

SUMMARY OF PRODUCT CHARACTERISTICS

LOSARGOOD 50H (Losartan Potassium 50 mg / Hydrochlorothiazide 12.5 mg Film-Coated Tablets)

1. NAME OF THE MEDICINAL PRODUCT

LOSARGOOD 50H (Losartan Potassium 50 mg and Hydrochlorothiazide 12.5 mg Film-Coated Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains losartan potassium 50 mg and hydrochlorothiazide 12.5 mg.

Excipients with known effect:

Contains lactose. Contains azo dye colourants (Ponceau 4R lake, tartrazine lake, and indigo carmine lake). For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

Yellow coloured, round, biconcave, film-coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

LOSARGOOD 50H is indicated for the treatment of essential hypertension in adult patients whose blood pressure is not adequately controlled on losartan or hydrochlorothiazide alone. LOSARGOOD 50H is not for use as initial antihypertensive therapy.

4.2 Posology and method of administration

Hypertension

Dose titration with the individual components (losartan and hydrochlorothiazide) is recommended before prescribing the fixed combination. When clinically appropriate, direct change from losartan or hydrochlorothiazide monotherapy to the fixed combination may be considered.

The usual maintenance dose is one tablet (losartan 50 mg/HCTZ 12.5 mg) once daily. For patients who do not respond adequately, the dose may be increased to a maximum of 2 tablets of LOSARGOOD 50H once daily, or one tablet of the 100 mg/25 mg strength once daily. The antihypertensive effect is generally attained within 3–4 weeks after initiation of therapy.

Renal impairment and haemodialysis

No initial dose adjustment is necessary in moderate renal impairment (creatinine clearance 30–50 ml/min). LOSARGOOD 50H is not recommended for haemodialysis patients and must not be used in patients with severe renal impairment (creatinine clearance <30 ml/min).

Volume and/or sodium depletion

Volume and/or sodium depletion should be corrected prior to administration.

Hepatic impairment

LOSARGOOD 50H is contraindicated in patients with severe hepatic impairment.

Elderly

Dose adjustment is not usually necessary for elderly patients.

Paediatric population

Safety and efficacy in children and adolescents under 18 years have not been established. LOSARGOOD 50H should not be used in this age group.

Method of administration

Oral. Swallowed with a glass of water. May be administered with or without food.

4.3 Contraindications

- Hypersensitivity to losartan, sulphonamide-derived substances (hydrochlorothiazide is a sulphonamide derivative), or to any of the excipients listed in section 6.1.
- Therapy-resistant hypokalaemia or hypercalcaemia.
- Severe hepatic impairment; cholestasis and biliary obstructive disorders.
- Refractory hyponatraemia.
- Symptomatic hyperuricaemia/gout.
- Second and third trimesters of pregnancy (see section 4.6).
- Severe renal impairment (creatinine clearance <30 ml/min).
- Anuria.
- Concomitant use with aliskiren-containing products in patients with diabetes mellitus or renal impairment (GFR <60 ml/min/1.73 m²).

4.4 Special warnings and precautions for use

Losartan

Angioedema: Patients with a history of angioedema (swelling of face, lips, throat and/or tongue) should be closely monitored. Hypotension and intravascular volume depletion: Symptomatic hypotension, especially after the first dose, may occur in volume- and/or sodium-depleted patients. Such conditions should be corrected before administration. Electrolyte imbalances: Monitor plasma potassium and creatinine clearance closely, especially in patients with heart failure (CrCl 30–50 ml/min). Concomitant use of potassium-sparing diuretics, potassium supplements or potassium-containing salt substitutes is not recommended. Renal impairment: Changes in renal function, including renal failure, have been reported. Use with caution in bilateral renal artery stenosis or artery to a solitary kidney. Dual RAAS blockade: Not recommended; if considered absolutely necessary, this should only occur under specialist supervision. Pregnancy: AllRAs should not be initiated during pregnancy (see sections 4.3 and 4.6). Non-melanoma skin cancer (NMSC): Although NMSC risk is primarily associated with HCTZ, see below. Ethnic differences: Losartan may be less effective in Black patients.

