Ripril™

Ramipril BP

PRESENTATION
Ripril™ 2.5 Tablet: Each tablet contains Ramipril BP 2.5 mg.
Ripril™ 5 Tablet: Each tablet contains Ramipril BP 5 mg.

PHARMACOLOGY
Ramipril is an angiotensin converting enzyme (ACE) inhibitor. This prodrug itself is a poor inhibitor of ACE but is rapidly hydrolyzed after absorption to active metabolite ramiprilat. Following oral administration of ramipril, peak plasma concentration of ramipril is reached within one hour. The extent of absorption is at least 50-60% and is not significantly influenced by the presence of food in the GI tract although the rate of absorption is reduced. Peak plasma concentration of ramiprilat is reached 2-4 hours after drug in take. The serum protein binding of ramipril is about 73% and that of ramiprilat about 56%. Ramiprii is almost completely metabolized to ramirprilat, which has about 6 times the ACE inhibitory activity of ramipril. After oral administration of ramipril, about 60% of the parent drug and its metabolites are eliminated through urine and about 40% is found in the feces.

INDICATIONS
1. Mild to severe hypertension, where it may be used alone or in combination with thiazide diuretics
2. Congestive heart failure
3. To reduce the risk of stroke, myocardial infarction and death from cardiovascular events in patients with a history of cardiovascular diseases
4. Proteinuric non-diabetic nephropathy

DOSAGE & ADMINISTRATION
Dosage of **Ripril**™ must be adjusted according to the patient's tolerance and response.

Hypertension
For the management of hypertension in adults not receiving a diuretic, the usual initial dose of Ramipril is1.25-2.5 mg once daily. Dosage is generally adjusted no more rapidly than at 2-weeks intervals. The usual maintenance dosage in adults is 2.5-20 mg daily given as a single dose or in 2 divided doses daily. If BP is not controlled with ramipril alone, a diuretic may be added.
Congestive Heart Failure after Myocardial Infarction
In this case, ramipril therapy may be initiated as early as 2 days after myocardial infarction.
An initial dose of 2.5 mg twice daily is recommended but if hypotension occurs, dose should be reduced to 1.25 mg twice daily. Therapy is then titrated to a target daily dose of 5 mg twice daily.
Prevention of major cardiovascular events
In this case, the recommended dose is 2.5 mg twice daily for the first week of therapy and 5 mg once daily for the following 3 weeks; dosage then may be increased as tolerated to a maintenance dosage of 10 mg once dally.
Renal Impairment
For the patients with hypertension and renal impairment, the recommended initial dose is 1.25 mg of ramipril once daily. Subsequent dosage should be titrated according to individual tolerance and BP response, up to a maximum of 5 mg daily. For the patients with heart failure and renal impairment, the recommended dose is 1.25 mg once daily. The dose may be increased to 1.25 mg twice daily and up to a maximum dose of 2.5 mg twice daily depending upon clinical response and tolerability.

CONTRAINDICATION
Ramipril is contraindicated in patients who are hypersensitive to any component of this product and in patients with a history of angioedema related to previous treatment with an ACE inhibitor.

SIDE EFFECT
Ramipril is generally well tolerated. Dizziness, headache, fatigue and asthenia are commonly reported side effects. Other side effects occurring less frequently include symptomatic hypotension, cough, nausea, vomiting, diarrhea, rash, urticaria, oliguria, anxiety, amnesia, etc.

WARNINGS
Ramipril should be used with caution in patients with impaired renal function, hyperkalemia, hypotension, surgery/anesthesia and impaired hepatic function.

DRUG INTERACTION
With Diuretics: Patients on diuretics, especially those in whom diuretic therapy was recently instituted, may occasionally experience an excessive reduction of blood pressure after initiation of therapy with ramipril.
With Potassium Supplements and Potassium-Sparing Diuretics: Ramipril can attenuate potassium loss caused by thiazide diuretics. Potassium-sparing diuretics (spironolactone, amiloride, triamterene and others) or potassium supplements can increase the risk of hyperkalemia.
Other: Neither ramipril nor its metabolites have been found to interact with food, digoxin, antacid, furosemide, cimetidine, indomethacin and simvastatin. The combination of ramipril and propranolol showed no adverse effects on dynamic parameters (blood pressure and heart rate). The co-administration of ramipril and warfarin did not adversely affect the anticoagulant effects of the latter drug.

USE IN PREGNANCY AND LACTATION
Pregnancy
If pregnancy is detected, ramipril should be discontinued as early as possible unless continued use is considered lifesaving.
Lactation
Ramipril should not be used during lactation.

USE IN PEDIATRIC PATIENTS
Safety and effectiveness in pediatric patients have not been established.

STORAGE
Store below 30^0 C., protected from light and moisture. Keep out of the reach of children.

HOW SUPPLIED
Ripril™ 2.5 Tablet: Each box contains 30 tablets in blister pack.
Ripril™ 5 Tablet: Each box contains 30 tablets in blister pack.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH