COMPOSITION*: AceryCal 5 mg/5 mg, 5 mg/10 mg, 10 mg/10 mg tablets contain 5 mg perindopril arginine (per)/5 mg amlodipine (amlo), 5 mg per/10 mg amlo, 10 mg per/10 mg amlo. Contains lactose as excipient. **INDICATIONS*:** Substitution therapy for treatment of essential hypertension and/or stable coronary artery disease, in patients already controlled with perindopril and amlodipine given concurrently at the same dose level. **DOSAGE AND ADMINISTRATION*:** One tablet per day in the morning before a meal. AceryCal is not suitable for initial therapy. If a change of posology is required, the dose could be modified or individual titration with free combination may be considered. *Elderly and patients with renal failure:* frequent monitoring of creatinine and potassium. Clcr < 60ml/min: not suitable. *Hepatic impairment*: individual titration with the free combination of amlodipine and perindopril. *Children and adolescents:* should not be used. **CONTRAINDICATIONS*:** Hypersensitivity to the active substance or to any other ACE inhibitor, or to dihydropyridines derivatives, or to any of the excipients, 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), severe hypotension, shock, including cardiogenic shock, obstruction of the outflow-tract of the left ventricule (e.g. high grade aortic stenosis), haemodynamically unstable heart failure after acute myocardial infarction, concomitant use with sacubitril/valsartan therapy, AceryCal 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*:** Special 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 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. *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. *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. *Precautions for use: Hypotension:* monitor blood pressure, renal function and potassium in patients at high risk of symptomatic hypotension (volume depleted or who have severe renin-dependent hypertension) 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. *Patients with cardiac failure:* use with caution. *Renal impairment:* monitor potassium and creatinine; individual dose titration with the monocomponents recommended if Clcr < 60 ml/min. In patients with renal artery stenosis, blood urea and creatinine may increase; with renovascular hypertension, risk of severe hypotension and renal insufficiency. *Renal failure:* amlodipine not dialysable. *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. *Impaired hepatic function:* slow dose titration and careful monitoring if severe hepatic impairment. *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. *Hypertensive crisis*: safety and efficacy not established. *Elderly patients*: dosage increase with care. *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 diuretics (triamterene, amiloride…), potassium salts, Lithium, dantrolene (infusion), grapefruit or grapefruit juice. *Special care*: Antidiabetic agents (insulins, oral hypoglycaemic agents), Non-potassium sparing diuretics, Potassium-sparing diuretics (eplerenone, spironolactone), racecadotril, mTOR inhibitors (sirolimus, everolimus, temsirolimus), gliptins (e.g. linagliptin, saxagliptin, sitagliptin, vildagliptin), Non-steroidal anti-inflammatory medicinal products (NSAIDs) including acetylsalicylic acid ≥ 3g/day, CYP3A4 inducers, CYP3A4 inhibitors, Baclofen. *To be taken into consideration:* Sympathomimetics, Gold, tacrolimus, ciclosporin, simvastatin, antihypertensive agents and vasodilatators, corticosteroids, tetracosactide, alpha-blockers (prazosin, alfuzosin, doxazosin, tamsulosin, terazosin), amifostine, tricyclic antidepressants, antipsychotics, anaesthetics, other medicinal products with antihypertensive properties. *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 and 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*:** May be impaired if dizziness, headache, fatigue, weariness or nausea. **UNDESIRABLE EFFECTS*:** *Very common:* oedema. *Common:* somnolence, dizziness, headache, dysgeusia, paraesthesia, vertigo, visual impairment, diplopia, tinnitus, palpitations, flushing, hypotension, dyspnea, cough, abdominal pain, nausea, vomiting, dyspepsia, change of bowel habit, diarrheoa, constipation, pruritus, rash, exanthema, joint swelling (ankle swelling), muscle spasms, fatigue, asthenia. *Uncommon:* rhinitis, eosinophilia, hypersensitivity, hypoglycaemia, hyperkalaemia, hyponatraemia, insomnia, mood altered, anxiety, depression, sleep disorder, tremor, hypoaesthesia, syncope, tachycardia, arrhythmia (including bradycardia, ventricular tachycardia and atrial fibrillation), vasculitis, bronchospasm, dry mouth, angioedema of face, extremities, lips, mucous membranes, tongue, glottis and/or larynx, alopecia, purpura, skin discolouration, hyperhidrosis, urticaria, photosensitivity reactions, pemphigoid, arthralgia, myalgia, back pain, micturition disorders, nocturia, pollakiuria, renal failure, erectile dysfunction, gynaecomastia, oedema peripheral, chest pain, pain, malaise, pyrexia, weight increased, weight decreased, blood urea increased, blood creatinine increased, fall. *Rare:* Syndrome of inappropriate antidiuretic hormone secretion (SIADH), confusional state, psoriasis aggravation, acute renal failure, anuria/oliguria, blood bilirubin increase, hepatic enzyme increase. *Very rare:* leukopenia/neutropenia, agranulocytosis or pancytopenia, thrombocytopenia, haemolytic anaemia enzyme specific in patients with a congenital deficiency of G-6PDH, hyperglycaemia, hypertonia, neuropathy peripheral, cerebrovascular accident possibly secondary to excessive hypotension in high-risk patients, angina pectoris, myocardial infarction, eosinophilic pneumonia, gingival hyperplasia, pancreatitis, gastritis, hepatitis, jaundice, hepatitis either cytolytic or cholestatic, hepatic enzymes increased, Quincke's oedema, erythema multiform, Stevens-Johnson Syndrome, exfoliative dermatitis, haemoglobin decreased and haematocrit decreased. *Not known*: extrapyramidal disorder (extrapyramidal syndrome), toxic epidermal necrolysis and raynaud's phenomenon. **OVERDOSE*. PROPERTIES*:** Perindopril is an inhibitor of the enzyme that converts angiotensin I into angiotensin II (Angiotensin Converting Enzyme ACE). Amlodipine is a calcium ion influx inhibitor of the dihydropyridine group (slow channel blocker or calcium ion antagonist) and inhibits the transmembrane influx of calcium ions into cardiac and vascular smooth muscle. **PRESENTATION***: Pack of 30 tablets of AceryCal 5 mg/5 mg, 5 mg/10 mg, 10 mg/10 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.**