

DIOVAN[®] (valsartan)

40 mg, 80 mg, 160 mg and 320 mg Film-coated tablets

Basic Succinct Statement

CODE: BSS RD 10 SEP 2018; APPR 17 APR 2019

This material is only meant for Healthcare Professionals

Diovan® Film-coated tablets (FCT)

Important note: Before prescribing, consult full prescribing information.

Presentation: Valsartan: film-coated tablets of 40 mg, 80 mg, 160 mg and 320 mg.

Indications: Hypertension (HTN), heart failure, post-myocardial infarction.

Dosage: ♦ **Hypertension (Adults):** 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 antihypertensive (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 20 mg twice daily. Uptitration 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 ♦ Concomitant use with aliskiren in diabetic type II patients.

Warnings & Precautions:

♦ Risk of hypotension in sodium- and/or volume-depleted patients. ♦ Caution is advised when administering valsartan to patients with renal artery stenosis, severe renal impairment (creatinine clearance < 10 mL/min), biliary cirrhosis or obstruction. ♦ Caution should be observed when initiating therapy in patients with heart failure or post-myocardial infarction. ♦ In patients with heart failure, caution should be observed with the triple combination of an ACE-inhibitor, beta blocker and Diovan. ♦ In patients with severe heart failure, treatment with Diovan may cause impairment of renal function. ♦ Caution in patients experiencing angioedema with Diovan or having history of angioedema with other drugs. Discontinue Diovan immediately and do not re-administer. ♦ Not recommended in children. ♦ Avoid concomitant use with aliskiren in patients with severe renal impairment (GFR < 30 mL/min). ♦ Caution is required while co-administering Diovan with other agents blocking the RAS such as ACEIs or aliskiren.

Adverse reactions:

In Hypertensive patients: ♦ **Uncommon:** Vertigo, cough, abdominal pain, fatigue ♦ **Frequency not known:** Hypersensitivity including serum sickness, vasculitis, angioedema, dermatitis bullous, rash, pruritus, myalgia, renal failure and impairment, haemoglobin decreased, haematocrit decreased, neutropenia, thrombocytopenia, blood potassium increased, liver function test abnormal including bilirubin increased, blood creatinine increased ♦ **Events** also observed during clinical trials irrespective of their causal association with the study drug: Arthralgia, asthenia, back pain, diarrhoea, dizziness, headache, insomnia, libido decrease, nausea, oedema, pharyngitis, rhinitis, sinusitis, upper respiratory tract infection, viral infections.

In Post-Myocardial Infarction and/or Heart Failure patients: ♦ **Common:** Dizziness, postural dizziness, hypotension, orthostatic hypotension, renal failure and impairment ♦ **Uncommon:** Hyperkalemia, syncope, headache, vertigo, cardiac failure, cough, nausea, diarrhea, angioedema, acute renal failure, serum creatinine increased, asthenia, fatigue ♦ **Frequency not known:** Hypersensitivity including serum sickness, vasculitis, dermatitis bullous, rash, pruritus, myalgia, thrombocytopenia, blood potassium increased, liver function test abnormal, Blood Urea Nitrogen

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