Cozaar® (losartan potassium)

PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics before prescribing

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MSD UK (Tel: 01992 467272).
By clicking the above link you will leave the MSD website and be taken to the MHRA website.

PRESENTATION

Tablets containing 12.5 mg, 25 mg, 50 mg or 100 mg losartan potassium.

USES
Treatment of essential hypertension in adults, children and adolescents 6-18 years of age.
Treatment of renal disease in adults with hypertension and type 2 diabetes mellitus with proteinuria ≥ 0.5 g/day, as part of an antihypertensive treatment.
Treatment of chronic heart failure in adults when treatment with ACE inhibitors is not considered suitable. Do not switch patients with heart failure who have been stabilised with an ACE inhibitor to losartan. Patients should have a LVEF ≤ 40%, be clinically stable and on an established treatment regimen for chronic heart failure.
Reduction in the risk of stroke in adult hypertensive patients with left ventricular hypertrophy documented by ECG.

DOSAGE AND ADMINISTRATION:
Swallow tablets whole with a glass of water. *Hypertension:* Starting and maintenance dose is 50 mg once daily. Some patients may benefit from 100 mg once daily. May be administered with other antihypertensive agents, especially diuretics. *Hypertensive type II diabetic patients with proteinuria ≥ 0.5 g/day:* Starting dose is 50 mg once daily with increase to 100 mg once daily based on response from one month onwards after initiation of therapy. May be administered with other antihypertensive agents, insulin and other commonly used hypoglycaemic agents. *Heart failure:* Usual initial dose is 12.5 mg once daily. Titrate at weekly intervals (i.e.12.5 mg daily, 25 mg daily, 50 mg daily, 100 mg daily) to maximum of 150 mg once daily, as tolerated. *Reduction in the risk of stroke in hypertensive patients with LVH documented by ECG:* Usual starting dose is 50 mg once daily. Add a low dose of hydrochlorothiazide and/ or increase the dose of losartan to 100 mg once daily based on blood pressure response. *Use in patients with intravascular volume depletion:* Consider a starting dose of 25 mg once daily. *Use in patients with renal impairment and haemodialysis patients*: No dose adjustment necessary. *Use in patients with hepatic impairment*: Consider a lower dose for patients with a history of hepatic impairment. *Paediatric population*: 6 - 18 years: Recommended dose is 25 mg once daily in patients >20 to <50 kg up to a maximum of 50 mg once daily. Adjust dosage according to response. In patients >50 kg, use 50 mg once daily, up to a maximum of 100 mg once daily. Doses above 1.4 mg/ kg (or in excess of 100 mg) daily have not been studied. Not recommended in children <6 years, in children with glomerular filtration rate <30ml/ min/1.73m2, or in children with hepatic impairment. *Use in elderly:* Consider initiating therapy with 25 mg in patients ≥75 years.

CONTRA-INDICATIONS: Hypersensitivity, 2nd and 3rd trimester of pregnancy, severe hepatic impairment, concomitant use with aliskiren containing products with patients with diabetes mellitus or renal impairment.

PRECAUTIONS: *Hypersensitivity*: monitor patients with a history of angioedema. *Hypotension and electrolyte/fluid imbalance*: Symptomatic hypotension, after the first dose and after increasing the dose, may occur in patients who are volume and/or sodium-depleted by vigorous diuretic therapy, dietary salt restriction, diarrhoea or vomiting. Correct these conditions prior to administration or use a lower starting dose. *Electrolyte imbalances*: Common in patients with renal impairment, with or without diabetes. Monitor plasma concentrations of potassium and creatinine clearance values. Concomitant use of potassium sparing diuretics, potassium supplements, potassium containing salt substitutes, or other drugs that may increase serum potassium (e.g. trimethoprim-containing products) is not recommended. *Hepatic impairment:* Consider using a lower dose. Not recommended for severe hepatic impairment. *Renal impairment:* changes in renal function including renal failure have been reported. Use with caution in patients with bilateral renal artery stenosis or stenosis of the artery to a solitary kidney.