Hydrochlorothiazide

Electrolyte/fluid imbalance: Monitor for volume depletion, hyponatraemia, hypochloraemic alkalosis, hypomagnesaemia or hypokalaemia, especially with intercurrent diarrhoea or vomiting. Dilutional hyponatraemia may occur in oedematous patients in hot weather. Metabolic effects: Thiazide therapy may impair glucose tolerance; antidiabetic dose adjustment may be required. Latent diabetes mellitus may become manifest. Thiazides may decrease urinary calcium excretion and cause mild hypercalcaemia; discontinue before parathyroid function tests. Increases in cholesterol and triglycerides may occur. Hyperuricaemia and/or gout may be precipitated (attenuated by the uricosuric effect of losartan). Non-melanoma skin cancer (NMSC): An increased risk of BCC and SCC with increasing cumulative dose of HCTZ has been observed in epidemiological studies. Patients should be informed of the risk and advised to regularly check their skin for new lesions. Sun protection measures are recommended. Hepatic impairment: Minor fluid and electrolyte imbalance may precipitate hepatic coma in patients with impaired hepatic function or progressive liver disease. Hypersensitivity: May occur with or without a history of allergy or bronchial asthma. Exacerbation or activation of systemic lupus erythematosus has been reported. Anti-doping: Hydrochlorothiazide may produce a positive result in anti-doping tests.

Lactose and dye content

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

This product contains azo dyes (Ponceau 4R lake / E124, tartrazine lake / E102 and indigo carmine lake / E132). These may cause allergic reactions, particularly in patients who are sensitive to aspirin.

4.5 Interaction with other medicinal products and other forms of interaction

Losartan

Rifampicin and fluconazole have been reported to reduce levels of the active metabolite. Potassium-raising agents (potassium-sparing diuretics, potassium supplements, salt substitutes): serum potassium may increase; co-medication not advisable. Lithium: diuretics reduce renal clearance of lithium — risk of toxicity; concomitant use not recommended. NSAIDs (including selective COX-2 inhibitors): may attenuate the antihypertensive effect and increase the risk of worsening renal function including acute renal failure, especially in the elderly. Dual RAAS blockade: higher risk of hypotension, hyperkalaemia and renal impairment.

Hydrochlorothiazide

Alcohol, barbiturates, narcotics or antidepressants: potentiation of orthostatic hypotension. Antidiabetic agents: HCTZ may influence glucose tolerance; dose adjustments may be required; metformin should be used with

caution due to lactic acidosis risk. Other antihypertensives: additive effect. Cholestyramine/colestipol: reduce HCTZ absorption by up to 85% and 43%, respectively; administer separately. Corticosteroids, ACTH: intensified electrolyte depletion (particularly hypokalaemia). Lithium: diuretics increase the risk of lithium toxicity; concomitant use not recommended. Digitalis glycosides: HCTZ-induced hypokalaemia or hypomagnesaemia may favour digitalis-induced arrhythmias. QT-prolonging drugs: periodic monitoring of serum potassium and ECG is recommended, as hypokalaemia is a predisposing factor to torsades de pointes. Iodine contrast media: in case of dehydration, increased risk of acute renal failure; patients should be rehydrated before administration. Calcium salts: thiazides may increase serum calcium; calcium levels should be monitored if calcium supplements are prescribed. Carbamazepine: risk of symptomatic hyponatraemia. Amphotericin B, corticosteroids, ACTH, stimulant laxatives, glycyrrhizin: may intensify electrolyte imbalance, particularly hypokalaemia. Other hypotensive agents (tricyclic antidepressants, baclofen, amifostine, antipsychotics): may increase the risk of hypotension.

4.6 Fertility, pregnancy and lactation

Pregnancy

AllIRAs: Use not recommended during the first trimester; contraindicated during the second and third trimesters. Exposure during the second and third trimesters induces human foetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia). Infants whose mothers have taken AllIRAs should be closely observed for hypotension. Hydrochlorothiazide: crosses the placenta. Use during the second and third trimesters may compromise foeto-placental perfusion and may cause foetal and neonatal icterus, electrolyte disturbance and thrombocytopenia. HCTZ should not be used for gestational oedema, gestational hypertension or pre-eclampsia.

Breast-feeding

Losartan: Not recommended; alternative treatments with better established safety profiles are preferable, especially while nursing a newborn or preterm infant. Hydrochlorothiazide: excreted in human milk in small amounts; thiazides in high doses causing intense diuresis can inhibit milk production. Use of LOSARGOOD 50H during breast-feeding is not recommended.

Fertility

No human data are available.

4.7 Effects on ability to drive and use machines

Dizziness or drowsiness may occasionally occur when taking antihypertensive therapy, particularly during initiation or when the dose is increased.

4.8 Undesirable effects

Summary of the safety profile

In controlled clinical trials for essential hypertension, dizziness was the only adverse reaction reported as drug-related with an incidence greater than placebo in $\geq 1\%$ of patients treated with losartan/HCTZ. Adverse reactions associated with the individual components are possible.

