telmisartan is a selective AT_1 subtype angiotensin II receptor antagonist. 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 aldosterone system (RAAS), 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_1 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.

There is also an AT_2 receptor found in many tissues, but AT_2 is not known to be associated with cardiovascular homeostasis. Telmisartan has much greater affinity (>3,000 fold) for the AT_1 receptor than for the AT_2 receptor.

5.2Pharmacodynamic Properties

Cilnidipine

Cilnidipine is a calcium channel blocker class of antihypertensive drugs. Cilnidipine decreases blood pressure safely and effectively without excessive blood pressure reduction or tachycardia. With chronic once daily oral administration of cilnidipine, antihypertensive effectiveness is maintained for about 24 hours.

Telmisartan

Telmisartan is an angiotensin receptor antagonist class of antihypertensive drugs. The antihypertensive effect of telmisartan persists constantly over 24 hours after dosing which includes the last 4 hours before the next dose. In patients with hypertension, telmisartan reduces both systolic and diastolic blood pressure without affecting pulse rate.

5.3Pharmacokinetic Properties

Cilnidipine

Absorption: After oral administration of cilnidipine, absorption is very rapid with peak plasma concentration reached after 2 hours.

Distribution: Distribution of cilnidipine tends to be higher in the liver as well as in kidneys, plasma, and other tissues. Cilnidipine has a large volume of distribution. Plasma protein binding of cilnidipine is very high i.e., 98% of the administered dose.

Metabolism: Cilnidipine is metabolized by both liver and kidney. It is rapidly metabolized by liver microsomes by a dehydrogenation process. The major enzymatic isoform involved in cilnidipine dehydrogenation of the dihydropyridine ring is CYP3A.

Excretion: Approximately 20% of the administered dose of cilnidipine gets eliminated through the urine, with the remainder (about 80%) being eliminated in feces.

Telmisartan

The pharmacokinetics of orally administered telmisartan is nonlinear over the dose range 20 to 160 mg, with greater than proportional increases of plasma concentrations (C_{max} and AUC) with increasing doses.

Absorption: Following oral administration, peak plasma concentration (C_{max}) of telmisartan is reached in 0.5 to 1 hour after dosing. Food slightly reduces the bioavailability of telmisartan. The absolute bioavailability of telmisartan is dose dependent. At 40 and 160 mg, the bioavailability was 42% and 58%, respectively.

Distribution: Telmisartan is highly bound to plasma proteins (>99.5%), mainly albumin and α_1-acid glycoprotein. The volume of distribution for telmisartan is approximately 500 liters indicating additional tissue binding.

Metabolism: Telmisartan is metabolized by conjugation to form a pharmacologically inactive acyl glucuronide. The cytochrome P450 isoenzymes are not involved in the metabolism of telmisartan.

Excretion: Most of the orally administered dose (>97%) was eliminated unchanged in feces via biliary excretion; only minute amount (0.49%) was found in the urine. Total plasma clearance of telmisartan is >800 ml/min. Telmisartan shows bi-exponential decay kinetics with a terminal elimination half-life of approximately 24 hours.

6. Nonclinical Properties

6.1 Animal Toxicology

Cilnidipine

No relevant information available.

Telmisartan

Carcinogenicity: There was no evidence of carcinogenicity when telmisartan was administered in the diet to mice and rats for up to 2 years. The highest doses administered to mice (1000 mg/kg/day) and rats (100 mg/kg/day) are, on a mg/m^2 basis, about 59 and 13 times, respectively, the maximum recommended human dose (MRHD) of telmisartan. These

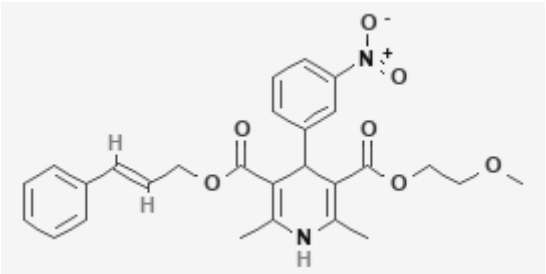
same doses have been shown to provide average systemic exposures to telmisartan >100 times and >25 times, respectively, the systemic exposure in humans receiving the MRHD (maximum recommended human dose) of telmisartan (80 mg/day).
Mutagenesis: Genotoxicity assays did not reveal any telmisartan-related effects at either the gene or chromosome level. These assays included bacterial mutagenicity tests with Salmonella and E. coli (Ames), a gene mutation test with Chinese hamster V79 cells, a cytogenetic test with human lymphocytes, and a mouse micronucleus test.
Impairment of Fertility: No drug-related effects on the reproductive performance of male and female rats were noted at 100 mg/kg/day (the highest dose administered), about 13 times, on a mg/m^2 basis, the MRHD of telmisartan. This dose in the rat resulted in an average systemic exposure (telmisartan AUC as determined on day 6 of pregnancy) at least 50 times the average systemic exposure in humans at the MRHD (80 mg/day).
Teratogenicity: No teratogenic effects were observed when telmisartan was administered to pregnant rats at oral doses of up to 50 mg/kg/day and to pregnant rabbits at oral doses of up to 45 mg/kg/day. In rabbits, embryo lethality associated with maternal toxicity (reduced body weight gain and food consumption) was observed at 45 mg/kg/day (approximately 12 times MRHD of 80 mg on a mg/m^2 basis). In rats, maternally toxic (reduced body weight gain and food consumption) telmisartan doses of 15 mg/kg/day (approximately 1.9 times the MRHD on a mg/m^2 basis), administered during late gestation and lactation, were observed to produce adverse effects in neonates, including reduced viability, low birth weight, delayed maturation, and decreased weight gain. The no-observed effect doses for developmental toxicity in rats and rabbits, 5 and 15 mg/kg/day, respectively, are approximately 0.64 and 3.7 times, respectively, on a mg/m^2 basis, the MRHD of telmisartan (80 mg/day).

