

LOSARTAN POTASSIUM

ARBLOC

50 mg Film-Coated Tablet

ANGIOTENSIN II RECEPTOR BLOCKER

**FORMULATION:**

Each film-coated tablet contains:

Losartan Potassium 50 mg

PRODUCT DESCRIPTION:

Losartan Potassium 50 mg Film-Coated Tablet is a white to off-white, oblong, biconvex, film-coated tablet.

PHARMACODYNAMICS AND PHARMACOKINETICS:

Losartan Potassium is an angiotensin II receptor antagonist with antihypertensive activity due mainly to selective blockade of AT₁ receptor and the consequent reduced pressor effect of angiotensin II. Losartan Potassium is readily absorbed from the gastrointestinal tract following oral administration, with an oral bioavailability of about 33%. It undergoes first-pass metabolism to form an active carboxylic acid metabolite E-3174 (EXP-3174), which has a greater pharmacological activity than losartan, and some inactive metabolites. 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 feces via bile as unchanged drug and metabolites. Following oral dosing about 35% of the dose is excreted in the urine and about 60% in the feces. The terminal elimination half-lives of losartan and E-3174 are about 1.5 to 2.5 hours and 3 to 9 hours respectively.

INDICATION:

Losartan Potassium is used in the management of hypertension.

DOSAGE AND ADMINISTRATION:

Usual dose is 50 mg once daily.

The dose may be increased, if necessary, to 100 mg daily as a single dose or in two divided doses. An initial dose of 25 mg once daily may be used in the elderly over 75 years, and for patients with moderate to severe renal impairment (creatinine clearance less than 20 mL per minute), or intravascular fluid depletion. A reduced dose should also be considered for patients with hepatic impairment.

Or as prescribed by a physician.

PRECAUTIONS:

Losartan Potassium should be used with care, if at all during breast feeding. It should be used with caution in patients with renal artery stenosis. Reduced doses may be required in patients with renal or hepatic impairment. Patients with volume depletion may experience hypotension.

CONTRAINDICATION:

Losartan Potassium is contraindicated in pregnancy.

PREGNANCY AND LACTATION:

Losartan is contraindicated in pregnancy because it has been associated with fetal toxicity.

DRUG INTERACTIONS:

The antihypertensive effects of losartan may be potentiated by drugs or other agents that lower blood pressure. 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. NSAIDs should be used with caution in patients taking losartan as the risk of renal impairment may be increased, particularly in those who are inadequately hydrated; use of NSAIDs may also attenuate the hypotensive effect of losartan.

ADVERSE DRUG REACTIONS:

Adverse effects include dizziness and dose-related orthostatic hypotension. Hypotension may occur particularly in patients with volume depletion (for example those who have received high-dose diuretics). Losartan Potassium may cause hyperkalaemia in patients with renal disease. Other adverse effects that have been reported with angiotensin II receptor antagonist include respiratory tract disorder, back pain, gastrointestinal disturbances, fatigue and neutropenia.

OVERDOSE AND TREATMENT:

Significant lethality was observed in mice and rats after oral administration of 1000 mg/Kg respectively, about 44 and 170 times the maximum recommended human dose on a mg/m² basis. Limited data are available in regard to overdosage in humans. The most likely manifestation of overdosage would be hypotension and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation. If symptomatic hypotension should occur, supportive treatment should be instituted. Neither losartan nor its active metabolite can be removed by haemodialysis.

AVAILABILITY:

White PVDC Blister pack x 10's (Box of 30's)

CAUTION:

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

ADR REPORTING:

For suspected adverse drug reaction, report to the FDA: www.fda.gov/ph

Patient should seek medical attention immediately at the first sign of any adverse drug reaction.

REGISTRATION NUMBER:

DRP-128-10

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14 October 2019

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STORE AT TEMPERATURES NOT EXCEEDING 30°C.

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