Summary of Product Characteristics
TELGOOD AM CT 12.5
(Telmisartan 40 mg, Amlodipine 5 mg and Chlorthalidone 12.5 mg Tablets)

1. Name of the medicinal product

TELGOOD AM CT 12.5 (Telmisartan 40 mg, Amlodipine 5 mg and Chlorthalidone 12.5 mg Tablets).

2. Qualitative and quantitative composition

Each uncoated tablet contains 40mg Telmisartan USP, 5mg Amlodipine Besylate USP and 12.5mg Chlorthalidone USP.

3. Pharmaceutical form

Tablets
White, round, uncoated tablets having breakline on one side & plain on other side

4.Clinical Particulars:

4.1 Therapeutic indications

TELGOOD AM CT 12.5 is an anti-hypertensive drug that treats high blood pressure (hypertension). It contains Amlodipine, Chlorthalidone, and Telmisartan. Amlodipine is a calcium channel blocker that dilates (widens) blood vessels and increases blood flow. It is used to treat high blood pressure, chest pain (angina), and other conditions caused by coronary artery disease. Chlorthalidone is a diuretic (water pill). It prevents the body from absorbing excess salts that cause fluid retention or build-up. It effectively treats high blood pressure, fluid retention in patients with congestive heart failure, cirrhosis (chronic damage) of the liver, kidney disorders, or edema caused by steroids or oestrogen therapy. Telmisartan is an angiotensin II receptor antagonist (angiotensin is a hormone that constricts blood vessels and increases blood pressure). It lowers blood pressure and increases blood flow by preventing the narrowing of blood vessels. It reduces the risk of stroke, heart attack, or death from heart problems.

4.2 Posology and method of administration

Posology

For high blood pressure:
Adults: At first, one tablet containing 40 milligrams (mg) of telmisartan, 5 mg of amlodipine and 12.5mg of Chlorthalidone once a day. Your doctor may adjust your dose as needed. However, the dose is usually not more than 80 mg of telmisartan and 10 mg of amlodipine once a day.

Method of administration

Use and dose must be determined by your doctor.

4.3 Contraindications

- If you are allergic to amlodipine, chlorthalidone, telmisartan, or any of the other ingredients of TELGOOD AM CT 12.5 Tablet.

- If you are allergic to other medicines of the dihydropyridine type (one type of calcium channel blocker) or other sulfonamide-derived medicines. If you are not sure what these medicines are, please confirm with your doctor.
- If you are more than 3 months pregnant.
- If you have liver or kidney problems.
- If your kidneys fail to produce urine (anuria).
- If you have biliary blockage (problems with the drainage of bile from the liver and gallbladder).
- If you have narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition
- where your heart is unable to supply enough blood to the body).
- If you have heart failure after a heart attack.
- If you have diabetes or kidney problems and you are treated with a blood pressure lowering medicine containing aliskiren.

4.4 Special warnings and precautions for use

- It is not recommended for use in patients with kidney stones and it should be taken with caution in patients having kidney artery stenosis (narrowing of blood vessels to one or both the kidneys) and kidney transplant. Consult your doctor before taking TELGOOD AM CT 12.5
- It is not recommended for use in patients with severe liver problems such as cholestasis or biliary obstruction (flow of bile from liver stops or slows). It should be used with caution in patients having liver disease. Consult your doctor before taking TELGOOD AM CT 12.5
- It isnot recommended for use in patients with cardiogenic shock (when the heart is unable to supply enough blood to the vital organs of the body), aortic stenosis (narrowed or blocked aortic valve), heart failure after heart attack. It should be used with caution in patients having heart trouble or low blood pressure (due to dehydration problems, low-salt intake, diarrhoea, or vomiting). Before taking TLEMED ACT consult with your doctor.
- It should be used with caution in elderly patients (above 65 years of age). Consult your doctor before taking TELGOOD AM CT 12.5

4.5 Interaction with other medicinal products and other forms of interaction

Before taking TELGOOD AM CT 12.5 inform your doctor if you are taking any of the following medicines:

- Medicines used to lower the blood pressure (Ex. enalapril, lisinopril, ramipril, verapamil, diltiazem, aliskiren, bosentan, methyldopa and guanethidine)
- Medicines that may increase blood potassium levels (Ex. amiloride, spironolactone)
- Medicines used to treat pain and inflammation (Ex. aspirin, ibuprofen)
- Heparin (used to prevent blood clots)
- Cyclosporin, tacrolimus, sirolimus, temsirolimus, and everolimus (used to prevent organ rejection after transplant)