7. Description

CILNIBLU-T Tablets are White, circular, biconvex, film coated tablets plain on both sides.
CILNIBLU-T Tablets contains 10 mg of cilnidipine and 40 mg of telmisartan for oral administration in adults.

Cilnidipine

Cilnidipine is a dihydropyridine calcium antagonist used in the management of hypertension.
Cilnidipine appears as a light yellowish powder.
Molecular Weight: 492.5 g/mol.
Molecular Formula: C27H28N2O7.
Chemical Name: 3-O-(2-methoxyethyl) 5-O-[(E)-3-phenylprop-2-enyl] 2,6-dimethyl-4-(3-nitrophenyl)-1,4-dihydropyridine-3,5-dicarboxylate.
Structural Formula:



Telmisartan

Telmisartan is a benzimidazole derivative and a non-peptide angiotensin II receptor antagonist with antihypertensive property. Telmisartan selectively antagonizes angiotensin II binding to the AT1 subtype receptor, located in vascular smooth muscle.

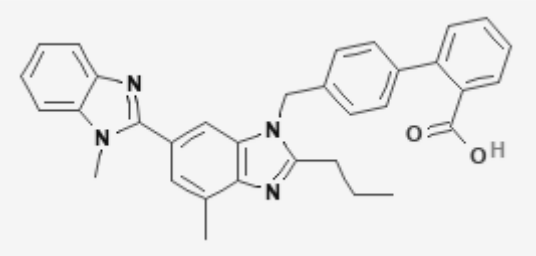
Telmisartan appears as white to slightly yellowish solid.

Molecular Weight: 514.6 g/mol.

Molecular Formula: C33H30N4O2.

Chemical Name: 2-[4-[[4-methyl-6-(1-methylbenzimidazol-2-yl)-2-propylbenzimidazol-1-yl]methyl]phenyl]benzoic acid.

Structural Formula:



Inactive ingredients (excipients) of CILNIBLU-T Tablets contain :Microcrystalline cellulose Dibasic calcium Phosphate, Maize Starch, Polyvinyl Pyrrolidone K-30, Isopropyl Alcohol Magnesium Stearate, Talcum , Sodium Starch Glycolate, Colloidal Silicon Dioxide Croscarmellose Sodium, Instacoat ICU 1308 & Methylene Chloride.

8. Pharmaceutical Particulars

8.1 Incompatibilities

None known.

8.2Shelf-life

24 Months

8.3Packaging Information

Blister of 15 tablets.

8.4Storage and Handling Instructions

Store protected from light and moisture at a temperature not exceeding 30°C.

Keep out of reach of children.

9. Patient Counseling Information

Administration Instructions to Patients

- Instruct patients to take this medicine exactly as prescribed by doctor. Do not change the dose or stop therapy without consulting doctor.

- Instruct patients to take CILNIBLU-T Tablets once a day, with or without food. It may be easier to take your dose if you do it at the same time every day, such as with breakfast or dinner, or at bedtime. Do not take more than one dose at a time.
- If patients miss a dose, they can take it as soon as they remember. Do not take if it has been more than 12 hours since the last missed dose. Wait and take the next dose at usual scheduled time.
- Pregnant women and lactating mothers should strictly avoid use of this medicine.
- This medicine is not recommended for use in children.
- Patients should be informed that while taking this medicine, do not stop use of other prescription medicines, including any other blood pressure medicines, without consulting their doctor.

10. Details of Manufacturer

AKUMS DRUGS & PHARMACEUTICALS LTD.
Plot No. 26A, 27-30, Sector-8A, I.I.E., SIDCUL, Ranipur, Haridwar – 249403 (Uttarakhand)

11. Details of Permission or License Number with Date

Mfg. Lic. No. : 4/UA/LL/2014, Date of FDA Product Permission: 12/11/2018

12. Date of Revision

April 2021.

Marketed by:
EXCEL BLUE CROSS || EXCEL
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Regd. Off.: Peninsula Chambers, G. K. Marg, Mumbai-400 013.