Arnigen

Sacubitril & Valsartan Tablet

Presentation

Arnigen 50 Tablet : Each film coated tablet contains Sacubitril Valsartan Sodium Hemipentahydrate equivalent to Sacubitril 24 mg INN & Valsartan 26 mg USP.

Arnigen 100 Tablet: Each film coated tablet contains Sacubitril Valsartan Sodium Hemipentahydrate equivalent to Sacubitril 49 mg INN & Valsartan 51 mg USP.

Indications

Heart Failure: Sacubitril/Valsartan is 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.

Sacubitril/Valsartan is usually administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB.

Dosage & Administration

The recommended starting dose of Sacubitril/Valsartan is 49/51 mg twice-daily.

Double the dose of Sacubitril/Valsartan after 2 to 4 weeks to the target maintenance dose of 97/103 mg twice daily, as tolerated by the patient.

Dose adjustment for patients not taking an ACE inhibitor or ARB or previously taking low doses of these agents: A starting dose of 24/26 mg twice-daily is recommended for patients not currently taking an ACE inhibitor or an angiotensin II receptor blocker (ARB) and for patients previously taking low doses of these agents. Double the dose of Sacubitril/Valsartan every 2 to 4 weeks to the target maintenance dose of 97/103 mg twice daily, as tolerated by the patient.

Patients with Renal Impairment: No dose adjustment is required in patients with mild (eGFR 60 to 90 mL/min/1.73 m2) to moderate (eGFR 30 to 60 mL/min/1.73 m2) renal impairment. The recommended starting dose in patients with severe renal impairment (eGFR <30 mL/min/1.73 m2) is 24/26 mg twice daily.

Patients with Hepatic Disease: No dose adjustment is required when administering Sacubitril/Valsartan to patients with mild hepatic impairment (Child-Pugh A classification). The recommended starting dose in patients with moderate hepatic impairment (Child-Pugh B classification) is 24/26 mg twice daily. The use of Sacubitril/Valsartan in patients with severe hepatic impairment (Child-Pugh C classification) is not recommended.

Side effects

Fetal Toxicity: Sacubitril/Valsartan can cause fetal harm when administered to a pregnant woman.

Angioedema: Sacubitril/Valsartan may cause angioedema.

Hypotension: Sacubitril/Valsartan lowers blood pressure and may cause symptomatic hypotension.

Impaired Renal Function: As a consequence of inhibiting the renin-angiotensin-aldosterone system (RAAS), Sacubitril/Valsartan decreases in renal function.

Hyperkalemia: Through its actions on the RAAS, hyperkalemia may occur with Sacubitril/Valsartan.

Contraindications

Sacubitril/Valsartan is contraindicated:

• hypersensitivity to any component of Sacubitril/Valsartan

• in patients with a history of angioedema related to previous ACE inhibitor or ARB therapy

• with concomitant use of ACE inhibitors

• with concomitant use of aliskiren in patients with diabetes

Drug interactions

Dual Blockade of the Renin-Angiotensin-Aldosterone System: Concomitant use of Sacubitril/Valsartan with an ACE inhibitor is contraindicated because of the increased risk of angioedema. Use of Sacubitril/Valsartan with an ARB should be avoided, because Sacubitril/Valsartan contains the angiotensin II receptor blocker valsartan. The concomitant use of Sacubitril/Valsartan with aliskiren is contraindicated in patients with diabetes.

Potassium-Sparing Diuretics: As with other drugs that block angiotensin II, concomitant use of potassium-sparing diuretics (e.g., spironolactone, triamterene, amiloride), potassium supplements, or salt substitutes containing potassium may lead to increases in serum potassium

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) Including Selective Cyclooxygenase-2 Inhibitors (COX-2 Inhibitors): In patients who are elderly concomitant use of NSAIDs, including COX-2 inhibitors, with Sacubitril/Valsartan may result in worsening of renal function, including possible acute renal failure.

Precautions

Sacubitril/Valsartan should be used cautiously in patients with Fetal Toxicity, Angioedema, Hypotension, Impaired Renal Function and Hyperkalemia.

Use in Pregnancy and Lactation

Sacubitril/Valsartan can cause fetal harm when administered to a pregnant woman. Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death.

There is no information regarding the presence of Sacubitril/Valsartan in human milk, the effects on the breastfed infant, or the effects on milk production.

Storage Conditions

Store in a cool and dry place, away from light. Keep out of the reach of children.

Commercial pack

Arnigen 50 Tablet : Each box contains 2 blister packs of 10 tablets.

Arnigen 100 Tablet: Each box contains 2 blister packs of 10 tablets.

Manufactured by:

general GENERAL Pharmaceuticals Ltd.

Kaliakair, Gazipur, Bangladesh

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