NOVARTIS

CO-DIOVAN® (valsartan / hydrochlorothiazide)

80/12.5 mg, 160/12.5 mg, 160/25 mg, 320/12.5 mg, 320/25 mg
Film-coated tablets

Basic Succinct Statement

CODE : BSS RD 10 SEP 18; APPR 18 MAR 20

This material is only meant for Healthcare Professionals

Co-Diovan® Film-coated tablets

Important note: Before prescribing, consult full prescribing information.

Presentation: Coated tablets containing 80 mg valsartan (an angiotensin II receptor antagonist) and 12.5 mg hydrochlorothiazide (a thiazide diuretic), or 160 mg valsartan and 12.5 mg hydrochlorothiazide or 160 mg valsartan and 25 mg hydrochlorothiazide.

Indications: Treatment of hypertension. Co-Diovan is indicated for the treatment of hypertension in patients whose blood pressure is not adequately controlled by monotherapy. These fixed dose combinations should be used as second-line therapy.

Dosage: One tablet of Co-Diovan 80/12.5 mg or 160/12.5 mg or 160/25 mg daily.

Contraindications: ♦Known hypersensitivity to the components of this product or to sulfonamide derivatives ♦pregnancy ♦severe hepatic impairment, biliary cirrhosis and cholestasis ♦anuria, severe renal impairment (creatinine clearance < 30 mL/min) ♦refractory hypokalemia ♦hyponatremia ♦hypercalcemia ♦Symptomatic hyperuricemia ♦Concomitant use with aliskiren in diabetic type II patients.

Warnings and Precautions: ♦ Risk of hypotension in sodium- and/or volume-depleted patients. ♦Caution is advised when administering Co-Diovan to patients with renal artery stenosis, renal and liver disease or systemic lupus erythematosus. ♦Caution in patients experiencing angioedema with Co-Diovan or having history of angioedema with other drugs. Discontinue Co-Diovan immediately and do not re-administer. ♦Caution in patients with heart failure, severe chronic heart failure or other conditions with stimulation of the renin angiotensin-aldosterone-system. Impairment of renal function may occur. ♦Like other thiazide diuretics, HCTZ can cause hypokalemia, which may favor the onset of digitalis-induced cardiac arrhythmias. ♦Disturbance of serum electrolyte balance, glucose tolerance and serum levels of cholesterol, tryglicerides and uric acid. ♦Acute angle-closure glaucoma. ♦Caution in patients with allergy or asthma. ♦Caution is required while co-administering Co-Diovan with other agents blocking the RAS such as ACEIs or aliskiren. ♦Increased risk of non-melanoma skin cancer (NMSC) [basal cell carcinoma (BCC) and squamous cell carcinoma (SCC)] with increasing cumulative dose of hydrochlorothiazide. Patients should protect their skin from excessive sun exposure, regularly check their skin for new lesions and promptly report any suspicious skin lesions while taking Co-Diovan.

Adverse reactions: **Uncommon**: Dehydration, paraesthesia, vision blurred, tinnitus, hypotension, cough, myalgia, fatigue. **Very rare:** Dizziness, diarrhea, arthralgia. **Frequency not known**: Syncope, non cardiogenic pulmonary edema, impaired renal function, blood uric acid increased, blood bilirubin and blood creatinine increased, hypokalemia, hyponatremia, Blood Urea Nitrogen increased, neutropenia.

For the **valsartan component**, other reported adverse reaction include: **Uncommon**: Vertigo, cough, abdominal pain, **Frequency not known:** Hypersensitivity including serum sickness, vasculitis, angioedema, dermatitis bullous, rash, pruritus, renal failure and impairment, haemoglobin decreased, haematocrit decreased, thrombocytopenia, blood potassium increased, liver function test abnormal including blood bilirubin, blood creatinine increased

♦**Events** also observed during clinical trials irrespective of their causal association with the study drug: Arthralgia, asthenia, back pain, diarrhea, dizziness, headache, insomnia, libido decrease, nausea, edema, pharyngitis, rhinitis, sinusitis, upper respiratory tract infection, viral infections.

For the **hydrochlorothiazide component**, other reported adverse reaction include: **Very common and common adverse reactions:** Hypokalaemia and rise in blood lipids, hypomagnesemia, hyperuricemia, hyponatremia, urticaria and other forms of rash, decreased appetite, mild nausea and vomiting, orthostatic hypotension, erectile dysfunction. ♦**Rare and very rare adverse reactions but potentially serious**: Jaundice, cardiac arrhythmias, vasculitis, lupus erythematosus, toxic epidermal necrolysis, erythema multiforme, pancreatitis, pneumonitis, pulmonary edema, skin rash with or without difficulties in breathing (hypersensitivity reactions), alkalosis hypochloremic, hypercalcemia, severe or persistent vomiting or diarrhea, thrombocytopenia with or without purpura, agranulocytosis, leucopenia, pancytopenia, bone marrow depression, hemolytic or aplastic anemia, renal failure or renal disorder, angle-closure glaucoma. ♦**Not known**: non-melanoma skin cancer (basal cell carcinoma and squamous cell carcinoma).