COMPOSITION*: Acertil AR 5 mg film-coated tablets contain 5 mg perindopril arginine. Contains lactose as excipient. **INDICATIONS*:** Hypertension: Treatment of hypertension. Stable coronary artery disease: Reduction of risk of cardiac events in patients with a history of myocardial infarction and/or revascularisation. Heart failure (Acertil AR 5 mg): Treatment of symptomatic heart failure. **DOSAGE AND ADMINISTRATION*:** One tablet per day in the morning before a meal. Hypertension: starting dose at 5 mg/day that may be increased to 10 mg/day after one month. In patients treated concurrently with a diuretic, use with caution. In patients with a strongly activated renin-angiotensin- aldosterone system, initiate treatment at 2.5 mg/day. *Elderly*: initiate treatment at 2.5 mg/day, that may be increased to 5 mg/day after one month and then to 10 mg. Stable coronary artery disease: 5 mg/day for two weeks, then increased to 10 mg/day, depending on renal function and if 5 mg is well tolerated. *Elderly*: 2.5 mg/day for one week, then 5 mg/day the next week, before increasing up to 10 mg/day. Heart failure: starting dose at 2.5 mg/day that may be increased to 5 mg/day after 2 weeks if tolerated. In severe heart failure and other patients at high risk, treatment initiation under careful supervision. Renal impairment: Clcr ≥ 60 ml/min: 5 mg/day; 30 < Clcr < 60 ml/min: 2.5 mg/day; 15 < Clcr < 30 ml/min: 2.5 mg every other day; Haemodialysed patients: Clcr < 15 ml/min: 2.5 mg on the day of dialysis. Children and adolescents: not recommended. **CONTRAINDICATIONS*:** Hypersensitivity to the active substance, to any of the excipients or to any other ACE inhibitor, history of angioedema associated with previous ACE inhibitor therapy, hereditary or idiopathic angioedema, second and third trimesters of pregnancy (see WARNINGS*, PREGNANCY*, BREASTFEEDING*), concomitant use with aliskiren-containing products in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m²) (see sections INTERACTIONS* and Pharmacodynamic properties), concomitant use with sacubitril/valsartan therapy, Acertil AR must not be initiated earlier than 36 hours after the last dose of sacubitril/valsartan. (see WARNING* and INTERACTIONS*), extracorporeal treatments leading to contact of blood with negatively charged surfaces (see INTERACTIONS*), significant bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney (see WARNING*). **WARNINGS*:** *Hypersensitivity/Angioedema/Intestinal angioedema*: stop treatment and monitor until complete resolution of symptoms. Angioedema associated with laryngeal oedema may be fatal. Combination with sacubitril/valsartan (contraindicated due to the increased risk of angioedema). Sacubitril/valsartan must not be initiated until 36 hours after taking the last dose of perindopril therapy. Perindopril therapy must not be started until 36 hours after the last dose of sacubitril/valsartan. Concomitant use of ACE inhibitors with NEP inhibitors (e.g. racecadotril), mTOR inhibitors (e.g. sirolimus, everolimus, temsirolimus) and gliptins (e.g. linagliptin, saxagliptin, sitagliptin, vildagliptin) may lead to an increased risk of angioedema (e.g. swelling of the airways or tongue, with or without respiratory impairment). Caution should be used when starting racecadotril, mTOR inhibitors (e.g. sirolimus, everolimus, temsirolimus) and gliptins (e.g. linagliptin, saxagliptin, sitagliptin, vildagliptin) in a patient already taking an ACE inhibitor. *Anaphylactoid reactions in patients dialysed with high flux membranes*: use different type of membrane or different class of antihypertensive agent. *Anaphylactoid reactions during low- density lipoproteins (LDL) apheresis*: rarely, patients have experienced life-threatening anaphylactoid reactions, temporarily withhold treatment prior to exams. *Anaphylactoid reactions during desensitisation*: temporarily withhold treatment prior to exams. These reactions reappeared upon inadvertent rechallenge. *Neutropenia/Agranulocytosis/Thrombocytopenia/Anaemia*: extreme caution in patients with collagen vascular disease, immunosuppressant therapy, treated with allopurinol or procainamide, periodic monitor of white blood cell counts advised. *Dual blockade of the renin-angiotensin-aldosterone system (RAAS):* concomitant use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren increases the risk of hypotension, hyperkalaemia and decreased renal function (including acute renal failure). Dual blockade of RAAS is therefore not recommended. ACE-inhibitors and angiotensin II receptor blockers should not be used concomitantly in patients with diabetic nephropathy. *Primary aldosteronism*: use not recommended in patients with primary hyperaldosteronism (not responding to drugs acting through inhibition of the renin-angiotensin system). *Pregnancy*: stop treatment. If appropriate, start alternative therapy. *Hypotension*: close monitoring at initiation of therapy and dose adjustment in patients at increased risk of symptomatic hypotension (volume depleted, with severe renin-dependent hypertension or with symptomatic or congestive heart failure) or with ischaemic heart or cerebrovascular disease. A transient hypotensive response is not a contraindication to further doses once the blood pressure has increased after volume expansion. *Aortic and mitral valve