Product information

Diован (valsartan)

See approved Product Information before prescribing. Approved Product Information available on request.

Indication: Treatment of hypertension. Treatment of heart failure (NYHA class II-IV) in patients receiving usual therapy (e.g. diuretics, digitalis) who are intolerant to ACE inhibitors. To improve survival following myocardial infarction in clinically stable patients with clinical or radiological evidence of left ventricular systolic dysfunction.

Dosage and administration: Hypertension: The recommended dose is 80 mg or 160 mg once daily. If the reduction in blood pressure is inadequate, dosage may be increased to 320 mg once daily, or another angiotensin (e.g. diuretic) may be added. Heart Failure: Starting dose is 40 mg twice daily. Up titration to 80 and 160 mg twice daily as tolerated by patient. The maximum daily dose administered in clinical trials is 320 mg in divided dose. Treatment of post-myocardial infarction: Starting dose is 40 mg twice daily. Up titration is to a maximum of 160 mg twice daily as tolerated by patient. 

Contraindications: Known hypersensitivity to valsartan or any of the other components of this product; Pregnancy; Severe hepatic impairment; biliary cirrhosis and cholestasis; Severe renal impairment; anuria; severe renal impairment (creatinine clearance < 30 mL/min); mild to moderate hepatic impairment; Caution should be observed when initiating therapy in patients with heart failure or post-myocardial infarction; Caution should be observed with the triple combination of an ACE-inhibitor, beta blocker and Diован; In patients with severe heart failure, treatment with Diован may cause impairment of renal function; Concomitant treatment with potassium-sparing diuretics or potassium supplements may increase serum potassium levels. Caution is advised when driving or operating machines; Avoid use in women planning to become pregnant and while breast-feeding.

Interactions: Concomitant treatment with potassium-sparring diuretics or potassium supplements may increase serum potassium levels. Side effects: Generally: Similar in incidence to patients receiving placebo in placebo-controlled clinical trials, e.g. headache, dizziness, fatigue. The observed incidence of cough with valsartan in controlled clinical trials was significantly less than that observed with ACE inhibitors and similar to that seen with placebo. Most common: viral infections, postural dizziness (reported in heart failure indication), orthostatic hypotension (reported in heart failure indication), neutropenia, upper respiratory tract infection, pharyngitis, sinusitis, hyperkalaemia (reported in post-myocardial infarction and heart failure indication), constipation, headache, dizziness, syncope (reported in post-myocardial infarction indication), cough, diarrhoeas, abdominal pain, fat back, pain, fatigue, asthenia, oedema, syncope (reported in post-myocardial infarction indication), cardiac failure (reported in post-myocardial infarction indication). Rare/serious: thrombocytopenia, hypersensitivity including serum sickness, vasculitis, angio-oedema, oedema (uncommon in post-myocardial infarction indication), renal impairment (common in heart failure indication), renal insufficiency, acute renal failure (uncommon in post-myocardial infarction indication); some patients with heart failure have developed increases in blood urea nitrogen, serum creatinine and potassium, usually minor and transient.

Co-Diован (valsartan + hydrochlorothiazide)

See approved Product Information before prescribing. Approved Product Information available on request.

Indication: Treatment of hypertension. Treatment should not be initiated with these combinations. Dosage and administration: one tablet of Co-Diован 80/12.5 mg or 160/12.5 mg or 320/12.5 mg or 320/25 mg daily. Contraindications: Hypersensitivity to the components of Co-Diован (valsartan and hydrochlorothiazide) or to sulphonamides; pregnancy; severe hepatic impairment; biliary cirrhosis and cholestasis; anuria, severe renal impairment (creatinine clearance < 30 mL/min); refractory hypokalaemia; hypophosphataemia; hyperkaalaeemia; symptomatic hyperuricaemia. Precautions: Risk of hypotension in sodium and/or volume-depleted patients. Caution is advised when administering Co-Diован to patients with NYHA III and IV heart failure of non-ischaemic aetiology, renal and liver disease or systemic stenosis, renal and liver dysfunction. Disturbance of serum electrolyte balance, glucose tolerance and serum levels of cholesterol, tryglicerides and uric acid. Caution in driving or operating machinery. Avoid use in patients with primary aldosteronism; chronic heart failure or other conditions with stimulation of the renin-angiotensin-aldosterone system. Avoid use in women planning to become pregnant and while breast-feeding. Interactions: Concomitant treatment with potassium-sparring diuretics or potassium supplements may increase potassium levels. Frequent monitoring of serum potassium is recommended. Risk of hyperkalaemia. As with all other vasodilators, special caution in patients suffering from aortic or mitral stenosis, or obstructive hypertrophic cardiomyopathy. Caution if combined with other antihypertensives, lithium (serum lithium monitoring), curare derivatives, NSAIDs, Digoxin, antidiabetic agents, alopurinol, amantadine, cytotoxic drugs, anticoagulants, vitamin D, calcium salts and cyclosporine and carbamazepine (blood sodium monitoring)*. Side effects: headache, dizziness, syncope* fatigue. For the hydrochlorothiazide component, other reported adverse reactions include hypokalaemia, hyperuricaemia and other electrolyte imbalance, orthostatic hypotension and lipids increased. Rare: jaundice, fever. Caution in patients with renal artery stenosis, severe renal impairment (creatinine clearance < 30 mL/min), patients with heart failure have developed increases in blood urea nitrogen, serum creatinine and potassium, usually minor and transient.

