COMPOSITION*: Triplixam 5mg/1.25mg/5mg film-coated tablets contains 5 mg perindopril arginine (per)/1.25 mg indapamide (ind)/5 mg of amlodipine (amlo); Triplixam 5mg/1.25mg/10mg film-coated tablets: 5 mg per/1.25 mg ind/10 mg amlo. **INDICATIONS*:** Substitution therapy for treatment of essential hypertension, in patients already controlled with perindopril/indapamide fixed dose combination and amlodipine, taken at the same dose level. **DOSAGE AND ADMINISTRATION*:** One tablet per day, preferably in the morning and before a meal. The fixed dose combination is not suitable for initial therapy. If a change of the posology is required, titration should be done with the individual components. *Paediatric population:* should not be used. **CONTRAINDICATIONS*:** Dialysis patients. Patients with untreated decompensated heart failure. Severe renal impairment (Clcr < 30 mL/min). Moderate renal impairment (Clcr < 60 mL/min) for Triplixam 10mg/2.5mg/5mg and 10mg/2.5mg/10mg. Hypersensitivity to the active substances, to other sulfonamides, to dihydropyridine derivatives, any other ACE-inhibitor or to any of the excipients. History of angioedema (Quincke's oedema) associated with previous ACE inhibitor therapy (see Warnings section). Hereditary/idiopathic angioedema. Second and third trimesters of pregnancy (see Warnings and Pregnancy and lactation sections). Hepatic encephalopathy. Severe hepatic impairment. Hypokalaemia. Severe hypotension. Shock, including cardiogenic shock. Obstruction of the outflow-tract of the left ventricle (e.g. high grade aortic stenosis). Haemodynamically unstable heart failure after acute myocardial infarction. Concomitant use of Triplixam with aliskiren-containing products in patients with diabetes mellitus or renal impairment (GFR < 60mL/min/1.73m^2) (see Interaction section), concomitant use with sacubitril/valsartan therapy. Triplixam 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: *Dual blockade of the renin-angiotensin-aldosterone system (RAAS):* ACE- inhibitors and angiotensin II receptor blockers should not be used concomitantly in patients with diabetic nephropathy. *Neutropenia/agranulocytosis/thrombocytopenia/anaemia*: caution if collagen vascular disease, immunosuppressant therapy, treatment with allopurinol or procainamide, or combination of these complicating factors, especially if pre-existing impaired renal function. Monitoring of white blood cell counts. *Renovascular hypertension*: increased risk of hypotension and renal insufficiency in patient 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. *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 desensitization*: Caution in allergic patients treated with desensitization and avoid if venom immunotherapy. Temporarily withdrawal of ACE- inhibitor at least 24 hours before desensitization. *Anaphylactoid reactions during LDL apheresis*: Temporarily withholding ACE-inhibitor prior to each apheresis. *Haemodialysis patients*: consideration to use dialysis membranes other than high flux or antihypertensive agents other than ACE inhibitors. *Primary aldosteronism*: use not recommended in patients with primary hyperaldosteronism (not responding to drugs acting through inhibition of the renin-angiotensin system). *Pregnancy*: no initiation during pregnancy, stop treatment and start alternative therapy if appropriate. *Hepatic encephalopathy which can progress to hepatic coma*: stop treatment. *Photosensitivity*: stop treatment. Precautions for use: *Renal function*: In certain hypertensive patients without pre-existing apparent renal lesions and for whom renal blood tests show renal insufficiency, stop treatment and restart at a low dose or with one constituent only. Monitoring of potassium and creatinine, after two weeks of treatment and then every two months during therapeutic stability period. If bilateral renal artery stenosis or single functioning kidney: not recommended. Risk of arterial hypotension and/or renal insufficiency (in cases of cardiac insufficiency, water and electrolyte depletion, in patients with low blood pressure, renal artery stenosis, congestive heart failure or cirrhosis with oedema and