Pharmacode position may change as per Supplier's m/c requirement & additional small pharma code may appear on the front / back panel

Summary of Product Characteristics

ANGIRAM

Ramipril Tablets BP 5 mg, 10 mg

RX Only

NAME OF THE DRUG PRODUCT: Ramipril Tablets BP 5 mg
Ramipril Tablets BP 10 mg

(TRADE) NAME OF THE PRODUCT: ANGIRAM 5
ANGIRAM 10

STRENGTH: 5 mg, 10 mg.

PHARMACEUTICAL DOSAGE FORM: Tablets

QUALITATIVE AND QUANTITATIVE COMPOSITIONS:

Each uncoated tablet contains Ramipril Ph.Eur. 5 mg.
Ramipril Tablets BP 10 mg:
Each uncoated tablet contains Ramipril Ph.Eur. 10 mg.

PHARMACEUTICAL FORM

Ramipril Tablets BP 5 mg: Light pink colored mottled, flat faced bevel edged round uncoated tablet debossed with “H” and “19” separated by score line on one side and plain on other side.

Ramipril Tablets BP 10 mg: White to off-white colored, flat faced bevel edged round uncoated tablet debossed with “H” and “20” separated by score line on one side and plain on other side.

CLINICAL PARTICULARS

Therapeutic indications

- Hypertension.
- Congestive heart failure.
- Treatment of patients who – within the first few days after an acute myocardial infarction – have demonstrated clinical signs of congestive heart failure.
- For reducing the risk of myocardial infarction, stroke, cardiovascular death or the need for revascularization procedures in patients 55 years or more who have clinical evidence of coronary artery disease, stroke, or peripheral vascular disease.
- For reducing the risk of myocardial infarction, stroke, cardiovascular death or revascularization procedures in diabetic patients 55 years or more with one or more of the following risk factors: systolic blood pressure > 160 mm Hg or diastolic blood pressure > 90 mm Hg (or on antihypertensive treatment); total cholesterol > 5.2 mmol/L; HDL cholesterol < 0.9 mmol/L; current smoker; known microalbuminuria; any evidence of previous vascular disease.
- Prevention of progressive renal failure in patients with persistent proteinuria.

Posology and method of administration

It is recommended that Angiram is taken each day at the same time of the day.

Can be taken before, with or after meals, because food intake does not modify its bioavailability. The tablet has to be swallowed with liquid. It must not be chewed or crushed.

Dosage

The dosage is based on the desired effect and on how the patient tolerates the medicine. Therapy with Angiram is usually long-term therapy; the doctor determines the duration of treatment individually for each patient.

Treatment of hypertension

The recommended initial dose is 2.5 mg once daily. Depending on the response, the dose may be increased. Any increase should be implemented by doubling the dose at intervals of 2 to 3 weeks. The usual maintenance dose is 2.5 to 5 mg daily, the maximum dose is 10 mg daily.

In impaired renal function, i.e. a creatinine clearance between 50 and 20 ml/min per 1.73 m^2 body surface area, the Initial dose is generally 1.25 mg and the maximum daily dose is 5 mg. When creatinine clearance cannot be measured, it can be calculated based on the serum creatinine level using the following formula (Cockcroft's equation).

$$\text{Men : Creatinine clearance (ml/min)} = \frac{\text{body weight in kg x (140 - age in years)}}{\text{72 x serum creatinine in mg/dl}}$$

Women: Multiply the product of the above equation by 0.85.

In patients with incompletely corrected fluid or salt deficiency, those with severe hypertension, as well as in those for whom a hypotensive reaction would constitute a particular risk (e.g. patients with haemodynamically relevant stenoses of the coronary arteries or of the blood vessels supplying the brain) and in the elderly. A reduced initial dose of 1.25 mg daily must be considered.

In patients pre-treated with a diuretic, consideration must be given to discontinuing the diuretic for at least 2 to 3 days or - depending on the duration of act ion of the diuretic - longer before starting treatment with Angiram, or at least to reducing the diuretic dose. The doctor will decide in each individual case whether such discontinuation or dose reduction is possible and how long it should last. The initial dose in such patients is generally 1.25 mg Angiram.

In impaired liver function, response to treatment may be either increased or decreased. Therefore, treatment must be initiated only under close medical supervision. The maximum daily dose is 2.5 mg.