stenosis/hypertrophic cardiomyopathy*: use with caution. *Stable coronary artery disease*: if unstable angina pectoris during first month, appraisal of benefit/risk before treatment continuation. *Renal impairment*: monitor potassium and creatinine. In patients with renal artery stenosis or renovascular hypertension, start treatment with low dose, careful titration and close medical supervision. *Hepatic failure*: rarely, ACE inhibitors have been associated with a syndrome that starts with cholestatic jaundice and progresses to fulminant hepatic necrosis and (sometimes) death: stop treatment if jaundice or marked elevations of hepatic enzymes. *Black people*: perindopril may be less effective and cause a higher rate of angioedema than in non-black. *Non- productive cough*. *Surgery/Anaesthesia*: stop treatment one day prior to surgery. *Hyperkalaemia*: frequent monitoring of blood potassium if renal insufficiency, worsening of renal function, age (>70 years), diabetes mellitus, dehydration, acute cardiac decompensation, metabolic acidosis, and concomitant use of potassium-sparing diuretics, potassium salts and especially aldosterone antagonists or angiotensin-receptor blockers. *Diabetic patients*: monitor glycaemia during first month. *Kidney transplantation*: no experience. *Renovascular hypertension:* increased risk of hypotension and renal insufficiency in patients with bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney. Diuretics may be a contributory factor. Loss of renal function may occur (minor changes in serum creatinine) even in patients with unilateral renal artery stenosis. *Galactose intolerance/glucose- galactose malabsorption/total lactase deficiency*: should not be taken. **INTERACTIONS*:** *Contra-indicated:* Aliskiren (in diabetic or impaired renal patients), Extracorporeal treatments, Sacubitril/Valsartan. *Not recommended*: Aliskiren (in other patients), Angiotensin-receptor blockers, Estramustine, Potassium-sparing drugs, Potassium-sparing diuretics (triamterene, amiloride…), potassium supplements or potassium salts, Lithium. *Special care*: Antidiabetic agents (insulins, oral hypoglycaemic agents), Baclofen, Non-potassium sparing diuretics, Potassium-sparing diuretics (eplerenone, spironolactone), Non-steroidal anti-inflammatory medicinal products (NSAIDs) including acetylsalicylic acid ≥ 3g/day, Racecadotril, mTOR inhibitors (e.g. sirolimus, everolimus, temsirolimus), gliptins (linagliptin, saxagliptin, sitagliptin, vildagliptin). *Some care*: Antihypertensive agents, Vasodilators, Tricyclic antidepressants, Antipsychotics, Anesthetics, Sympathomimetics, Gold. *Drugs inducing hyperkalaemia:* aliskiren, potassium salts, potassium-sparing diuretics, ACE inhibitors, angiotensin-II receptors antagonists, NSAIDs, heparins, immunosuppressant agents such as ciclosporin or tacrolimus, trimethoprim, co-trimoxazole (trimethoprim/sulfamethoxazole). **PREGNANCY AND BREASTFEEDING*:** Not recommended during the first trimester of pregnancy and lactation. Contraindicated during the second and third trimesters of pregnancy. **DRIVE AND USE MACHINES*:** Low blood pressure may occur in some patients. **UNDESIRABLE EFFECTS*:** *Common:* Dizziness, headache, paraesthesia, vertigo, visual disturbances, tinnitus, hypotension, cough, dyspnoea, abdominal pain, constipation, diarrhoea, dysgeusia, dyspepsia, nausea, vomiting, prurit, rash, muscle cramps, asthenia. *Uncommon:* Eosinophilia, hypoglycaemia, hyperkalaemia, hyponatraemia, depression, mood disturbances, sleep disorder, somnolence, syncope, palpitations, tachycardia, vasculitis, bronchospasm, dry mouth, urticaria, angioedema of face, extremities, lips, mucous membranes, tongue, glottis and/or larynx, photosensitivity reactions, pemphigoid, hyperhydrosis, arthralgia, myalgia, renal insufficiency, erectile dysfunction, chest pain, malaise, oedema peripheral, pyrexia, blood urea increased, blood creatinine increased, fall. *Rare:* Acute renal failure, anuria/oliguria, flushing, syndrome of inappropriate antidiuretic hormone secretion (SIADH), psoriasis aggravation, blood bilirubin increased, hepatic enzyme increased. *Very rare:* Agranulocytosis or pancytopenia, haemoglobin decreased and haematocrit decreased, leucopenia/neutropenia, haemolytic anaemia in patients with a congenital deficiency of G-6PDH, thrombocytopenia, confusion, angina pectoris, arrhythmia, myocardial infraction, stroke, eosinophilic pneumonia, rhinitis, pancreatitis, hepatitis either cytolitic or cholestatic, erythema multiform. *Not known*: raynaud's phenomenon. **OVERDOSE*. PROPERTIES*:** Perindopril is an inhibitor of the enzyme that converts angiotensin I into angiotensin II (ACE). The converting enzyme allows conversion of angiotensin I into the vasoconstrictor angiotensin II as well as causing the degradation of the vasodilator bradykinin into an inactive heptapeptide. Perindopril reduces peripheral vascular resistance, leading to blood pressure reduction, and reduces cardiac work by a decrease in pre-load and after- load. **PRESENTATION***: Pack of 30 tablets of Acertil AR 5 mg. **SERVIER HONG KONG LIMITED,** Flat 08-09, 43/F, Times Square Tower One, 1 Matheson Street, Causeway Bay, Hong Kong. **www.servier.hk *For complete information, please refer to the Summaries of Product Characteristics for Hong Kong.**