ascites): start treatment at low doses and increase progressively. *Hypotension and water and sodium depletion*: Risk of sudden hypotension in presence of pre-existing sodium depletion (in particular if renal artery stenosis): Monitoring of plasma electrolytes, re-establish blood volume and pressure, restart treatment at a reduced dose or with only one of the constituents. Sodium levels: More frequent monitoring in elderly and cirrhotic patients. *Potassium levels*: Hyperkalaemia: Monitoring of serum potassium if renal insufficiency, worsening of renal function, age (> 70 years), diabetes mellitus, intercurrent events, in particular dehydration, acute cardiac decompensation, metabolic acidosis and concomitant use of potassium-sparing diuretics, potassium supplements or potassium salts, or other drugs associated with increases in serum potassium and especially aldosterone antagonists or angiotensin-receptor blockers. *Hypokalaemia*: high risk for elderly and/or malnourished subjects, cirrhotic patients with oedema and ascites, coronary patients, patients with renal failure or heart failure, long QT interval: monitoring of serum potassium, may cause muscle disorders and rhabdomyolysis, may favor the onset of torsades de pointes, which may be fatal: associated with hypomagnesaemia can be refractory to treatment unless serum magnesium is corrected. *Calcium levels:* hypercalcemia: stop treatment before investigating the parathyroid function. *Renovascular hypertension*: if renal artery stenosis: start treatment at hospital at low dose; monitor renal function and potassium. *Dry cough*. *Atherosclerosis*: start treatment at low dose in patients with ischaemic heart disease or cerebral circulatory insufficiency. *Hypertensive crisis. Cardiac failure/severe cardiac insufficiency*: Caution if heart failure. Severe cardiac insufficiency (grade IV): start treatment under medical supervision with reduced initial dose. *Aortic or mitral valve stenosis / hypertrophic cardiomyopathy*: Caution if obstruction in the outflow tract of the left ventricle. *Diabetic patients*: If insulin dependent diabetes mellitus, start treatment under medical supervision with reduced initial dose; monitor blood glucose during the first month and/or in the case of hypokalaemia. *Black people*: higher incidence of angioedema and apparently less effective in lowering blood pressure than in non- blacks. *Surgery / anaesthesia*: stop treatment one day before surgery. *Hepatic impairment*: Mild to moderate: caution. 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. *Uric acid:* hyperuricemia: Increased tendency to gout attacks. *Elderly:* testing of renal function and potassium levels before treatment start. Dosage increase with care. *Excipients*: sodium-free. *Choroidal effusion, acute myopia and secondary angle-closure glaucoma:* discontinue drug intake as rapidly as possible. Prompt medical or surgical treatments may need to be considered if the intraocular pressure remains uncontrolled. *Athletes*: may cause positive doping test. **INTERACTION(S)*** *Contraindicated*: Aliskiren in diabetic or impaired renal patients, Extracorporeal treatments, Sacubitril/Valsartan. *Not recommended*: Lithium, Aliskiren in patients other than diabetic or impaired renal patients, Concomitant therapy with ACE inhibitor and angiotensin-receptor blocker, Estramustine, Potassium- sparing drugs (e.g triamterene,amiloride,…), Potassium salts, , Dantrolene (infusion), Grapefruit or grapefruit juice. *Special care*: Baclofen, Non-steroidal anti- inflammatory medicinal products (included acetylsalicylic acid at high doses), Antidiabetic agents (insulin, hypoglycaemic agents), Non-potassium-sparing diuretics and Potassium-sparing diuretics (eplerenone, spironolactone), Racecadotril, mTOR inhibitors (e.g. sirolimus, everolimus, temsirolimus), Torsades de pointes inducing drugs, Amphotericin B (IV route), glucocorticoids and mineralocorticoids (systemic route), tetracosactide, stimulant laxatives, Cardiac glycosides, Allopurinol, CYP3A4 inducers, CYP3A4 inhibitors. *To be taken into consideration*: Imipramine-like antidepressants (tricyclics), neuroleptics, other