

COMPOSITION:* NATRIXAM 1.5 mg / 5 mg: indapamide 1.5 mg – amlodipine 5 mg. NATRIXAM 1.5 mg / 10 mg: indapamide 1.5 mg – amlodipine 10 mg.

INDICATIONS:* Substitution therapy for treatment of essential hypertension in patients already controlled with indapamide and amlodipine given concurrently at the same dose level. **DOSAGE AND ADMINISTRATION:*** One tablet per day as single dose, preferably to be taken in the morning. Natrixam is not suitable for initiation therapy. If a change of the posology is required, titration should be done with the individual components. Children and adolescents: efficacy and safety not established. Severe renal impairment (creatinine clearance <30 mL/min): contraindicated. Older people: to be treated according to renal function. Hepatic impairment: contraindicated in severe hepatic impairment; in mild to moderate hepatic impairment, treatment start with the lowest dose. **CONTRAINDICATIONS:*** Hypersensitivity to the active substances, to other sulfonamides, to dihydropyridine derivatives or to any of the excipients. Severe renal failure (creatinine clearance <30 mL/min). Hepatic encephalopathy or severe impairment of liver function. Hypokalaemia. Lactation. 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. **WARNINGS:*** *Special warnings:* Hepatic encephalopathy: stop treatment. Photosensitivity: stop treatment. *Precautions for use:* Hypertensive crisis: efficacy not established. Water and electrolyte balance: Sodium and potassium levels: to be measured before and during treatment. Monitoring of sodium should be more frequent in elderly and cirrhotic patients. Hypokalaemia: high risk in the elderly, malnourished and/or polymedicated, cirrhotic patients with oedema and ascites, and patients with coronary artery disease, cardiac failure or long QT interval; first measurement of plasma potassium one week after start of treatment and more frequent monitoring required. Calcium levels: stop treatment before investigating parathyroid function. Blood glucose: to be monitored in diabetic patients, especially those with hypokalaemia. Cardiac failure: use with caution. Renal function: pre-existing renal insufficiency may worsen at start of the treatment due to reduction in glomerular filtration; amlodipine not dialysable. Hyperuricaemia: increased frequency of gout attacks. Hepatic function: caution to be exercised in mild to moderate hepatic impairment; start at the lowest dose. Older people: to be treated according to renal function. Galactose intolerance/ Lapp lactase deficiency/glucose-galactose malabsorption: should not be taken. **INTERACTION(S):*** *Not recommended:* lithium, dantrolene, grapefruit or grapefruit juice. *Precautions for use:* torsades de pointes-inducing medicines, N.S.A.I.Ds. (systemic route) including COX-2 selective inhibitors, high-dose salicylic acid (≥ 3 g/day), angiotensin-converting enzyme (A.C.E.) inhibitors, other compounds causing hypokalaemia, digitalis preparations, baclofen, allopurinol, CYP3A4 inhibitors, CYP3A4 inducers and simvastatin. To be taken into consideration: potassium-sparing diuretics, metformin, iodinated contrast media, imipramine-like antidepressants, neuroleptics, calcium (salts), ciclosporin, tacrolimus, corticosteroids, tetracosactide (systemic route), and other medicinal products with antihypertensive properties. **FERTILITY* / PREGNANCY* / BREASTFEEDING:*** Not recommended during pregnancy. Contraindicated during lactation. **DRIVING & USING MACHINES:*** There may be impairment due to a decrease in blood pressure or to dizziness, headache, fatigue or nausea. **UNDESIRABLE EFFECTS:*** *Very common:* oedema. *Common:* hypokalaemia, somnolence, dizziness, headache, palpitations, flushing, visual impairment, diplopia, dyspnoea, abdominal pain, nausea, dyspepsia, change of bowel habit, diarrhoea, constipation, rash maculo-papular, ankle swelling, muscle spasms, fatigue, asthaenia. *Uncommon:* insomnia, mood altered (including anxiety), depression, tremor, dysgeusia, syncope, hypoesthesia, paraesthesia, tinnitus, hypotension, arrhythmia (including bradycardia, ventricular tachycardia and atrial fibrillation), cough, rhinitis, vomiting, dry mouth, purpura, alopecia, skin discolouration, hyperhidrosis, pruritus, rash, exanthema, urticaria, arthralgia, myalgia, back pain, micturition disorder, nocturia, pollakiuria, erectile dysfunction, gynaecomastia, chest pain, pain, malaise, weight increased, weight decreased. *Rare:* confusional state, vertigo. *Very rare:* leukopenia, thrombocytopenia, agranulocytosis, aplastic anaemia, haemolytic anaemia, hypersensitivity, hyperglycaemia, hypercalcaemia, hypertension, neuropathy peripheral, myocardial infarction, vasculitis, pancreatitis, gastritis, gingival hyperplasia, hepatitis, jaundice, hepatic enzyme levels increased, hepatic function abnormal, angioedema, toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme, exfoliative dermatitis, Quincke's oedema, photosensitivity, renal failure. Not known: hyponatraemia with hypovolaemia, torsades de pointes (potentially fatal), possibility of onset of hepatic encephalopathy in cases of hepatic insufficiency, possible worsening of pre-existing systemic lupus erythematosus, electrocardiogram QT prolonged, blood glucose increased and blood uric acid increased, extrapyramidal disorder (extrapyramidal syndrome), myopia, vision blurred. **OVERDOSE*** **PROPERTIES:*** Indapamide is a sulfonamide, pharmacologically related to thiazide diuretics, which acts by inhibiting the reabsorption of sodium in the cortical dilution segment. Indapamide does not interfere with lipid and carbohydrate metabolism. 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. **MANUFACTURER:*** 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.