Treatment of congestive heart failure

The recommended initial dose is 1.25 mg once daily. Depending on the response, the dose may be increased. Any increase should be implemented by doubling the dose at intervals of 1 to 2 weeks. The maximum daily dose is 10 mg. The required daily dose, if equaling or exceeding 2.5 mg, may be taken as a single dose or in two separate doses.

In impaired liver or renal function and in patients pre-treated with a diuretic, dosage recommendations for Angiram are identical to those given above in Treatment of hypertension. The recommendations given there in conjunction with diuretic pre-treatment also apply.

Treatment after myocardial infarction

The recommended initial dose is 5 mg daily, divided into two single doses of 2.5 mg each, one in the morning and one in the evening. If this dose is not well tolerated, 1.25 mg should be taken twice daily over two days. In either event, depending on the response, the dose may then be increased. Any increase should be implemented by doubling the dose at intervals of 1 to 3 days. As treatment progresses, the total daily dose may be taken as a single dose. The maximum daily dose is 10 mg.

Sufficient experience is still lacking in the treatment of patients with severe (NYHA IV) heart failure immediately after myocardial infarction. Treatment, if nevertheless given, should be started with 1.25 mg once daily, and increased only with particular caution.

In patients with impaired liver or renal function, with incompletely corrected fluid or salt deficiency, or with severe hypertension, and in those for whom a hypotensive reaction would constitute a particular risk (e.g. patients with haemodynamically relevant stenoses of the coronary arteries or of the blood vessels supplying the brain), as well as in those pre-treated with a diuretic and in the elderly, the recommendations are identical to those given above in *Treatment of hypertension.*

Prevention of progressive renal failure in patients with persistent proteinuria

The recommended initial dose is 1.25mg Angiram once daily. This should be doubled at intervals of 2-3 weeks, depending on how the drug is tolerated. There are no efficacy data regarding doses above 5 mg/day in patients with nephropathy.

In hypertensive patients, a target diastolic blood pressure of <90mmHg should be pursued. In patients pre-treated with a diuretic, consideration must be given to discontinuing the diuretic for at least 2-3 days or longer (depending on duration of action) or at least consideration should be given to reducing the dose, before initiating Angiram.

Dosage in patients at increased cardiovascular risk

The recommended initial dose is 2.5 mg once daily. Depending on the tolerability, the dose should be doubled after one week of treatment and, after three weeks, should be increased to 10 mg. The usual maintenance dose is Angiram 10 mg daily.

Dosage in patients with impaired renal function

In hypertensive patients with creatinine clearance level of 50 mL/min and above (serum creatinine < 1.5 mg/dL) a dosage adjustment is not required.

For patients with creatinine clearance levels between 20 and 50 mL/min (serum creatinine between 1.5 and 3 mg/dL), the recommended initial dose is 1.25 mg Angiram once daily. This should be doubled at intervals of 2-3 weeks, depending on how the drug is tolerated.

Particular care should be exercised in patients with impaired renal function who are to be treated for heart failure post MI as such patients may be susceptible to hypotension. Patients with impaired renal function treated for heart failure post MI have not been studied systematically.

Dosage in patients with impaired liver function

In patients with impaired liver function, the metabolism of ramipril - and therefore the formation of the bioactive metabolite ramiprilat - is delayed due to diminished activity of the esterases in the liver, resulting in elevated plasma ramipril levels. Treatment with Angiram should therefore be initiated under close medical supervision and should not exceed 2.5 mg daily.

Dosage in elderly

The recommended starting dose is 1.25 mg once daily, which can then be increased according to the individual patient's BP response.

Paediatric population

Angiram is not recommended for use in children and adolescents below 18 years of age due to insufficient data on safety and efficacy.

Contraindications

- Hypersensitivity to the active substance, to any of the excipients or any other ACE (Angiotensin Converting Enzyme) inhibitors.
- History of angioedema (hereditary, idiopathic or due to previous angioedema with ACE inhibitors or AIIRAs).
- Extracorporeal treatments leading to contact of blood with negatively charged surfaces. Significant bilateral renal artery stenosis or renal artery stenosis in a single functioning kidney.
- 2nd and 3rd trimester of pregnancy.
- Ramipril must not be used in patients with hypotensive or haemodynamically unstable states.