- Medicines used to treat bacterial infections (Ex. clarithromycin, erythromycin, amphotericin, telithromycin, rifampicin, rifabutin and trimethoprim)
- Furosemide, hydrochlorothiazide (used to treat oedema or high blood pressure)
- Medicines used to suppress inflammation (Ex. prednisolone, betamethasone, dexamethasone and hydrocortisone)
- Medicines used to treat depression (Ex. lithium, citalopram, fluoxetine, paroxetine, nefazodone and St. John's wort (herbal medicine))
- Itraconazole, ketoconazole (used to treat fungal infections)
- Antiviral medicines used to treat HIV infections (Ex. ritonavir, indinavir, nelfinavir, nevirapine)
- Simvastatin, colestyramine (used to treat high cholesterol)
- Adrenocorticotropic hormone (ACTH) (used to treat ulcerative colitis, crohn's disease)
- Cyclophosphamide or methotrexate (used in cancer treatment)
- Salbutamol or formoterol (used to treat asthma)
- Carbenoxolone (used to treat stomach ulcers)
- Insulin, chlorpropamide or glibenclamide (medicine used to treat diabetes)
- Atropine (used to treat symptoms of low heart rate)
- Amantadine (used to treat parkinson's disease or viral infections)
- Allopurinol (used to treat gout)
- Calcium salts or vitamin D (used for vitamin deficiency)
- Avoid eating or drinking grapefruit juice while taking TLEMED ACT as it may potentiate the blood pressure lowering effect. Consult your doctor before taking TELGOOD AM CT 12.5

4.6 Fertility, pregnancy and lactation

Pregnancy: TELGOOD AM CT 12.5 is not generally recommended for pregnant women as it may cause serious harm to the baby. Consult your doctor before taking TELGOOD AM CT 12.5

Breast-feeding: TELGOOD AM CT 12.5 is not recommended for use in breastfeeding women, as it may pass through breast milk. Your doctor may choose another treatment especially if you want to breast-feed when your baby is new-born or born prematurely. Consult your doctor before taking TELGOOD AM CT 12.5.

Fertility: There are no fertility data with TELGOOD AM CT 12.5. It was not shown to alter fertility in animal studies.

4.7 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.

Amlodipine can have minor or moderate influence on the ability to drive and use machines. If patients taking amlodipine suffer from dizziness, headache, fatigue or nausea the ability to react may be impaired. Caution is recommended especially at the start of treatment.

Patients should be warned of the potential hazards of driving or operating machinery if they experience side effects such as dizziness.

4.8 Undesirable effects

COMMON

- Oedema (swelling due to fluid retention)
- Low blood levels of potassium which can cause muscle weakness, muscle twitching
- Low blood pressure
- Low levels of sodium which can cause tiredness, confusion, muscle twitching
- Fits or coma, Dizziness, Loss of appetite, stomach upset
- High blood sugar levels which can cause tiredness, weakness or feeling thirsty
- Nettle like skin rash
- Impotence in men

UNCOMMON

- Urinary tract infections
- Upper respiratory tract infections (signs include sore throat, inflamed sinuses, common cold)
- Decreased red blood cells (anemia)
- Difficulty falling asleep
- Fainting, Head spinning sensation (vertigo)
- Slow heart rate, Dizziness on standing up (orthostatic hypotension)
- Shortness of breath, cough
- Abdominal pain, diarrhoea, vomiting and bloating
- Itching and increased sweating
- Back pain, muscle cramps and muscle pain
- Chest pain, feeling of weakness
- Ringing in the ears
- Sneezing/running nose caused by inflammation of the lining of the nose
- Dry mouth, Hair loss, red patches on skin, skin discoloration
- Difficulty in passing urine, increased urge to urinate at night, increased frequency of passing urine
- Discomfort or enlargement of the breasts in men
- Weight gain or decrease
- Gout (pain and swelling in the joint)

RARE

- Signs of increased calcium levels (agitation, sore eyes, abdominal pain)
- Swelling of face or gums
- Low blood sugar level in diabetic patients, worsening of diabetes
- Signs of jaundice (yellowing of skin or eyes)
- Increased skin sensitivity to sunlight
- Impaired vision
- Fast heartbeat

- Altered taste sensation
- Eczema, hives (urticaria)
- Severe skin rash caused by drug, joint, tendon and extremities pain
- Flulike illness such as fever, chills and throat pain
- Signs of kidney problems (such as loss of appetite, decreased urinary output, fatigue)
- Confusion and anxiety
- Palpitations
- Tingling and prickling sensation in arms, legs or feet

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to National Regulatory Agents.

4.9 Overdose

Telmisartan

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.
Treatment: 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.

