SUMMARY OF PRODUCT CHARACTERISTICS
TELGOOD 80 CT 12.5 (Telmisartan 80 mg and Chlorthalidone 12.5 mg Tablets)

1. NAME OF THE MEDICINAL PRODUCT

TELGOOD 80 CT 12.5 (Telmisartan 80 mg and Chlorthalidone 12.5 mg Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains 80 mg telmisartan and 12.5 mg chlorthalidone.

Excipients with known effect:

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Uncoated tablet.

White, round, biconvex uncoated tablet, plain on both sides.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of essential hypertension in adults, as substitution therapy in patients whose blood pressure is adequately controlled with telmisartan and chlorthalidone given concurrently at the same doses as in the fixed-dose combination.

Reduction of cardiovascular risk in adults with manifest atherothrombotic cardiovascular disease or type 2 diabetes mellitus with documented target organ damage.

4.2 Posology and method of administration

Posology

One tablet of TELGOOD 80 CT 12.5 (telmisartan 80 mg/chlorthalidone 12.5 mg) once daily. The maximum antihypertensive effect is generally attained 4–8 weeks after the start of treatment.

Special populations

Renal impairment:

This medicinal product is contraindicated in patients with anuria or severe renal impairment. No dose adjustment is required in patients with mild to moderate renal impairment. Periodic monitoring of potassium, creatinine and uric acid is recommended in patients with renal impairment.

Hepatic impairment:

This medicinal product is contraindicated in patients with severe hepatic impairment or biliary obstructive disorders. In mild to moderate hepatic impairment, the dose of telmisartan should not exceed 40 mg once daily; therefore this fixed-dose combination (80 mg telmisartan) should generally not be used in these patients.

Elderly:

No dose adjustment is necessary for elderly patients.

Paediatric population:

The safety and efficacy of this combination in children and adolescents aged below 18 years have not been established.

Method of administration

Oral. The tablets should be taken once daily with liquid, with or without food.

4.3 Contraindications

- Hypersensitivity to the active substances, to other sulphonamide-derived substances, or to any of the excipients listed in section 6.1.
- Second and third trimester of pregnancy (see section 4.6).

- Biliary obstructive disorders and severe hepatic impairment.
- Severe renal impairment (eGFR <30 ml/min/1.73 m²) and anuria (because chlorthalidone efficacy depends on renal function).
- Refractory hypokalaemia, hypercalcaemia, hyponatraemia and symptomatic hyperuricaemia.
- Concomitant use with aliskiren-containing products in patients with diabetes mellitus or renal impairment (eGFR <60 ml/min/1.73 m²).

4.4 Special warnings and precautions for use

Dual blockade of the RAAS

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 is therefore not recommended. ACE-inhibitors and angiotensin II receptor blockers should not be used concomitantly in patients with diabetic nephropathy.

Renal impairment and hypotension

The antihypertensive activity of thiazide/thiazide-like diuretics is enhanced in patients with renal impairment. Chlorthalidone may precipitate azotaemia in patients with chronic kidney disease. Periodic monitoring of serum electrolytes, creatinine and uric acid is recommended.

Electrolyte disturbances

Chlorthalidone may cause hypokalaemia, hyponatraemia, hypomagnesaemia, hypercalcaemia and hyperuricaemia. Periodic monitoring of serum electrolytes is recommended during chlorthalidone treatment. Hypokalaemia potentiates the toxic effects of digitalis glycosides and increases the risk of arrhythmias. Chlorthalidone may decrease urinary calcium excretion and can cause elevated serum calcium levels; frank hypercalcaemia may be evidence of hidden hyperparathyroidism.

Metabolic effects

Chlorthalidone may decrease glucose tolerance; dose adjustment of antidiabetic agents, including insulin, may be required. Latent diabetes mellitus may become manifest during chlorthalidone therapy. Chlorthalidone may raise cholesterol and triglyceride levels and cause hyperuricaemia or precipitate gout in susceptible patients.