Special warnings and precautions for use

Patients with Strongly Activated Renin-Angiotensin-Aldosterone System:Patients with strongly activated renin-angiotensin-aldosterone system are at risk of an acute pronounced fall in blood pressure and deterioration of renal function due to ACE inhibition, especially when an ACE inhibitor or a concomitant diuretic is given for the 1st time or at 1st dose increase.

Significant activation of renin-angiotensin-aldosterone system is to be anticipated and medical supervision including blood pressure monitoring is necessary, for example in patients with severe hypertension; patients with decompensated congestive heart failure; patients with haemodynamically relevant left ventricular inflow or outflow impediment (eg, stenosis of the aortic or mitral valve); patients with unilateral renal artery stenosis with a 2nd functional kidney; patients in whom fluid or salt depletion exists or may develop (including patients with diuretics); patients with liver cirrhosis and/or ascites; patients undergoing major surgery or during anaesthesia with agents that produce hypotension. Generally, it is recommended to correct dehydration, hypovolaemia or salt depletion before initiating treatment (in patients with heart failure, however, such corrective action must be carefully weighed out against the risk of volume overload).

Transient or persistent heart failure post MI.

Patients at Risk of Cardiac or Cerebral Ischemia in Case of Acute Hypotension:The initial phase of treatment requires special medical supervision.

Elderly Patients: See Dosage & Administration.

Surgery:It is recommended that treatment with angiotensin-converting enzyme inhibitors e.g., Ramipril should be discontinued where possible 1 day before surgery.

Monitoring of Renal Function: Renal function should be assessed before and during treatment and dosage adjusted especially in the initial weeks of treatment. Particularly careful monitoring is required in patients with renal impairment (see Dosage & Administration). There is a risk of impairment of renal function, particularly in patients with congestive heart failure or after a renal transplant.

Angioedema: Angioedema has been reported in patients treated with ACE inhibitors including Ramipril. In case of angioedema, ANGIRAM must be discontinued.

Emergency therapy should be instituted promptly. Patient should be kept under observation for at least 12-24 hrs and discharged after complete resolution of the symptoms.

Intestinal angioedema has been reported in patients treated with ACE inhibitors including ANGIRAM. These patients presented with abdominal pain (with or without nausea or vomiting).

Anaphylactic Reactions during Desensitization: The likelihood and severity of anaphylactic and anaphylactoid reactions to insect venom and other allergens are increased under ACE inhibition. A temporary discontinuation of ANGIRAM should be considered prior to desensitization.

Hyperkalaemia: Hyperkalaemia has been observed in some patients treated with ACE inhibitors including ANGIRAM. Patients at risk for development of hyperkalaemia include those with renal insufficiency, age (>70 years), uncontrolled diabetes mellitus or those using potassium salts, potassium-retaining diuretics and other plasma potassium-increasing active substances or conditions eg, dehydration, acute cardiac decompensation, metabolic acidosis. If concomitant use of the above mentioned agents is deemed appropriate, regular monitoring of serum potassium is recommended.

Neutropenia/Agranulocytosis: Neutropenia/agranulocytosis, as well as thrombocytopenia and anaemia, have been rarely seen and bone marrow depression has also been reported. It is recommended to monitor the white blood cell count to permit detection of a possible leucopoenia. More frequent monitoring is advised in the initial phase of treatment and in patients with impaired renal function, those with concomitant collagen disease (e.g., lupus erythematosus or scleroderma) and all those treated with other medicinal products that can cause changes in the blood picture.

Ethnic Differences: ACE inhibitors cause higher rate of angioedema in Black patients than in Non-Black patients. As with other ACE inhibitors, Ramipril may be less effective in lowering blood pressure in Black people than in Non-Black patients, possibly because of a higher prevalence of hypertension with low renin level in the Black hypertensive population.

Cough: Cough has been reported with the use of ACE inhibitors. Characteristically, the cough is non-productive, persistent and resolves after discontinuation of therapy. ACE inhibitor-induced cough should be considered as part of the differential diagnosis of cough.

Effects on the Ability to Drive or Operate Machinery: Some adverse effects (e.g., symptoms of a reduction in blood pressure e.g., dizziness) may impair the patient's ability to concentrate and react and, therefore, constitute a risk in situations where these abilities are of particular importance (e.g., operating a vehicle or machinery).

This can happen especially at the start of treatment or when changing over from other preparations.

After the 1st dose or subsequent increases in dose, it is not advisable to drive or operate machinery for several hours.