Amlodipine Besylate

In humans experience with intentional overdose is limited
Symptoms
Available data suggest that gross overdosage could result in excessive peripheral vasodilatation and possibly reflex tachycardia. Marked and probably prolonged systemic hypotension up to and including shock with fatal outcome have been reported.
Non-cardiogenic pulmonary oedema has rarely been reported as a consequence of Amlodipine
overdose that may manifest with a delayed onset (24-48 hours post-ingestion) and require ventilatory support. Early resuscitative measures (including fluid overload) to maintain perfusion and cardiac output may be precipitating factors.
Treatment

Clinically significant hypotension due to amlodipine overdosage calls for active cardiovascular support including frequent monitoring of cardiac and respiratory function, elevation of extremities and attention to circulating fluid volume and urine output.
A vasoconstrictor may be helpful in restoring vascular tone and blood pressure, provided that there is no contraindication to its use. Intravenous calcium gluconate may be beneficial in reversing the effects of calcium channel blockade. Gastric lavage may be worthwhile in some cases. In healthy volunteers the use of charcoal up to 2 hours after administration of amlodipine 10 mg has been shown to reduce the absorption rate of amlodipine.
Since amlodipine is highly protein-bound, dialysis is not likely to be of benefit.
Chlorthalidone
Signs and symptoms
In poisoning due to an overdosage the following signs and symptoms may occur: dizziness, nausea, somnolence, hypovolaemia, hypotension and electrolyte disturbances associated with cardiac arrhythmias and muscle spasms.
Treatment
There is no specific antidote to chlortalidone. Gastric lavage, emesis or activated charcoal should be employed to reduce absorption. Blood pressure and fluid and electrolyte balance should be monitored and appropriate corrective measures taken intravenous fluid and electrolyte replacement may be indicated.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Angiotensin II Antagonists, plain
ATC code: C09CA07.

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 AT 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 AT1 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.

Amlodipine Besylate

Pharmacotherapeutic group: Calcium channel blockers, selective calcium channel
blockers with mainly vascular effects, dihydropyridine derivatives.

ATC code: C08CA01

Mechanism of action

Amlodipine is a calcium ion influx inhibitor of the dihydropyridine group (slow channel blocker or calcium ion antagonist) and inhibits the transmembrane influx of calcium ions into cardiac and vascular smooth muscle.

The mechanism of the antihypertensive action of amlodipine is due to a direct relaxant effect on vascular smooth muscle. The precise mechanism by which amlodipine relieves angina has not been fully determined but amlodipine reduces total ischaemic burden by the following two actions:

1. Amlodipine dilates peripheral arterioles and thus, reduces the total peripheral resistance (afterload) against which the heart works. Since the heart rate remains stable, this unloading of the heart reduces myocardial energy consumption and oxygen requirements.
2. The mechanism of action of amlodipine also probably involves dilatation of the main coronary arteries and coronary arterioles, both in normal and ischaemic regions. This dilatation increases myocardial oxygen delivery in patients with coronary artery spasm (Prinzmetal's or variant angina).

Pharmacodynamic effects

In patients with hypertension, once daily dosing provides clinically significant reductions of blood pressure in both the supine and standing positions throughout the 24-hour interval. Due to the slow onset of action, acute hypotension is not a feature of amlodipine administration.

In patients with angina, once daily administration of amlodipine increases total exercise time, time to angina onset and time to 1mm ST segment depression, and decreases both angina attack frequency and glyceryl trinitrate tablet consumption.

Amlodipine has not been associated with any adverse metabolic effects or changes in plasma lipids and is suitable for use in patients with asthma, diabetes and gout.

Chlorthalidone

Pharmacotherapeutic group: benzothiadiazine (thiazide)-related diuretic

ATC Code: C03BA04

Thiazide and thiazide-like diuretics act primarily on the distal renal tubule (early convoluted part), inhibiting $NaCl^-$ reabsorption (by antagonising the Na^+Cl^- cotransporter) and promoting Ca++ reabsorption (by an unknownmechanism). The enhanced delivery of Na+ and water to the cortical collection tubule and/or the increased flow rate leads to increased secretion and excretion of K+ and H+.

In persons with normal renal function, diuresis is induced after the administration of 12.5mg chlortalidone. The resulting increase in urinary excretion of sodium and

