Ramoril®

Ramipril tablet

Presentation:
Ramoril®1.25: Each film coated tablet contains Ramipril BP 1.25mg
Ramoril®2.5: Each film coated tablet contains Ramipril BP 2.5 mg
Ramoril®5: Each film coated tablet contains Ramipril BP 5 mg
Ramoril®10: Each film coated tablet contains Ramipril BP 10 mg

Description:
Ramipril is an angiotensin converting enzyme (ACE) inhibitor, which after hydrolysis to ramiprilat, blocks the conversion of angiotensin I to the vasoconstrictor substance, angiotensin II. So, inhibition of ACE by ramipril results in decreased plasma angiotensin II, which leads to decreased vasopressor activity and decreased aldosterone secretion. Thus ramipril exerts its antihypertensive activity. It is also effective in the management of heart failure and reduction of the risk of stroke, myocardial infarction and death from cardiovascular events. It is long acting and well tolerated; so, can be used in long term therapy.

Indications and uses:
Ramoril is indicated in the following cases-
- Mild to severe hypertension, where it may be used alone or in combination with thiazide diuretics.
- Congestive heart failure.
- To reduce the risk of stroke, myocardial infarction and death from cardiovascular events in patients with a history of cardiovascular disease.
- Proteinuric non-diabetic nephropathy.

Dosage and administration:
Dosage of Ramoril must be adjusted according to the patient tolerance and response.

Hypertension: For the management of hypertension in adults not receiving a diuretic, the usual initial dose of Ramoril is 1.25 - 2.5 mg once daily. Dosage generally is adjusted no more rapidly than at 2-week 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 Ramoril alone, a diuretic may be added.
Congestive heart failure after myocardial infarction: In this case, Ramoril 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 once 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 daily.
Dosage in renal impairment: For the patients with hypertension and renal impairment, the recommended initial dose is 1.25 mg Ramoril 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.

Contraindications:
Ramoril 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 a ACE inhibitor.

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

Side effects:
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. Angioneurotic edema, anaphylactic reactions and hyperkalemia have also been reported rarely.

Use in pregnancy and lactation:
Pregnancy: Pregnancy should be excluded before start of treatment with Ramipril and avoided during treatment. However, if pregnancy is detected, Ramipril should be discontinued as early as possible unless continued use is considered life saving.
Lactation: Ramipril should not be used during lactation.

Use in children:
No information is yet available on the use of Ramipril in children.

Drug interactions:
Concomitant administration with diuretics may lead to serious hypotension and in addition dangerous hyperkalemia with potassium sparing diuretics. Concomitant therapy with lithium may increase the serum lithium concentration. Reduction in BP may affect the ability to drive and operate machinery and this may be exacerbated by alcohol. NSAIDs may reduce the antihypertensive effect of Ramipril and cause deterioration of renal function.

Overdosage:
Limited data on human overdosage are available. The most likely clinical manifestations would be symptoms attributable to hypotension. Because the hypotensive effect of Ramipril is achieved through vasodilation and effective hypovolemia, it is reasonable to treat Ramipril overdosage by infusion of normal saline solution.

Commercial Pack:
Ramoril®1.25 : Each box contains 5 blister strips of 10 tablets
Ramoril®2.5 : Each box contains 5 blister strips of 10 tablets
Ramoril®5 : Each box contains 5 blister strips of 10 tablets
Ramoril 10 : Each box contains 3 blister strips of 10 tablets

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh

V.N. 02

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