SINA PISHGAM DAROU NOVIN

کد نسخه نویسی: ۷۲۴۷۹

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RAMIPRIL GP®

5 mg

GENERICOS PORTUGUESES

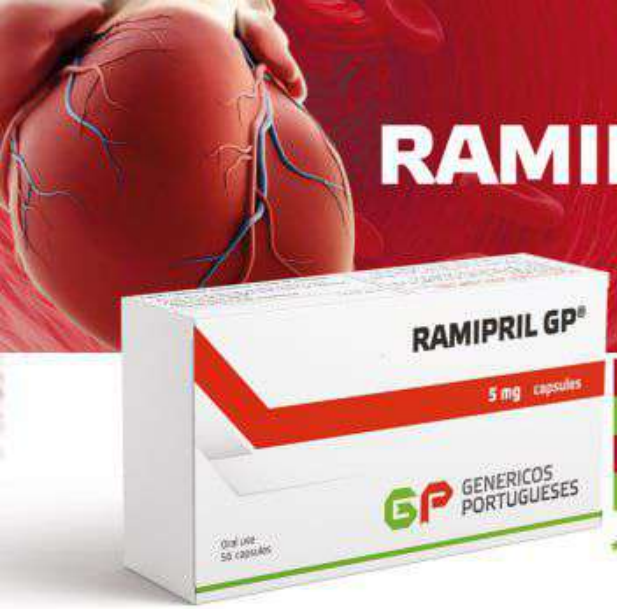
MADE IN PORTUGAL

Key points:

- improved life expectancy
- prevention of heart failure progression following a myocardial infarction (MI)
- reduce the risk of stroke, and mortality
- Rapidly absorbed
- Peak plasma concentration at 1h after oral administration
- Peak effect at 3-6h after ingestion
- Food does not interfere with absorption
- Lowers blood pressure, when lying down and standing
- Hypertension: It can be used in association with other group of anti-hypertensive drugs

RAMIPRIL GP®

5 mg capsules



	Ramipril	Enalapril	Lisinopril	Valsartan	Amlodipine
Absorption	%56	%60	%25	-	-
Bioavailability	%45	%40*	%16	%23	%90-64
Peak plasma conc.	1h	1h	8-5 h	6-4 h	12-6 h
Half-life conc.	17h-13	14-11h	12.6 h	6 h*	50-30 h

*After intravenous administration

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Pharmaceutical Forms: Capsule 5 mg

Pharmacotherapeutic group:
ACE inhibitor (Angiotensin Converting Enzyme Inhibitors)

Indication:
- **Treatment of hypertension.**
- **Cardiovascular prevention: reduction of cardiovascular morbidity and mortality in patients with:**
• Manifest atherothrombotic cardiovascular disease (history of coronary heart disease or stroke, or peripheral vascular disease) or
• Diabetes with at least one cardiovascular risk factor.
- **Treatment of renal disease:**
• Incipient glomerular diabetic nephropathy as defined by the presence of microalbuminuria,
• Manifest glomerular diabetic nephropathy as defined by macroproteinuria in patients with at least one cardiovascular risk factor.
• Manifest glomerular non-diabetic nephropathy as defined by macroproteinuria ≥ 3 g/day.
- **Treatment of symptomatic heart failure.**
- **Secondary prevention after acute myocardial infarction: reduction of mortality from the acute phase of myocardial infarction in patients with clinical signs of heart failure when started > 48 hours following acute myocardial infarction.**

Dosage and Administration;
Hypertension
Adult: Initially 1.25–2.5 mg once daily, increased if necessary up to 10 mg once daily, dose to be increased at intervals of 2–4 weeks
Symptomatic heart failure (adjunct) (under close medical supervision)
Adult: Initially 1.25 mg once daily, increased if tolerated to 10 mg daily, preferably taken in 2 divided doses, increase dose gradually at intervals of 1–2 weeks
Prophylaxis after myocardial infarction in patients with clinical evidence of heart failure (started at least 48 hours after infarction)
Adult: Initially 2.5 mg twice daily for 3 days, then increased to 5 mg twice daily
Prophylaxis after myocardial infarction in patients with clinical evidence of heart failure (started at least 48 hours after infarction) when initial dose not tolerated
Adult: 1.25 mg twice daily for 2 days, then increased to 2.5 mg twice daily, then increased to 5 mg twice daily, withdraw treatment if dose cannot be increased to 2.5 mg twice daily.
Prevention of cardiovascular events in patients with atherosclerotic cardiovascular disease or with diabetes mellitus and at least one additional risk factor for cardiovascular disease
Adult: Initially 2.5 mg once daily for 1–2 weeks, then increased to 5 mg once daily for a further 2–3 weeks, then increased to 10 mg once daily.
Nephropathy (consult product literature)
1.25 mg once daily for 2 weeks, then increased to 2.5 mg once daily for a further 2 weeks, then increased if tolerated to 5 mg once daily.

Pregnancy:
ACE inhibitors such as ramipril, or Angiotensin II Receptor Antagonists (AIIRAs) should not be initiated during pregnancy. Unless continued ACE inhibitor/ AIIRAs therapy is considered essential, patients planning pregnancy should be changed to alternative anti-hypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with ACE inhibitors/ AIIRAs should be stopped immediately.

Breast feeding:
Because insufficient information is available regarding the use of ramipril during breastfeeding, ramipril is not recommended and alternative treatments with better established safety profiles during breast-feeding are preferable, especially while nursing a newborn or preterm infant.

References: https://www.medicines.org.uk/emc/product/7142/smpc#gref Uptodate