INCREASED RISK OF BIRTH DEFECTS, FOETAL AND NEONATAL MORBIDITY AND DEATH WHEN USED THROUGHOUT PREGNANCY

Interaction with other medicinal products and other forms of interaction

Contra-indicated combinations

Extracorporeal treatments leading to contact of blood with negatively charged surfaces such as dialysis or haemofiltration with certain high-flux membranes (e.g. polyacrylonitril membranes) and low density lipoprotein apheresis with dextran sulphate due to increased risk of severe anaphylactoid reactions. If such treatment is required, consideration should be given to using a different type of dialysis membrane or a different class of antihypertensive agent.

Precautions for use

Potassium salts, heparin, potassium-retaining diuretics and other plasma potassium increasing active substances (including Angiotensin II antagonists, trimethoprim, tacrolimus, ciclosporin): Hyperkalaemia may occur, therefore close monitoring of serum potassium is required.

Antihypertensive agents (e.g. diuretics) and other substances that may decrease blood pressure (e.g. nitrates, tricyclic antidepressants, anaesthetics, acute alcohol intake, baclofen, alfuzosin, doxazosin, prazosin, tamsulosin, terazosin): Potentiation of the risk of hypotension is to be anticipated.

Vasopressor sympathomimetics and other substances (e.g. isoproterenol, dobutamine, dopamine, epinephrine) that may reduce the antihypertensive effect of Angiram: Blood pressure monitoring is recommended.

Allopurinol, immunosuppressants, corticosteroids, procainamide, cytostatics and other substances that may change the blood cell count: Increased likelihood of haematological reactions.

Lithium salts: Excretion of lithium may be reduced by ACE inhibitors and therefore lithium toxicity may be increased. Lithium level must be monitored.

Antidiabetic agents including insulin: Hypoglycaemic reactions may occur. Blood glucose monitoring is recommended.

Non-steroidal anti-inflammatory drugs and acetylsalicylic acid: Reduction of the antihypertensive effect of Angiram is to be anticipated. Furthermore, concomitant treatment of ACE inhibitors and NSAIDs may lead to an increased risk of worsening of renal function and to an increase in kalaemia.

Pregnancy and lactation

Angiram is not recommended during the first trimester of pregnancy and contraindicated during the second and third trimesters of pregnancy.

Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive; however a small increase in risk cannot be excluded. Unless continued ACE inhibitor 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 should be stopped immediately, and, if appropriate, alternative therapy should be started.

ACE inhibitor/Angiotensin II Receptor Antagonist (AIIRA) therapy exposure during the second and third trimesters is known to induce human fetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia). Should exposure to ACE inhibitor have occurred from the second trimester of pregnancy, ultrasound check of renal function and skull is recommended. Newborns whose mothers have taken ACE inhibitors should be closely observed for hypotension, oliguria and hyperkalaemia.

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.

INCREASED RISK OF BIRTH DEFECTS, FOETAL AND NEONATAL MORBIDITY AND DEATH WHEN USED THROUGHOUT PREGNANCY

Undesirable Effects

The safety profile of ramipril includes persistent dry cough and reactions due to hypotension. Serious adverse reactions include angioedema, hyperkalaemia, renal or hepatic impairment, pancreatitis, severe skin reactions and neutropenia/agranulocytosis.

Adverse reactions frequency is defined using the following convention:

Very common; common; uncommon; rare; very rare, not known.

Within each frequency grouping undesirable effects are presented in order of decreasing seriousness.

A/s: 280 x 360 mm ■Black Booklet Size: 35 x 60 mm

AUROBINDO Packaging Development	**Product Name** ANGIRAM	**Component** Leaflet	**Item Code** P1530310	**Date & Time** 22.05.2024 & 04:30 pm
		Version No. 04	**Reason Of Issue** Submission	Reviewed / Approved by
Team Leader: Kiran	**Customer / Country** Malaysia	**No. of Colours :** 01		
Initiator: Shirisha	**Dimensions** 280 x 360 mm			
Artist: SCD	**Pharmacode** 30310	30310		Sign / Date

