SUMMARY OF PRODUCT CHARACTERISTICS
TELGOOD 80 (Telmisartan Tablets USP 80 mg)

1. NAME OF THE MEDICINAL PRODUCT

TELGOOD 80 (Telmisartan Tablets USP 80 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 80 mg telmisartan.

Excipients with known effect:

Each tablet contains lactose monohydrate and sodium (as sodium lauryl sulphate and sodium starch glycolate). This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'. For warnings regarding lactose, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

White coloured, round, biconvex, film-coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of essential hypertension in adults.

Cardiovascular prevention: Reduction of cardiovascular morbidity in adults with manifest atherothrombotic cardiovascular disease or type 2 diabetes mellitus with documented target organ damage.

4.2 Posology and method of administration

Treatment of essential hypertension

The usually effective dose is 40 mg once daily. Some patients may 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 medicinal products that lower blood pressure may be necessary.

Special populations

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 is contraindicated in patients with severe hepatic impairment. In patients with mild to moderate hepatic impairment, the posology should not exceed 40 mg once daily.

Elderly:

No dose adjustment is necessary for elderly patients.

Paediatric population:

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

Method of administration

Telmisartan tablets are for once-daily oral administration and should be taken with liquid, with or without food.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Second and third trimester of pregnancy (see section 4.6).
- Biliary obstructive disorders.
- Severe hepatic impairment.
- Concomitant use of telmisartan 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

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 (see sections 4.3 and 4.6).

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. These patients can be expected to have reduced hepatic clearance for telmisartan. Telmisartan should be used only with caution in patients with mild to moderate hepatic impairment.

Renovascular hypertension

There is an increased risk of severe hypotension and renal insufficiency when patients with bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney are treated with medicinal products that affect the renin-angiotensin-aldosterone system.

Renal impairment and kidney transplantation

When telmisartan is used in patients with impaired renal function, periodic monitoring of potassium and creatinine serum levels is recommended. There is no experience regarding the administration of telmisartan in patients with a recent kidney transplantation.

Intravascular hypovolaemia

Symptomatic hypotension, especially after the first dose of telmisartan, may occur in patients who are volume and/or sodium depleted by vigorous diuretic therapy, dietary salt restriction, diarrhoea or vomiting. Such conditions should be corrected before the administration of telmisartan.

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 with frequent 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.

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 intercurrent 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. Close monitoring of serum potassium in at-risk patients is 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.

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.

Diabetic patients treated with insulin or antidiabetics

In these patients, hypoglycaemia may occur under telmisartan treatment. Appropriate blood glucose monitoring should be considered; dose adjustment of insulin or antidiabetics may be required when indicated.

Ethnic differences

As observed for ACE inhibitors, telmisartan and other angiotensin II receptor antagonists are apparently less effective in lowering blood pressure in black patients than in non-black patients, possibly because of higher prevalence of low-renin states in the black hypertensive population.

Lactose content

This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

4.5 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.

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 II receptor antagonists including telmisartan. If the combination proves necessary, careful monitoring of serum lithium levels is recommended.

Non-steroidal anti-inflammatory drugs (NSAIDs):

NSAIDs (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, co-administration may result in further deterioration of renal function, including possible acute renal failure, which is usually reversible. Patients should be adequately hydrated and monitoring of renal function should be considered.

Diuretics (thiazide or loop diuretics):

Prior treatment with high-dose diuretics such as furosemide or hydrochlorothiazide may result in volume depletion and a risk of hypotension when initiating therapy with telmisartan.

Other antihypertensive agents:

The blood pressure lowering effect of telmisartan can be increased by concomitant use of other antihypertensive medicinal products. Baclofen and amifostine may potentiate the hypotensive effects. Orthostatic hypotension may be aggravated by alcohol, barbiturates, narcotics or antidepressants. Corticosteroids (systemic use) may reduce the antihypertensive effect. Ramipril: co-administration of telmisartan and ramipril led to an increase of up to 2.5-fold in the AUC0-24 and Cmax of ramipril and ramiprilat; the clinical relevance is not known.

4.6 Fertility, 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 (see section 4.3).

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 medicinal products. Unless continued angiotensin II receptor antagonist therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments with 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 foetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and

neonatal toxicity (renal failure, hypotension, hyperkalaemia). Should exposure 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 during breast-feeding, telmisartan is not recommended and alternative treatments with better-established safety profiles during breast-feeding are preferable, especially while nursing a newborn or preterm infant.

Fertility

In non-clinical studies, no effects of telmisartan on male and female fertility were observed.

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.

4.8 Undesirable effects

Summary of the safety profile

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. Serious adverse reactions include anaphylactic reaction and angioedema (rare) and acute renal failure.

Tabulated list of adverse reactions

Adverse reactions have been accumulated from controlled clinical trials in patients treated for hypertension and from post-marketing reports, including long-term studies involving 21,642 patients treated for the reduction of cardiovascular morbidity for up to six years. Frequencies: 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).