antihypertensive agents and vasodilatators, tetracosactide, Allopurinol, cytostatic or immunosuppressive agents, systemic corticosteroids or procainamide, Anaesthetic drugs, Diuretics (thiazide or loop diuretics), Gliptines (linagliptine, saxagliptine, sitagliptine, vildagliptine), Sympathomimetics, Gold, Metformin, Iodinated contrast media, Calcium (salts), Ciclosporin, Atorvastatin, digoxin, warfarin, Tacrolimus, Simvastatin. *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*** Contraindicated during the second and third trimesters of pregnancy. Not recommended during the first trimester of pregnancy and lactation. **FERTILITY*** Reversible biochemical changes of spermatozoa in some patients treated by calcium channel blockers. **DRIVE & USE MACHINES*** May be impaired due to low blood pressure that may occur in some patients, especially at the start of treatment. **UNDESIRABLE EFFECTS*** *Very common:* oedema. *Common*: hypokalaemia, dizziness, headache, paraesthesia, vertigo, somnolence, dysgeusia, visual impairment, diplopia, tinnitus, palpitations, flushing, hypotension (and effects related to hypotension), cough, dyspnoea, abdominal pain, constipation, diarrhoea, dyspepsia, nausea, vomiting, change of bowel habit, pruritus, rash, rash maculo-papular, muscle spasms, ankle swelling, asthenia, fatigue. *Uncommon*: rhinitis, eosinophilia, hypersensitivity, hypoglycaemia, hyperkalaemia reversible on discontinuation, hyponatraemia, insomnia, mood altered (including anxiety), depression, sleep disorder, hypoaesthesia, tremor, syncope, tachycardia, arrhythmia (including bradycardia, ventricular tachycardia and atrial fibrillation), vasculitis, bronchospasm, dry mouth, urticaria, angioedema, alopecia, purpura, skin discoloration, hyperhidrosis, exanthema, photosensitivity reaction, pemphigoid, arthralgia, myalgia, back pain, micturition disorder, nocturia, pollakiuria, renal failure, erectile dysfunction, gynaecomastia, pain, chest pain, malaise, oedema peripheral, pyrexia, weight increased, weight decreased, blood urea increased, blood creatinine increased, fall. *Rare*: Syndrome of inappropriate antidiuretic hormone secretion (SIADH), anuria/oliguria, acute renal failure, hypochloraemia, hypomagnesaemia, confusional state, blood bilirubin increased, hepatic enzyme increased, psoriasis aggravation. *Very rare*: agranulocytosis, aplastic anaemia, pancytopenia, leukopenia, neutropenia, haemolytic anaemia, thrombocytopenia, allergic reactions, hyperglycaemia, hypercalcaemia, hypertonia, neuropathy peripheral, stroke possibly secondary to excessive hypotension in high-risk patients angina pectoris, myocardial infarction, possibly secondary to excessive hypotension in high risk patients, eosinophilic pneumonia, gingival hyperplasia, pancreatitis, gastritis, hepatitis, jaundice, hepatic function abnormal, erythema multiforme, Stevens-Johnson Syndrome, exfoliative dermatitis, toxic epidermal necrolysis, Quincke's oedema, haemoglobin decreased and haematocrit decreased. *Not known*: extrapyramidal disorder (extrapyramidal syndrome), myopia, vision blurred, acute angle-closure glaucoma, choroidal effusion, torsades de pointes (potentially fatal), rhabdomyolysis, muscular weakness, possibility of onset of hepatic encephalopathy in case of hepatic insufficiency, possible worsening of pre-existing systemic lupus erythematosus, electrocardiogram QT prolonged, blood glucose increased, blood uric acid increased. Raynaud's phenomenon. **OVERDOSE* PROPERTIES*** Perindopril is an inhibitor of the angiotensin converting enzyme (ACE inhibitor) which converts angiotensin I to angiotensin II. Indapamide is a sulfonamide derivative with an indole ring, pharmacologically related to the thiazide group of diuretics. Amlodipine is a calcium ion influx inhibitor of the dihydropyridine group (slow calcium channel blocker or calcium ion antagonist) and inhibits the transmembrane influx of calcium ions into cardiac and vascular smooth muscle. PRESENTATION* Box of 30 tablets of Triplixam 5mg/1.25mg/5mg, 5mg/1.25mg/10mg. **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 Summary of Product Characteristics for Hong Kong.**