	Common	Uncommon	Rare	Very rare	Not known
Cardiac disorders		Myocardial ischaemia including angina pectoris or myocardial infarction, tachycardia, arrhythmia, palpitations, oedema peripheral.			
Blood and lymphatic system disorders		Eosinophilia	White blood cell count decreased (including neutropenia or agranulocytosis), red blood cell count decreased, haemoglobin decreased, platelet count decreased.		Bone marrow failure, pancytopenia, haemolytic anaemi.
Nervous system disorders	Headache, dizziness.	Vertigo, paraesthesia, ageusia, dysgeusia,	Tremor, balance disorder.		Cerebral ischaemia including ischaemic stroke and transient ischaemic attack, psychomotor skills impaired, burning sensation, parosmia.
Eye disorders		Visual disturbance including blurred vision.	Conjunctivitis		
Ear and labyrinth disorders			Hearing impaired, tinnitus.		
Respiratory, thoracic and mediastinal disorders	Non-productive tickling cough, bronchitis, sinusitis, dyspnoea.	Bronchospasm including asthma aggravated, nasal congestion.			
Gastrointestinal disorders	Gastrointestinal inflammation, digestive disturbances, abdominal discomfort, dyspepsia, diarrhoea, nausea, vomiting	Pancreatitis (cases of fatal outcome have been very exceptionally reported with ACE inhibitors), pancreatic enzymes increased, small bowel angioedema abdominal pain upper including gastritis, constipation, dry mouth.	Glossitis		Aphtous stomatitis
Renal and urinary disorders		Renal impairment including renal failure acute, urine output increased, worsening of a pre-existing proteinuria, blood urea increased, blood creatinine increased.			
Skin and subcutaneous tissue disorders	Rash in particular maculo popular.	Angioedema; very exceptionally, the airway obstruction resulting from angioedema may have a fatal outcome; pruritus, hyperhidrosis.	Exfoliative dermatitis, urticaria, onycholysis.	Photosensitivity reaction	Toxic epidermal necrolysis, Stevens Johnson syndrome, erythema multiforme, pemphigus, psoriasis aggravated, dermatitis psoriasiform, pemphigoid or lichenoid exanthema or enanthema, alopecia.
Musculoskeletal and connective tissue disorders	Muscle spasms, myalgia.	Arthralgia			
Metabolism and nutrition disorders	Blood potassium increased.	Anorexia, decreased appetite.			Blood sodium decreased
Vascular disorders	Hypotension, orthostatic blood pressure decreased syncope.	Flushing	Vascular stenosis, hypoperfusion vasculitis		Raynaud's phenomenon
General disorders and administration site conditions	Chest pain, fatigue.	Pyrexia	Asthenia		
Immune system disorders					Anaphylactic or anaphylactoid reactions, antinuclear antibody increased.
Hepatobiliary disorders		Hepatic enzymes and/or bilirubin conjugated increased.	Jaundice cholestatic, hepatocellular damage.		Acute hepatic failure, cholestatic or cytolytic hepatitis (fatal outcome has been very exceptional).
Reproductive system and breast disorders		Transient erectile impotence, libido decreased.			Gynaecomastia
Psychiatric disorders		Depressed mood, anxiety, nervousness, restlessness, sleep disorder including somnolence.	Confusional state		Disturbance in attention.

Overdose

Symptoms associated with overdosage of ACE inhibitors may include excessive peripheral vasodilatation (with marked hypotension, shock), bradycardia, electrolyte disturbances, and renal failure. The patient should be closely monitored and the treatment should be symptomatic and supportive. Suggested measures include primary detoxification (gastric lavage, administration of adsorbents) and measures to restore haemodynamic stability, including, administration of alpha 1 adrenergic agonists or angiotensin II (angiotensinamide) administration. Ramiprilat, the active metabolite of ramipril is poorly removed from the general circulation by haemodialysis.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Mechanism of action

Ramiprilat, the active metabolite of the prodrug ramipril, inhibits the enzyme dipeptidyl carboxypeptidase I (synonyms: angiotensin-converting enzyme; kininase II). In plasma and tissue this enzyme catalyses the conversion of angiotensin I to the active vasoconstrictor substance angiotensin II, as well as the breakdown of the active vasodilator bradykinin. Reduced angiotensin II formation and inhibition of bradykinin breakdown lead to vasodilatation.

Since angiotensin II also stimulates the release of aldosterone, ramiprilat causes a reduction in aldosterone secretion. The average response to ACE inhibitor monotherapy was lower in black (Afro-Caribbean) hypertensive patients (usually a low-renin hypertensive population) than in non-black patients.