Hepatic impairment

Telmisartan should not be given to patients with cholestasis, biliary obstructive disorders or severe hepatic impairment since telmisartan is mostly eliminated with the bile. Chlorthalidone should be used with caution in patients with hepatic impairment, as minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

Hyperkalaemia

The use of medicinal products that affect the RAAS may cause hyperkalaemia. Close monitoring of serum potassium in at-risk patients is recommended.

Photosensitivity

Cases of photosensitivity reactions have been reported with thiazide diuretics. If photosensitivity occurs, treatment should be discontinued.

Systemic lupus erythematosus

Thiazide and thiazide-like diuretics have been reported to exacerbate or activate systemic lupus erythematosus.

4.5 Interaction with other medicinal products and other forms of interaction

Lithium:

Reversible increases in serum lithium concentrations and toxicity have been reported with concomitant use of lithium and angiotensin II receptor antagonists or diuretics. Careful monitoring of serum lithium levels is recommended if this combination is necessary.

Digoxin:

When telmisartan was co-administered with digoxin, median increases in digoxin peak plasma concentration (49%) and trough concentration (20%) were observed. Monitor digoxin levels when initiating, adjusting and discontinuing telmisartan.

NSAIDs:

NSAIDs may reduce the antihypertensive effect and diuretic effect of this combination. In patients with compromised renal function, co-administration may lead to further deterioration of renal function.

Antidiabetic drugs (insulin and oral antidiabetics):

Chlorthalidone may reduce the effect of antidiabetic drugs. Dose adjustment may be required.

Potassium-depleting agents (corticosteroids, ACTH, amphotericin B, laxatives):

Concomitant use with chlorthalidone may increase risk of hypokalaemia.

Potassium-sparing diuretics and potassium supplements:

May lead to significant increase in serum potassium when combined with telmisartan.

Alcohol, barbiturates and narcotics:

May potentiate orthostatic hypotension.

Other antihypertensive agents:

Additive blood pressure lowering effect; baclofen and amifostine may potentiate hypotensive effects.

4.6 Fertility, pregnancy and lactation

Pregnancy

The use of angiotensin II receptor antagonists is not recommended during the first trimester of pregnancy and is contraindicated during the second and third trimesters. Chlorthalidone crosses the placental barrier and may cause foetal or neonatal jaundice, thrombocytopenia and possibly other adverse reactions associated with thiazide diuretics in adults. There is a risk of foeto-neonatal hypokalaemia. When pregnancy is diagnosed, treatment should be stopped immediately and alternative therapy started.

Breast-feeding

Telmisartan is not recommended during breast-feeding; alternative treatments with better-established safety profiles are preferable. Chlorthalidone passes into breast milk; breast-feeding is not recommended during treatment with chlorthalidone.

Fertility

No effects of telmisartan on male and female fertility were observed in non-clinical studies. No data are available on the effect of chlorthalidone on fertility.

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 and chlorthalidone.

4.8 Undesirable effects

Summary of the safety profile

The adverse reaction profile of this combination product is expected to be consistent with the individual components. The most clinically important adverse reactions include hypokalaemia, hyperuricaemia, electrolyte disturbances (from chlorthalidone) and hypotension, angioedema, and renal impairment (from telmisartan).

Tabulated list of adverse reactions

Adverse reactions are listed by MedDRA System Organ Class and frequency: common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); not known (frequency cannot be estimated from the available data).

System Organ Class	Common	Uncommon	Rare	Not Known
Infections and infestations		Upper respiratory tract infection, urinary tract infection	Sepsis	
Blood and lymphatic system disorders		Anaemia	Eosinophilia, thrombocytopenia	
Immune system disorders			Anaphylactic reaction, hypersensitivity	
Metabolism and nutrition disorders	Hypokalaemia, hyperuricaemia	Hyperkalaemia	Hypoglycaemia (diabetic patients)	
Psychiatric disorders		Depression, insomnia	Anxiety	

