LOSARTAN POTASSIUM

WILOPRES®

50 mg and 100 mg Film-Coated Tablet
ANGIOTENSIN II RECEPTOR BLOCKER

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FORMULATION:
Each film-coated tablet contains:
Losartan Potassium ……50 mg and 100 mg

PRODUCT DESCRIPTION:
50 mg: White to off-white, oval, biconvex, film-coated tablet, bisected on one side and plain on the other.
100 mg: White to off-white, oval, biconvex, film-coated tablet, plain on both sides.

PHARMACODYNAMICS:
Losartan Potassium is an angiotensin II receptor antagonist with antihypertensive activity due mainly to selective blockade of AT_1 receptors and the consequent reduced pressor effect of angiotensin II.

PHARMACOKINETICS:
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-1374 (EXP-3174), which has 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-1374 are about 1.5 to 2.5 hours and 3 to 9 hours respectively.

INDICATIONS:
For the management of hypertension, particularly in patients who develop cough with ACE inhibitors; for the treatment of diabetic nephropathy.

DOSAGE AND ADMINISTRATION:
Usual dose is 50 mg once daily.

The dose may be increased if necessary to 100 mg daily as single dose or 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 the physician.

PRECAUTIONS:
Losartan Potassium should be used with care, if at all, during breastfeeding. It should be used with caution in patients with renal artery stenosis. Reduced does 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 effect that has 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 1000mg/kg and 2000mg/kg respectively about 44 and 170 times the maximum recommended human dose on a mg/m^2 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.

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

REGISTRATION NUMBER:
50 mg Film-coated Tablet: DR-XY37022
100 mg Film-coated Tablet: DRP-1667-01

DATE OF FIRST AUTHORIZATION:
50 mg Film-coated Tablet: 26 November 2009
100 mg Film-coated Tablet: 01 August 2016

AVAILABILITY:
50 mg Film-coated Tablet: Alu/White PVDC Blister pack x 10's (Box of 100's)
100 mg Film-coated Tablet: Alu/White PVDC Blister pack x 10's (Box of 100's)

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

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