chloride and the less prominent increase in urinary potassium are dose dependent and occur both in normal and in oedematous patients. The diuretic effect sets in after 2 to 3 hours, reaches its maximum after 4 to 24 hours and may persist for 2 to 3 days.
Thiazide-induced diuresis initially leads to decreases in plasma volume, cardiac output, and systemic blood pressure. The renin-angiotensinaldosterone system may possibly become activated.
In hypertensive individuals, chlortalidone gently reduces blood pressure. On continued administration, the hypotensive effect is maintained, probably due to the fall in peripheral resistance; cardiac output returns to pre-treatment values, plasma volume remains somewhat reduced and plasma renin activity may be elevated.
On chronic administration, the antihypertensive effect of chlortalidone is dose dependent between 12.5 and 50mg/day. Raising the dose above 50mg increases metabolic complications and is rarely of therapeutic benefit.
As with other diuretics when chlortalidone is given as monotherapy, blood pressure control is achieved in about half of patients with mild to moderate hypertension. In general, elderly and black patients are found to respond well to diuretics given as primary therapy. Randomised clinical trials in the elderly have shown that treatment of hypertension or predominant systolic hypertension in older persons with low-dose thiazide diuretics, including chlortalidone, reduces cerebrovascular (stroke) coronary heart and total cardiovascular morbidity and mortality.
Combined treatment with other antihypertensives potentiates the blood pressure lowering effects.
In the large proportion of patients failing to respond adequately to monotherapy, a further decrease in blood pressure can thus be achieved.
In renal diabetes insipidus, chlortalidone Paradoxically reduces polyuria. The mechanism of action has not been elucidated. Combined treatment with other antihypertensives Potentiates the blood-pressure lowering effects. In the large proportion of patients failing to respond adequately
To monotherapy, a further decrease in blood pressure can thus be achieved.

5.2 Pharmacokinetic properties

Telmisartan

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) 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.

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

Amlodipine Besylate

Absorption
After oral administration of therapeutic doses, amlodipine is well absorbed with peak blood levels between 6-12 hours post dose. Absolute bioavailability has been estimated to be between 64 and 80%.
The bioavailability of amlodipine is not affected by food intake.
Distribution
The volume of distribution is approximately 21 l/kg. In vitro studies have shown that approximately 97.5% of circulating amlodipine is bound to plasma proteins.
Biotransformation
Amlodipine is extensively metabolised by the liver to inactive metabolites with 10% of the parent compound and 60% of metabolites excreted in the urine
Elimination
The terminal plasma elimination half-life is about 35-50 hours and is consistent with once daily dosing.

Chlorthalidone

Absorption
The bioavailability of an oral dose of 50 mg chlortalidone is approximately 64%, peak blood concentrations being attained after 8 to 12 hours. For doses of 25 and 50 mg, Cmax values average 1.5 µg/ml (4.4 µmol/L) and 3.2µg/ml (9.4 µmol/L) respectively. For doses up to 100 mg there is a proportional increase in AUC. On repeated daily doses of 50 mg, mean steady state blood concentrations of 7.2 µg/ml (21.2 µmol/L), measured at the end of the 24-hour dosage interval, are reached after 1 to 2 weeks.
Distribution
In blood, only a small fraction of chlortalidone is free, due to extensive accumulation in erythrocytes and binding to plasma proteins. Owing to the large degree of high affinity binding to the carbonic anhydrase of erythrocytes, only some

1.4% of the total amount of chlortalidone in whole blood was found in plasma at steady state during treatment with 50 mg doses. In vitro, plasma protein binding of chlortalidone is about 76% and the major binding protein is albumin.
Chlortalidone crosses the placental barrier and passes into the breast milk. In mothers treated with 50 mg chlortalidone daily before and after delivery, chlortalidone levels in foetal whole blood are about 15% of those found in maternal blood. Chlortalidone concentrations in amniotic fluid and in the maternal milk are approximately 4% of the corresponding maternal blood level.
Metabolism
Metabolism and hepatic excretion into bile constitute a minor pathway of elimination. Within 120 hours, about 70% of the dose is excreted in the urine and the faeces, mainly in unchanged form.
Elimination
Chlortalidone is eliminated from whole blood and plasma with an elimination half life averaging
50 hours. The elimination half-life is unaltered after chronic administration. The major part of an absorbed dose of chlortalidone is excreted by the kidneys, with a mean renal clearance of 60 ml/min.

5.3 Preclinical safety data
Not Known

6. Pharmaceutical particulars
6.1 List of excipients

Mannitol DC
Microcrystalline Cellulose
Meglumine
PVPK 30
Isopropyl Alcohol
Cross Povidone
Aspartame
Magnesium Stearate

6.2 Incompatibilities
Not Applicable

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store below 30℃. Protect from light and moisture.
Keep medicines out of reach of children.

6.5 Nature and contents of container
10 tablets are packed in one Alu-Alu blister, such 3 blister are packed in a carton with insert.

6.6 Special precautions for disposal and other handling
No special requirements

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURER

Marketing Authorisation Holder:
ZAIN PHARMA LTD.
Plot No: 209/13741, Colchester Park,
Go-Down No.1, 2, 3, Off Mombasa Road,
Behind Nice and Lovely House,
P.O. Box: 100167-00101, Nairobi, Kenya

8. Marketing Authorization Number: H2025/CTD11873/25336

9. Date of First <Registration> / Renewal of The <Registration>
October 2025
10. Date of Revision of the Text: october 2025