

# Ripril<sup>®</sup> plus

Ramipril + Hydrochlorothiazide

## PRESENTATION

**Ripril<sup>®</sup> plus 2.5/12.5** : Each film coated tablet contains Ramipril BP 2.5 mg and Hydrochlorothiazide BP 12.5 mg.

**Ripril<sup>®</sup> plus 5/25** : Each film coated tablet contains Ramipril BP 5 mg and Hydrochlorothiazide BP 25 mg.

## INDICATION AND USAGE

Treatment of mild to moderate hypertension in patients (in whom combination therapy is appropriate) who have been established on the individual components given in the same proportion.

## DOSAGE AND ADMINISTRATION

*Dose Titration Guided by Clinical Effect*

A patient whose blood pressure is not adequately controlled with ramipril (or another ACE inhibitor) alone or with hydrochlorothiazide (or another thiazide diuretic) alone may be switched to combination therapy with **Ripril plus 2.5/12.5** or **Ripril plus 5/25** tablet.

**Replacement Therapy:** For convenience, patients receiving ramipril and hydrochlorothiazide from separate tablets may instead wish to receive tablets of combination of **Ripril plus 2.5/12.5** or **Ripril plus 5/25**.

If necessary, the dose may be increased to two tablets of **Ripril plus 2.5/12.5** or **Ripril plus 5/25** once daily.

Maximum daily dose: 10 mg ramipril and 50 mg hydrochlorothiazide (four tablets of **Ripril plus 2.5/12.5** or two tablets of **Ripril plus 5/25**).

**Dosage in patients with impaired renal function:** In patients with a creatinine clearance between 60 and 30 ml/min per 1.73 m<sup>2</sup> body surface area, treatment should be initiated with ramipril 1.25 mg monotherapy. If blood pressure is not adequately controlled, the dose of ramipril may be increased to 2.5 mg. If blood pressure is still not controlled, patient may be switched to one tablet of **Ripril plus 2.5/12.5** once daily. Dosage may be titrated upward to **Ripril plus 5/25** until blood pressure is controlled.

## CONTRAINDICATION

This product must not be used in patients with hypersensitivity to ramipril, hydrochlorothiazide or other thiazide diuretics. History of hereditary angioneurotic oedema. Severe impairment of renal function. Haemodynamically relevant unilateral or bilateral renal artery stenosis, mitral stenosis, aortic stenosis, and in patients with low blood pressure (hypotensive patients) or in patients with an unstable circulatory situation (haemodynamically unstable patients) where there might be a risk of life-threatening fall in blood pressure and renal failure. Clinically relevant electrolyte disturbances e.g. hypokalemia, hyponatremia or hypercalcemia which may worsen following treatment.

## SIDE EFFECT

The combination of Ramipril and Hydrochlorothiazide is generally well tolerated. Side effects commonly reported include headache, dizziness, asthenia, nausea, vomiting, hypotension, cough, weakness, diarrhoea, fever, gastric irritation, pulmonary oedema, photosensitivity, electrolyte imbalance, hyperglycaemia, hyperuricaemia and vertigo.

## PRECAUTION

Treatment with Ramipril and Hydrochlorothiazide combination requires regular medical supervision. Generally dehydration, reduced blood volume (hypovolemia) or salt depletion should be corrected before initiating the treatment (in patients with concomitant heart failure, however, this must be carefully weighed against the risk of volume overload).

**Special caution is necessary during the treatment of :** Patients with severe and particularly with malignant hypertension. Patients with concomitant and particularly with severe heart failure. Patients in whom fluid or salt deficiency exists or may develop (as a result of inadequate fluid or salt intake) or as a result of diarrhoea, vomiting or excessive sweating in cases where salt and fluid replacement is inadequate. Patients with haemodynamically relevant renal artery stenosis. In patients with pre-existing impairment of renal function or in kidney transplant patients. White blood cell count should be monitored (more frequent in the initial phase of the treatment) so that leucopenia can be detected. Insufficient experience has been gained concerning the use of Ramipril and Hydrochlorothiazide combination in children.

## USE IN PREGNANCY AND LACTATION

ACE inhibitors can cause foetal and neonatal morbidity and death when administered to pregnant women. Also, thiazides cross the placental barrier and appear in cord blood. There is a risk of foetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions that have occurred in adults. When pregnancy is detected, Ramipril and Hydrochlorothiazide combination should be discontinued as soon as possible. This product is excreted in breast milk. Because of the potential for serious adverse reactions in nursing infants, women receiving Ramipril and Hydrochlorothiazide combination should not breast feed.

## USE IN CHILDREN

Safety and effectiveness in paediatric patients have not been established.

## DRUG INTERACTION

Combination with diuretics or other antihypertensive agents or nitrates and tricyclic antidepressants may potentiate the antihypertensive response to Ramipril and Hydrochlorothiazide combination. Patients previously treated with diuretics may experience a marked drop in blood pressure. Ramipril/Hydrochlorothiazide may weaken the effectiveness of blood sugar lowering medications (antidiabetic agents, e.g. insulin and sulphonylurea derivatives). When Ramipril/Hydrochlorothiazide is administered simultaneously with acetyl salicylic acid or indomethacin, attenuation of antihypertensive effect and moreover acute renal failure may occur. Ramipril / Hydrochlorothiazide may potentiate the effects of alcohol.

## STORAGE CONDITION


Store at a cool & dry place, protected from light & moisture.

## HOW SUPPLIED

**Ripril plus 2.5/12.5** : Each box contains 30 tablets in Alu-Alu blister pack.

**Ripril plus 5/25** : Each box contains 30 tablets in Alu-Alu blister pack.

Manufactured by :

 **SQUARE**  
PHARMACEUTICALS LTD.  
BANGLADESH

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