System Organ Class	Common	Uncommon	Rare	Not Known
Nervous system disorders		Syncope, dizziness	Somnolence	
Vascular disorders		Hypotension, orthostatic hypotension		
Respiratory disorders		Dyspnoea, cough	Interstitial lung disease (very rare)	
Gastrointestinal disorders		Abdominal pain, diarrhoea, dyspepsia, nausea, vomiting	Dry mouth, dysgeusia	
Hepatobiliary disorders			Hepatic function abnormal	
Skin and subcutaneous tissue disorders		Rash, pruritus, photosensitivity	Angioedema, urticaria, toxic skin eruption	
Musculoskeletal disorders		Myalgia, back pain, muscle spasms	Arthralgia, tendon pain	
Renal and urinary disorders		Renal impairment including acute renal failure		
General disorders		Chest pain, asthenia, fatigue		
Investigations		Blood creatinine increased, blood uric acid increased	Hepatic enzyme increased	

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 via the National Regulatory Authority.

4.9 Overdose
The most likely manifestations of overdosage are hypotension and tachycardia due to telmisartan. Chlorthalidone overdose may result in electrolyte depletion (hypokalaemia, hyponatraemia) and dehydration due to excessive diuresis. Symptomatic and supportive treatment should be given. Telmisartan is not removed by haemodialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Angiotensin II antagonists and diuretics. ATC code: C09DA07.

Telmisartan — mechanism of action
Telmisartan is an orally active and specific angiotensin II receptor (type AT1) antagonist that displaces angiotensin II with very high affinity from its binding site at the AT1 receptor subtype. An 80 mg dose of telmisartan almost completely inhibits the angiotensin II evoked blood pressure increase, with the inhibitory effect maintained over 24 hours and measurable up to 48 hours. Plasma aldosterone levels are decreased by telmisartan.

Chlorthalidone — mechanism of action
Chlorthalidone exerts its therapeutic action by antagonising the sodium-chloride symporter in the distal convoluted tubule of the nephron, inhibiting sodium reabsorption and thereby promoting diuresis. The increased excretion of sodium and extracellular fluid decreases intravascular water and solute concentration, lowering hydrostatic pressure and reducing blood pressure.

5.2 Pharmacokinetic properties
Telmisartan

The mean absolute bioavailability for telmisartan is about 50%. Telmisartan is largely bound to plasma protein (>99.5%), with an apparent volume of distribution of approximately 500 litres. Telmisartan is metabolised by conjugation to the glucuronide of the parent compound. After oral administration, telmisartan is nearly exclusively excreted with the faeces as unchanged compound; cumulative urinary excretion is <1% of dose. The terminal elimination half-life is >20 hours.

Chlorthalidone

Chlorthalidone rapidly concentrates within erythrocytes, resulting in a large volume of distribution. Approximately 75% of the drug is bound to plasma proteins. Chlorthalidone is primarily excreted unchanged in the urine. The elimination half-life of chlorthalidone is approximately 40–60 hours.

5.3 Preclinical safety data

In preclinical safety studies, doses of telmisartan comparable to the clinical therapeutic range caused reduced red cell parameters, changes in renal haemodynamics, increased serum potassium, and in dogs, renal tubular dilation and atrophy. These are pharmacologically-mediated class effects of ARBs. No evidence of mutagenicity, relevant clastogenic activity, or carcinogenicity was found. The combination of telmisartan and chlorthalidone is not expected to produce toxicity not already identified for the individual components.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The following excipients are present in the tablet:

Not fully stated in the submitted SmPC. The applicant should provide a complete excipient list for PPB registration. Based on the telmisartan component, excipients would be expected to include: microcrystalline cellulose, magnesium oxide (light), meglumine, sodium hydroxide, povidone, sodium lauryl sulphate, colloidal anhydrous silica, magnesium stearate, and suitable binders/disintegrants for the chlorthalidone component.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture. Keep out of the reach and sight of children.

6.5 Nature and contents of container

10 tablets packed in one ALU-ALU blister; 3 such blisters packed in one carton with package insert. Pack size: 30 tablets.

6.6 Special precautions for disposal and other handling

No special requirements. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. 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 AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2025/CTD12003/25334

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

20.12.2025

10. DATE OF REVISION OF THE TEXT

20.12.2025