For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information

Sacubitril and Valsartan Tablets (24+26) 50mg / (49+51) 100mg / (97+103) 200mg

CARMADA™ 50 / 100 / 200

Composition: CARMADA™ 50/100/200 : Each film coated tablet contains Sacubitril 24 mg / Valsartan 26 mg; Sacubitril 49 mg / Valsartan 51 mg; Sacubitril 97 mg / Valsartan 103 mg.

Indications: Sacubitril/Valsartan tablets are indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction.

Posology and Method of Administration: The recommended starting dose of Sacubitril/Valsartan tablets is 49mg/51mg orally twice daily. Double the dose of Sacubitril/Valsartan tablets after 2 to 4 weeks to the target maintenance dose of 97mg/103mg twice daily, as tolerated by the patient.

Contraindications: Contraindicated in patients with hypersensitivity to any component; in patients with a history of angioedema related to previous ACE inhibitor or ARB therapy; with concomitant use of ACE inhibitors. Do not administer within 36 hours of switching from or to an ACE inhibitor; contraindicated with concomitant use of aliskiren in patients with diabetes; severe hepatic impairment, biliary cirrhosis and cholestasis; second and third trimester of pregnancy.

Special Warnings and Precautions for Use: Fetal Toxicity : Can cause fetal harm when administered to a pregnant woman. When pregnancy is detected, consider alternative drug treatment and discontinue. Angioedema: May cause angioedema, if angioedema occurs, discontinue Sacubitril/Valsartan tablets immediately, provide appropriate therapy, and monitor for airway compromise. Angioedema associated with laryngeal edema may be fatal. Hypotension: May lower blood pressure and may cause symptomatic hypotension. Correct volume or salt depletion prior to administration of Sacubitril/Valsartan tablets or start at a lower dose. Impaired Renal Function: Decrease in renal function may be anticipated in susceptible individuals treated with Sacubitril/valsartan tablets. May increase blood urea and serum creatinine levels in patients with bilateral or unilateral renal artery stenosis. In patients with renal artery stenosis, monitor renal function. Hyperkalemia: Hyperkalemia may occur, monitor serum potassium periodically and treat appropriately.

Pregnancy: Sacubitril/valsartan tablets can cause fetal harm when administered to a pregnant woman. *Fetal/Neonatal Adverse Reactions :* Oligohydramnios in pregnant women in the second and third trimesters can result in reduced fetal renal function leading to anuria and renal failure, fetal lung hypoplasia, skeletal deformations, including skull hypoplasia, hypotension and death.

Lactation: Because of the potential for serious adverse reactions in breastfed infants from exposure to sacubitril/valsartan, advise a nursing woman that breastfeeding is not recommended. **Paediatric Use :** Safety and effectiveness have not been established in pediatric patients.

Geriatric Use: No relevant pharmacokinetic differences have been observed in elderly (≥ 65 years) or very elderly (≥ 75 years) patients compared to the overall population.

Hepatic Impairment: Use in severe hepatic impairment (Child-Pugh C classification) is not recommended.

Undesirable Effects: Clinically significant adverse reactions that appear include angioedema, hypotension, impaired renal function, hyperkalemia. **Common:** Anemia, hypokalemia, hypoglycemia, dizziness, headache, syncope, vertigo, orthostatic hypotension, cough, diarrhea, nausea, gastritis, renal failure, fatigue, asthenia. **Very common** : Hyperkalemia, hypotension and renal impairment.

For full prescribing information please write to: Sanofi India Ltd., Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

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Source: Prescribing information of Sacubitril and Valsartan Tablets, MSN Laboratories Private Limited dated Apr 2023 and US Prescribing Information of Entresto updated Feb 2021