Paediatric patients with renal impairment: Monitor renal function regularly, particularly in the presence of other conditions (fever, dehydration) likely to impair renal function. Concomitant use with ACE inhibitors is not recommended. *Renal transplants:* No experience. *Primary hyperaldosteronism:* not recommended. *Coronary heart disease and cerebrovascular disease:* As with any antihypertensive agents, excessive blood pressure decrease in patients with ischaemic cardiovascular and cerebrovascular disease could result in a myocardial infarction or stroke. *Heart failure:* Use with caution as there is a risk of severe arterial hypotension and renal impairment. Combination with a beta blocker should be used with caution. *Aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy:* use with caution. *Excipients:* Contains lactose. Not recommended for patients with galactose intolerance, Lapp lactase deficiency or glucose galactose malabsorption. General: losartan and other angiotensin antagonists are less effective in lowering blood pressure in black people than in non-blacks.

Drug interactions: Other antihypertensive agents: may increase the hypotensive action of losartan. Fluconazole decreases exposure to active metabolite by approximately 50% Other substances inducing hypotension (e.g. tricyclic antidepressants, antipsychotics, baclofen, amifostine): may increase the risk of hypotension. Drugs which retain potassium (e.g. potassium sparing diuretics: amiloride, triamterene, spironolactone) or may increase potassium levels (e.g. heparin, trimethoprim-containing products potassium supplements or salt substitutes containing potassium): may lead to increases in serum potassium. Co medication is not advisable. Lithium: rare cases of lithium toxicity have been reported. Co-administer with caution. If combination is essential, monitor serum lithium levels. NSAIDS: attenuation of the antihypertensive effect may occur and may lead to an increased risk of worsening of renal function especially in patients with poor pre-existing renal function. Administer with caution, especially in the elderly. Clinical trial data have shown that dual blockade of the renin-angiotensin-aldosterone system (RAAS) through the combined use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren is associated with a higher frequency of adverse events such as hypotension, hyperkalaemia and decreased renal function compared to the use of a single RAAS-acting agent.

Pregnancy: not recommended during first trimester and contra-indicated during 2nd and 3rd trimester. Breast feeding: not recommended.

SIDE EFFECTS

Refer to Summary of Product Characteristics for complete information on side-effects

Common: anaemia, dizziness, vertigo, (orthostatic) hypotension, renal impairment, renal failure, asthenia, fatigue, increase in blood urea, serum creatinine and serum potassium, hyperkalaemia, hypoglycaemia.

Serious: *Uncommon:* dyspnoea, oedema palpitations, angina pectoris. *Rare:* vasculitis including Henoch-Schonlein purpura, hypersensitivity, anaphylaxis, angioedema including swelling of the larynx, glottis, face, lips, pharynx, and/or tongue (causing airway obstruction) paraesthesia, syncope, atrial fibrillation, cerebrovascular accident, hepatitis, increase in ALT. *Frequency not known:* thrombocytopenia, depression, pancreatitis, liver function abnormalities, myalgia, arthralgia, rhabdomyolysis, hyponatraemia, dysgeusia, tinnitus.

Paediatric population: similar adverse reaction as seen in adult patients. Data in the paediatric population are limited.

PACKAGE QUANTITIES AND BASIC NHS COST

12.5 mg tablets: £9.70 for 28-day pack.
25 mg tablets: £16.18 for 28-day pack.
50 mg tablets: £12.80 for 28-day pack.
100 mg tablets: £16.18 for 28-day pack.

Marketing Authorisation number

12.5 mg tablets: PL 00025/0515
25 mg tablets: PL 00025/0336
50 mg tablets: PL 00025/0324
100 mg tablets: PL 00025/0416

Marketing Authorisation holder

Merck Sharp & Dohme Limited
Hertford Road, Hoddesdon, Hertfordshire
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Legal Category: POM

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