

Ramipress®

ramipril

Presentation

Ramipress® 1.25 : Each film-coated tablet contains Ramipril BP 1.25 mg

Ramipress® 2.5 : Each film-coated tablet contains Ramipril BP 2.5 mg

Ramipress® 5 : Each film-coated tablet contains Ramipril BP 5 mg

Ramipress® 10 : Each film-coated tablet contains Ramipril BP 10 mg

Indications, dosage and administration

Mild to moderate hypertension: Initially 1.25 mg once daily, increased at intervals

of 1-2 weeks; usual range 2.5-5 mg once daily; max. 10 mg once daily..

Chronic congestive heart failure (adjunct): Initially 1.25 mg once daily under close medical

supervision, increased if necessary at intervals of 1-2 weeks; max.10mg daily (daily

doses of 2.5 mg or more may be taken in 1-2 divided doses).

Acute myocardial infarction after myocardial infarction in patients with clinical evidence of heart

failure: (Started in hospital 3 to 10 days after infarction), initially 2.5 mg twice daily,

increased after 2 days to 5 mg twice daily, maintenance 2.5-5 mg twice daily

or more. If initial 2.5-mg dose not tolerated, give 1.25 mg twice daily for 2 days before

increasing to 2.5 mg twice daily, then 5 mg twice daily; withdraw if 2.5 mg twice daily

is not tolerated.

Prevention of myocardial infarction, stroke, cardiovascular

events in high risk patients: Initially 2.5 mg once daily, increased

after 1 week to 5 mg once daily, then increased after a further 3 weeks to 10 mg once

daily.

Contraindications

Hypersensitivity to ramipril or any of the excipients. History of angioneurotic oedema,

hemodynamically relevant renal artery stenosis, hypotensive or haemodynamically

unstable patients.

Special warnings and precautions for use

Warnings:

Ramipril should not be used in patients with aortic or mitral valve stenosis or outflow

tract obstruction.

Precautions:

ACE inhibitors need to be initiated with care in patients receiving diuretics; first doses

may cause hypotension especially in patients taking high doses of diuretics on a low

sodium diet, on dialysis, dehydrated or with heart failure. They should also be used

with caution in peripheral vascular disease or generalized atherosclerosis owing to risk

of clinically silent renovascular disease. renal function should be monitored before

starting treatment, and the dose reduced in renal impairment.

The risk of agranulocytosis is possibly increased in collagen vascular disease (blood

counts recommended).

ACE inhibitors should be used with care in patients with severe or symptomatic aortic

stenosis (risk of hypotension).

Ramipril should be used with care (or avoided) in those with a history of idiopathic or

hereditary angioedema.

Anaphylactoid reactions. To prevent anaphylactoid reactions, ACE inhibitors should be

avoided during dialysis with high-flux polyacrylonitrile membranes and during low-

density lipoprotein apheresis with dextran sulphate; they should also be withheld

before desensitisation with wasp or bee venom.

Drug interaction

Combination with diuretics or other antihypertensive agents may potentiate the

antihypertensive response to Ramipril. Adrenergic-blocking drugs should only be

combined with ramipril under careful supervision.

Potassium sparing diuretics (spironolactone, amiloride, triamterene) or potassium

supplements may increase the risk of hyperkalaemia. Ramipril may attenuate the

potassium loss caused by thiazide-type diuretics. If concomitant use of these agents

is indicated, they should be given with caution and serum potassium should be

monitored regularly.

When antidiabetic agents (insulin and sulphonylurea derivatives) are used

concurrently, the possibility of increased blood-sugar reduction must be considered.

When ACE inhibitors are administered simultaneously with non-steroidal anti-

inflammatory drugs (e.g. acetylsalicylic acid and indomethacin), attenuation of the

antihypertensive effect may occur. If Ramipril is given with lithium, an increase in

serum lithium concentration may occur.

Pregnancy and lactation

Pregnancy should be excluded before start of treatment with Ramipril and avoided

during treatment; exposure of the mother to ACE inhibitors in mid or late pregnancy

has been associated with oligohydramnios and neonatal hypotension with anuria and

renal failure.

From animal experiments it is known that use of ramipril may cause a decrease in

uteroplacental perfusion. There is also a potential risk of fetal or post-natal effects

from ACE inhibitors also influence the local renin-angiotensin system. In peri-post natal

studies increased renal pelvic dilatation was observed in the first generation offspring.

However, ramipril was not fetotoxic in our studies although ACE inhibitors have

been shown fetotoxicity in some species. Ramipril should not be used during lactation.

Side-effects

Generally, adverse reactions have been mild and transient, and do not require

discontinuation of therapy. The most frequently reported adverse reactions are

nausea, dizziness and headache.

Storage

Store below 25°C

Commercial packaging

Ramipress® 1.25 : 3 x 10's tablets in Blister Pack.

Ramipress® 2.5 : 3 x 10's tablets in Blister Pack.

Ramipress® 5 : 3 x 10's tablets in Blister Pack.

Ramipress® 10 : 3 x 10's tablets in Blister Pack.

Manufactured by :
 **Silva**
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