Pharmacodynamic effects

Antihypertensive properties:

Administration of ramipril causes a marked reduction in peripheral arterial resistance. Generally, there are no major changes in renal plasma flow and glomerular filtration rate. Administration of ramipril to patients with hypertension leads to a reduction in supine and standing blood pressure without a compensatory rise in heart rate.

In most patients the onset of the antihypertensive effect of a single dose becomes apparent 1 to 2 hours after oral administration. The peak effect of a single dose is usually reached 3 to 6 hours after oral administration. The antihypertensive effect of a single dose usually lasts for 24 hours. The maximum antihypertensive effect of continued treatment with ramipril is generally apparent after 3 to 4 weeks. It has been shown that the antihypertensive effect is sustained under long term therapy lasting 2 years.

Abrupt discontinuation of ramipril does not produce a rapid and excessive rebound increase in blood pressure.

Heart failure:

The drug had beneficial effects on cardiac haemodynamics (decreased left and right ventricular filling pressures, reduced total peripheral vascular resistance, increased cardiac output and improved cardiac index). It also reduced neuroendocrine activation.

Pharmacokinetic properties

Pharmacokinetics and Metabolism

Absorption

Following oral administration ramipril is rapidly absorbed from the gastrointestinal tract: peak plasma concentrations of ramipril are reached within one hour. Based on urinary recovery, the extent of absorption is at least 56 % and is not significantly influenced by the presence of food in the gastrointestinal tract. The bioavailability of the active metabolite ramiprilat after oral administration of 2.5 mg and 5 mg ramipril is 45 %.

Peak plasma concentrations of ramiprilat, the sole active metabolite of ramipril are reached 2-4 hours after Ramipril intake. Steady state plasma concentrations of ramiprilat after once daily dosing with the usual doses of ramipril are reached by about the fourth day of treatment.

Distribution

The serum protein binding of ramipril is about 73 % and that of ramiprilat about 56 %.

Metabolism

Ramipril is almost completely metabolised to ramiprilat, and to the diketopiperazine ester, the diketopiperazine acid, and the glucuronides of ramipril and ramiprilat.

Elimination

Excretion of the metabolites is primarily renal.

Plasma concentrations of ramiprilat decline in a polyphasic manner. Because of its potent, saturable binding to ACE and slow dissociation from the enzyme, ramiprilat shows a prolonged terminal elimination phase at very low plasma concentrations.

After multiple once-daily doses of ramipril, the effective half-life of ramiprilat concentrations was 13-17 hours for the 5-10 mg doses and longer for the lower 1.25-2.5mg doses. This difference is related to the saturable capacity of the enzyme to bind ramiprilat.

A single oral dose of ramipril produced an undetectable level of ramipril and its metabolite in breast milk. However the effect of multiple doses is not known.

Patients with renal impairment

Renal excretion of ramiprilat is reduced in patients with impaired renal function, and renal ramiprilat clearance is proportionally related to creatinine clearance. This results in elevated plasma concentrations of ramiprilat, which decrease more slowly than in subjects with normal renal function.

Patients with hepatic impairment

In patients with impaired liver function, the metabolism of ramipril to ramiprilat was delayed, due to diminished activity of hepatic esterases, and plasma ramipril levels in these patients were increased. Peak concentrations of ramiprilat in these patients, however, are not different from those seen in subjects with normal hepatic function.

PHARMACEUTICAL PARTICULARS

List of excipients

Ramipril Tablets BP 5 mg: Starch, Pregelatinized, Lactose Monohydrate, Sodium Hydrogen Carbonate, Croscarmellose Sodium, Ferric Oxide Red, Sodium Stearyl Fumarate.

Ramipril Tablets BP 10 mg: Starch, Pregelatinized, Lactose Monohydrate, Sodium Hydrogen Carbonate, Croscarmellose Sodium, Sodium Stearyl Fumarate.

Incompatibilities

Not applicable.

Shelf life

24 months.

Special precautions for storage

Store in a dry place below 30°C

Nature and contents of container

3x10's Blister

Manufactured by:

AUROBINDO

Aurobindo Pharma Limited, Unit - XV,
Plot No. 17 A, E. Bonangi (V),
Jawaharlal Nehru Pharma City,
Parawada (M), Anakapalli District,
Andhra Pradesh, India.

Product Registration Holder in Malaysia:
Healol Pharmaceuticals Sdn. Bhd,
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Kuala Lumpur, Malaysia.

DATE OF PREPARATION OF THIS LEAFLET
May 2024

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