
CODAL-SYNTO

# Sartovan®

Valsartan

**SARTOVAN®** 40mg f.c. tablets • **SARTOVAN®** 80mg f.c. tablets • **SARTOVAN®** 160mg f.c. tablets

## Summary of SPC for Sartovan®

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| **Trade Name of the Medicinal Product:** | Sartovan® |
| **Qualitative and Quantitative Composition:** | Each tablet contains 40/80/160 mg of valsartan. |
| **Pharmaceutical Form:** | Film-coated tablets. |
| **Therapeutic indications:** | Hypertension; Recent myocardial infraction; Heart failure. |
| **Posology and Method of Administration:** | **Hypertension:** Recommended dose is 80 mg once daily. In some patients whose blood pressure is not adequately controlled, the dose can be increased to 160 mg and to a maximum of 320 mg. **Recent myocardial infarction:** In clinically stable patients, therapy may be initiated as early as 12 hours after a myocardial infarction. After an initial dose of 20 mg twice daily, valsartan should be titrated to 40 mg, 80 mg, and 160 mg twice daily over the next few weeks. **Heart failure:** Starting dose is 40 mg twice daily. Uptitration to 80 mg and 160 mg twice daily should be done at intervals of at least two weeks to the highest dose, as tolerated by the patient. Maximum daily dose is 320 mg in divided doses. Patients with mild to moderate hepatic impairment without cholestasis: The dose of valsartan should not exceed 80 mg. **Paediatric hypertension:** Children 6 to 18 years of age: Initial dose is 40 mg once daily for children weighing below 35 kg and 80 mg once daily for those weighing 35 kg or more. Children less than 6 years of age: Safety and efficacy of valsartan have not been established. Paediatric patients aged 6 to 18 years with hepatic impairment: The dose of valsartan should not exceed 80 mg in these patients. Paediatric heart failure and recent myocardial infarction: Not recommended in children and adolescents below the age of 18 years. |
| **Contra-indications:** | Hypersensitivity; Severe hepatic impairment, biliary cirrhosis and cholestasis; Second and third trimester of pregnancy; Concomitant use with aliskiren containing products in patients with diabetes mellitus or renal impairment. |
| **Special Warnings and Precautions for Use:** | Hyperkalaemia; Impaired renal function; Hepatic impairment; Sodium depleted and/or volume depleted patients; Renal artery stenosis; Kidney transplantation; Primary hyperaldosteronism; Aortic and mitral valve stenosis, hypertrophic obstructive cardiomyopathy; Pregnancy; Initial therapy in post-myocardial infarction patients; ACE inhibitors and angiotensin II receptor blockers should not be used in patients with diabetic nephropathy; Triple combination of an ACE inhibitor, a mineralocorticoid receptor antagonist and valsartan is not recommended in patients with heart failure. |
| **Interactions with other Medicaments and other forms of Interaction:** | Concomitant use of ARBs, ACEIs, or aliskiren; Lithium; Potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium and other substances that may increase potassium levels; NSAIDs, acetylsalicylic acid; Paediatric: In hypertension where underlying renal abnormalities are common, caution is recommended with the concomitant use of valsartan and other substances that inhibit the renin angiotensin aldosterone system which may increase serum potassium. |
| **Pregnancy and Lactation:** | Not recommended during the first trimester of pregnancy. The use of AIIRAs is contra-indicated during the second and third trimester of pregnancy. Breast-feeding: Not recommended. |
| **Undesirable Effects:** | Decrease in haemoglobin and haematocrit, neutropenia, thrombocytopenia; Hypersensitivity; Increase of serum potassium, hyponatraemia; Vertigo; Vasculitis; Cough; Abdominal pain; Elevation of liver function values; Angioedema, rash, pruritus; Myalgia; Renal failure and impairment, elevation of serum creatinine; Fatigue; Hyperkalaemia; Dizziness, syncope, headache; Cardiac failure; Hypotension, orthostatic hypotension, vasculitis; Nausea, diarrhoea; Increase in blood urea nitrogen; Asthenia. |
| **Date of Revision of the Text:** | 09/2014 |
| | **MAH:** Codal Synto Ltd. |