Source	System Organ Class	Adverse Reaction	Frequency
Combination	Hepatobiliary	Hepatitis	Rare
Combination	Investigations	Hyperkalaemia, elevated ALT	Rare
Losartan	Gastrointestinal	Abdominal pain, nausea, diarrhoea, dyspepsia	Common
Losartan	General	Asthenia, fatigue, chest pain	Common
Losartan	Immune system	Anaphylaxis, angioedema (larynx, glottis, face, lips, pharynx, tongue)	Rare
Losartan	Musculoskeletal	Muscle cramps, back pain, myalgia	Common
Losartan	Investigations	Hyperkalaemia; mild reduction in haematocrit/haemoglobin; hypoglycaemia	Common
Losartan	Renal and urinary	Renal impairment, renal failure	Common
Losartan	Respiratory	Cough, upper respiratory infection, nasal congestion	Common
HCTZ	Blood/lymphatic	Agranulocytosis, aplastic anaemia, haemolytic anaemia, leucopenia, thrombocytopenia	Uncommon

Source	System Organ Class	Adverse Reaction	Frequency
HCTZ	Metabolism	Anorexia, hyperglycaemia, hyperuricaemia, hypokalaemia, hyponatraemia	Uncommon
HCTZ	Renal	Glycosuria, interstitial nephritis, renal dysfunction, renal failure	Uncommon
HCTZ	Neoplasms	Non-melanoma skin cancer (BCC and SCC)	Not known

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

No specific information is available for losartan/HCTZ overdose. Treatment is symptomatic and supportive. Therapy should be discontinued and the patient observed closely. Losartan: most likely manifestations are hypotension and tachycardia; bradycardia from vagal stimulation is possible. Neither losartan nor its active metabolite can be removed by haemodialysis. HCTZ overdose: signs are electrolyte depletion (hypokalaemia, hypochloraemia, hyponatraemia) and dehydration from excessive diuresis. If digitalis has also been administered, hypokalaemia may accentuate cardiac arrhythmias. The degree to which HCTZ is removed by haemodialysis has not been established.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Agents acting on the renin-angiotensin system; angiotensin II antagonists and diuretics. ATC code: C09DA01.

The components of LOSARGOOD 50H have been shown to have an additive antihypertensive effect, reducing blood pressure to a greater degree than either component alone. Hydrochlorothiazide (HCTZ): a thiazide diuretic that inhibits the renal tubular mechanism of electrolyte reabsorption, directly increasing excretion of sodium and chloride. Diuretic action reduces plasma volume and increases plasma renin activity, aldosterone secretion and angiotensin II levels. Administration of losartan blocks all physiologically relevant actions of angiotensin II and, through inhibition of aldosterone, tends to attenuate the potassium loss associated with HCTZ. Losartan also has a mild uricosuric effect that attenuates the diuretic-induced hyperuricaemia. The antihypertensive effect of losartan/HCTZ is sustained for 24 hours. The combination is effective in males and females, Black and non-Black patients, and in younger and older patients. See section 4.4 regarding efficacy data in Black patients with LVH (LIFE study).

5.2 Pharmacokinetic properties

Losartan: see LOSARGOOD 50 SmPC (section 5.2) for full details. Briefly: bioavailability approximately 33%; >99% protein-bound; terminal half-life of losartan approximately 2 hours, active metabolite 6–9 hours; eliminated via bile and urine; not removed by haemodialysis. Plasma concentrations in elderly hypertensives are not significantly different from those in young hypertensives.

Hydrochlorothiazide: not metabolised; eliminated rapidly by the kidney. Plasma half-life 5.6–14.8 hours. At least 61% of the oral dose is eliminated unchanged within 24 hours. Distributes across the placenta but not the blood-brain barrier; excreted in breast milk.

5.3 Preclinical safety data

No special hazard for humans based on conventional studies of general pharmacology, genotoxicity and carcinogenic potential for the combination. Changes in chronic toxicity studies were mainly produced by the losartan component. No teratogenicity in rats or rabbits; foetal toxicity was observed in rats exposed during late gestation and/or lactation. Hydrochlorothiazide has been shown to be non-genotoxic in standard assays.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Starch, dichloromethane, hydroxypropyl methylcellulose (HPMC), isopropyl alcohol, sodium starch glycolate, Ponceau 4R lake (E124; excipient with known effect), Aerosil (colloidal silicon dioxide), tartrazine lake (E102;

excipient with known effect), sodium carboxymethylcellulose (sodium CMC), indigo carmine lake (E132; excipient with known effect), magnesium stearate, titanium dioxide (E171), propylene glycol.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store in a dry place at a temperature below 30°C. Keep out of the reach and sight of children.

6.5 Nature and contents of container

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

6.6 Special precautions for disposal and other handling

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

7. MARKETING AUTHORISATION HOLDER

SHALINA HEALTHCARE KENYA LIMITED

Mombasa/Block XXX/178, Nkurumah Road,
P.O. Box 80436-80100, Mombasa, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2026/CTD12076/25311

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

17.02.2026

10. DATE OF REVISION OF THE TEXT

17.02.2026