System Organ Class	Frequency	Adverse Reaction
Infections and infestations	Uncommon	Upper respiratory tract infection, urinary tract infection
	Rare	Sepsis including fatal outcome
Blood and lymphatic system disorders	Uncommon	Anaemia
	Rare	Eosinophilia, thrombocytopenia
Immune system disorders	Rare	Anaphylactic reaction, hypersensitivity
Metabolism and nutrition disorders	Uncommon	Hyperkalaemia
	Rare	Hypoglycaemia (in diabetic patients)
Psychiatric disorders	Uncommon	Depression, insomnia
	Rare	Anxiety
Nervous system disorders	Uncommon	Syncope
	Rare	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	Dyspnoea, cough
	Very rare	Interstitial lung disease
Gastrointestinal disorders	Uncommon	Abdominal pain, diarrhoea, dyspepsia, flatulence, vomiting

System Organ Class	Frequency	Adverse Reaction
	Rare	Stomach discomfort, dry mouth, dysgeusia
Hepatobiliary disorders	Rare	Hepatic function abnormal/liver disorder
Skin and subcutaneous tissue disorders	Uncommon	Hyperhidrosis, pruritus, rash
	Rare	Angioedema (also with fatal outcome), eczema, erythema, urticaria, toxic skin eruption
Musculoskeletal disorders	Uncommon	Myalgia, back pain, muscle spasms
	Rare	Arthralgia, pain in extremity, tendon pain
Renal and urinary disorders	Uncommon	Renal impairment including acute renal failure
General disorders	Uncommon	Chest pain, asthenia
	Rare	Influenza-like illness
Investigations	Uncommon	Blood creatinine increased
	Rare	Blood uric acid increased, hepatic enzyme increased, haemoglobin decreased

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; bradycardia could also occur. If overdose occurs, 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, 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 AT1 receptor subtype, which is responsible for the known actions of angiotensin II. Telmisartan does not exhibit any partial agonist activity at the AT1 receptor. Telmisartan selectively binds the AT1 receptor with a long-lasting binding. Telmisartan does not inhibit human plasma renin or block ion channels, and does not inhibit ACE (kininase II). Plasma aldosterone levels are decreased by telmisartan. 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.

Clinical efficacy and safety

After the first dose of telmisartan, the antihypertensive activity gradually becomes evident within 3 hours. The maximum reduction in blood pressure is generally attained 4 to 8 weeks after the start of treatment and is sustained during long-term therapy. In patients with hypertension, telmisartan reduces both systolic and diastolic blood pressure without affecting pulse rate. Telmisartan demonstrated non-inferiority to ramipril in cardiovascular mortality and morbidity in the ONTARGET trial (n=25,620 patients), with fewer cough and angioedema events compared to ramipril.

Paediatric population

The safety and efficacy of telmisartan in children and adolescents aged below 18 years have not been established. Blood pressure-lowering effects were demonstrated in 76 hypertensive patients aged 6 to <18 years, but these data do not allow conclusions on the efficacy and safety of telmisartan in hypertensive paediatric populations.

5.2 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 AUC0-∞ varies from approximately 6% (80 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. There is no linear relationship between doses and plasma levels; Cmax and to a lesser extent AUC increase disproportionately at doses above 80 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 is approximately 500 litres.

Biotransformation

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

Elimination

Telmisartan has a terminal elimination half-life of >20 hours. After oral administration, telmisartan is nearly exclusively excreted with the faeces, mainly as unchanged compound. Cumulative urinary excretion is <1% of dose. Total plasma clearance is high (approximately 1,000 ml/min) compared with hepatic blood flow (about 1,500 ml/min).

Special populations

Renal impairment: In patients with mild to moderate and severe renal impairment, doubling of plasma concentrations was observed. Telmisartan is highly bound to plasma protein in renal-insufficient patients and cannot be removed by dialysis.

Hepatic impairment: Pharmacokinetic studies showed an increase in absolute bioavailability up to nearly 100% in patients with hepatic impairment.

Gender: Cmax and AUC are approximately 3- and 2-fold higher, respectively, in females compared to males.

Elderly: The pharmacokinetics of telmisartan do not differ between the elderly and those younger than 65 years.

5.3 Preclinical safety data

In preclinical safety studies, doses producing exposure comparable to the clinical therapeutic range caused reduced red cell parameters, changes in renal haemodynamics, increased serum potassium in normotensive animals, and renal tubular dilation and atrophy in dogs. These pharmacologically-mediated effects are known class effects of ARBs. No clear evidence of a teratogenic effect was observed; however, at toxic dose levels of telmisartan, an effect on postnatal development was observed. There was no evidence of mutagenicity, relevant clastogenic activity, or carcinogenicity in rats and mice.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The following excipients are present in the film-coated tablet:

No.	Ingredient
1	Microcrystalline cellulose (MCC 102)
2	Magnesium oxide, light
3	Meglumine (N-methyl glucamine)
4	Sodium lauryl sulphate
5	Sodium starch glycolate
6	Povidone (PVP K-30)
7	Isopropyl alcohol
8	Magnesium stearate
9	Talc
10	Colloidal anhydrous silica (fumed silica)
11	Film coat (ready-mix colour coat)
12	Methylene dichloride

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

6.6 Special precautions for disposal and other handling
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)
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