

Carditan[®] (Tablets)



22300

Ref. No: B2122300/22.01

Losartan Potassium
Angiotensin Receptor Blocker
Antihypertensive

CARDITAN[®] 50MG TABLETS (FILM COATED)

PRESENTATION:

Carditan[®] Tablets 50mg: White, circular, biconvex film coated tablet embossed 'C' on one side and a breakline on the other side. Each film coated tablet contains: Losartan Potassium 50mg, Lactose and other excipients.

CLINICAL PHARMACOLOGY:

Losartan is an angiotensin II receptor antagonist with antihypertensive activity due mainly to selective blockade of AT₁ receptors and the consequent reduced pressor effect of angiotensin II.

Pharmacokinetics:

Losartan is readily absorbed from the gastrointestinal tract after oral doses, but undergoes substantial first-pass metabolism resulting in a systematic bioavailability of about 33%. It is metabolised to an active carboxylic acid metabolite E-3174 (EXP-3174), which has greater pharmacological activity than losartan; some inactive metabolites are also formed. Metabolism is primarily by cytochrome P450 isoenzymes CYP2C9 and CYP3A4. Peak plasma concentrations of losartan and E-3174 occur about 1 hour and 3 to 4 hours, respectively, after an oral dose. Both losartan and E-3174 are more than 98% bound to plasma proteins. Losartan is excreted in the urine, and in the faeces via bile, as unchanged drug and metabolites. About 4% of an oral dose is excreted unchanged in the urine and about 6% is excreted in urine as the active metabolite. The terminal elimination half-lives of losartan and E-3174 are about 1.5 to 2.5 hours and 3 to 9 hours, respectively.

USES:

It is used in the management of hypertension particularly in patients who develop cough with ACE inhibitors and to reduce the risk of stroke in patient with left ventricular hypertrophy, and in the treatment of diabetic nephropathy. It has also been tried in heart failure and in myocardial infarction.

DOSAGE AND ADMINISTRATION:

Losartan is given by mouth as the potassium salt. The maximum hypotensive effect is achieved in about 3 to 6 weeks after initiating treatment. In **hypertension** the usual dose is 50mg once daily. The dose may be increased, if necessary, to 100mg daily as a daily dose or in two divided doses. An initial dose of 25mg once daily should be given to patients with intravascular fluid depletion, and is recommended in the elderly over 75 years of age. Similar reductions may be appropriate in patients with hepatic or renal impairment. Children aged 6 years or over with hypotension may be given an initial dose of 700 micrograms/kg once daily, with a maximum of 50mg, adjusted according to response.

In **diabetic nephropathy** Losartan is given in an initial dose of 50mg once daily, increased to 100mg once daily depending on the blood pressure.

CONTRA-INDICATIONS AND WARNINGS:

Precautions:

Losartan is contra-indicated in pregnancy. It should be used with caution in patients with renal artery stenosis. Losartan is excreted in urine and in bile and reduced doses may therefore be required in patients with renal impairment and should be considered in patients with hepatic impairment. Patients with volume depletion (for example those who have received

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high-dose diuretic therapy) may experience hypotension; volume depletion should be corrected before starting therapy, or a low initial dose should be used. Since hyperkalaemia may occur, serum-potassium concentrations should be monitored, especially in the elderly and patients with renal impairment, and the concomitant use of potassium-sparing diuretics should generally be avoided.

Adverse Effects:

Adverse effects of losartan have been reported to be usually mild and transient, and include dizziness, headache, and dose-related orthostatic hypotension. Hypotension may occur particularly in patients with volume depletion. Impaired renal function and, rarely, rash, urticaria, pruritus, angioedema, and raised liver enzymes values may occur. Hyperkalaemia, myalgia, and arthralgia have been reported. Losartan appears less likely than ACE inhibitors to cause cough. Other adverse effects that have been reported with angiotensin II receptor antagonists include respiratory-tract disorders, back pain, gastrointestinal disturbances, fatigue, and neutropenia.

Interactions:

The antihypertensive effects of Losartan may be potentiated by drugs or other agents that lower blood pressure. An additive hyperkalaemic effect is possible with potassium supplements, potassium-sparing diuretics, or other drugs that can cause hyperkalaemia; losartan and potassium –sparing diuretics should not generally be given together. Losartan and some other angiotensin II receptor antagonists are metabolised by cytochrome P450 isoenzymes and interactions may occur with drugs that affect these enzymes.

Pregnancy and Lactation:

Pregnancy: The use of losartan is not recommended during the first trimester of pregnancy. The use of losartan is contraindicated during the 2nd and 3rd trimester of pregnancy

Lactation: Because no information is available regarding the use of losartan during breastfeeding, losartan is not recommended and alternative treatments with better established safety profiles during breastfeeding are preferable, especially while nursing a newborn or preterm infant.

PHARMACEUTICAL PRECAUTIONS:

Store in a dry place below 30°C. Protect from light. Keep all medicines out of the reach of children.

LEGAL CATEGORY:

Prescription Only Medicine (POM)

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