Exforge (valsartan + amlodipine)

See approved Product Information before prescribing. Approved Product Information available on request.

Indication: Treatment of hypertension. Treatment should not be initiated with this fixed dose combination. Dosage and administration: Recommended dose is one film-coated tablet per day (5 mg amlopidine and 80 mg valsartan, or 5 mg amlopidine and 160 mg valsartan, or 10 mg amlopidine and 160 mg valsartan). Contraindications: Hypersensitivity to the active substances (valsartan and amlodipine), dihydroxyindoline derivatives, or to any of the excipients; Severe hepatic impairment; biliary cirrhosis and cholestasis; Severe renal impairment (GFR=30 mL/min/1.73 m²) and patients undergoing dialysis; Pregnancy. Precautions: Risk of hypotension in sodium and/or volume-depleted patients. Risk of increased angina in patients with severe obstructive coronary artery disease. Beta-blocker withdrawal should be gradual. Caution in patients with mild to moderate renal impairment. No data available in patients with unilateral or bilateral renal artery stenosis, stenosis to a solitary kidney or after recent kidney transplantation. Caution in patients with mild to moderate hepatic impairment without cholestasis. As with all other vasodilators, special caution in patients suffering from aortic or mitral stenosis, or obstructive hypertrophic cardiomyopathy. Caution should be observed when initiating therapy in patients with heart failure or post-myocardial infarction. Caution should be observed with the triple combination of an ACE-inhibitor, beta blocker and Diован. Beta-blocker withdrawal may increase the risk of angina, myocardial infarction or serious arrhythmias. Caution should be observed when administering Co-Diован to patients with NYHA III and IV heart failure of non-ischaemic aetiology, renal and liver disease or systemic stenosis, renal and liver dysfunction. Disturbance of serum electrolyte balance, glucose tolerance and serum levels of cholesterol, tryglicerides and uric acid. Caution in driving or operating machinery. Avoid use in women planning to become pregnant and while breast-feeding. Not recommended in patients below 18 years of age. Interactions: Caution and monitoring of serum potassium levels should be used when concomitantly with potassium supplements, potassium sparing diuretics, salt substitutes containing potassium, or other drugs that may increase potassium level. Side effects: Most common: Nasopharyngitis, influenza, headache, oedema peripheral, oedema, fatigue, flushing, asthenia, hot flush. Rare: serious; Hypersensitivity. Additional or potentially serious adverse experiences reported in clinical trials with amlodipine monotherapy: Vomiting, gastritis, gingival hyperplasia, gynaecomastia, leucopenia, myalgia, pancreatitis, hepatitis, thrombocytopenia, vasculitis. In a long-term, placebo controlled study (PRAISE-2) of amlopidine in patients with NYHA III and IV heart failure of nonischaemic aetiology, amlopidine was associated with an increased risk of pulmonary oedema despite no significant difference in the incidence of worsening heart failure as compared to placebo. Myocardial infarction or increased angina and arrhythmia (including ventricular tachycardia and atrial fibrillation) have also been reported. These adverse events may not be distinguishable from the natural history of the underlying disease*. Additional potentially serious adverse experiences reported in clinical trials with valsartan are: Neutropenia in 3.9% of valsartan-treated patients compared to 0.9% of placebo-treated patients. >50% increases in serum potassium in 10% of valsartan-treated patients compared to 5.1% of placebo-treated patients. >50% increases in BUN in 16.6% of valsartan-treated patients compared to 6.3% of placebo-treated patients. Post-myocardial infarction patients: doubling of serum creatinine in 4.2% of valsartan-treated patients, 4.8% of valsartan plus captopril-treated patients, and 3.4% of captopril-treated patients. Neutropenia observed in 1.9% of patients treated with 80% of patients treated with placebo*. Elevated liver enzymes have also been reported in post-marketing surveillance. > 20% decreases in haemoglobin and haematocrit observed in 0.4% and 0.8% respectively, of valsartan patients compared with 0.1% and 0.1% in placebo-treated patients.

* Please note changes in Product Information