Sabitar™

Sacubitril and Valsartan

1522

Presentation

Sabitar™ 50: Each film coated tablet contains Sacubitril Valsartan Sodium Hemipentahydrate INN equivalent to Sacubitril 24 mg and Valsartan 26 mg.
Sabitar™ 100: Each film coated tablet contains Sacubitril Valsartan Sodium Hemipentahydrate INN equivalent to Sacubitril 49 mg and Valsartan 51 mg.
Sabitar™ 200: Each film coated tablet contains Sacubitril Valsartan Sodium Hemipentahydrate INN equivalent to Sacubitril 97 mg and Valsartan 103 mg.

Description

Sacubitril, a neprilysin inhibitor that inhibits neprilysin (neutral endopeptidase; NEP) via active metabolite of the prodrug sacubitril. Valsartan, a angiotensin receptor blocker that blocks the angiotensin II type-1 (AT1) receptor. The cardiovascular and renal effects of Sacubitril/Valsartan in heart failure patients are attributed to the increased levels of peptides that are degraded by neprilysin, such as natriuretic peptides by the active metabolite of sacubitril and the simultaneous inhibition of the effects of angiotensin II by valsartan. Valsartan inhibits the effects of angiotensin II by selectively blocking the AT1 receptor, and also inhibits angiotensin II-dependent aldosterone release.

Indication and Uses

Sacubitril/Valsartan combination 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 and administration

• The recommended starting dose of Sacubitril/Valsartan is 100 mg twice-daily. Double the dose of Sacubitril/Valsartan after 2 to 4 weeks to the target maintenance dose of 200 mg twice-daily, as tolerated by the patient.
• Reduce the starting dose to 50 mg twice-daily for:
- Patients not currently taking an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin II receptor blocker (ARB) or previously taking a low dose of these agents
- Patients with severe renal impairment
- Patients with moderate hepatic impairment
Double the dose of Sacubitril/Valsartan every 2 to 4 weeks to the target maintenance dose of 200 mg twice-daily, as tolerated by the patient

Side-effects

The most common side effects are low blood pressure, high potassium, cough, dizziness, and kidney problems. It may cause some serious side-effects like angioedema (that may cause trouble in breath and death) and Hyperkalemia.

Contraindications

Sacubitril/Valsartan is contraindicated to the following cases-
- Hypersensitivity to any component
- History of angioedema related to previous ACE inhibitor or ARB therapy
- Concomitant use with ACE inhibitors
- Concomitant use with aliskiren in patients with diabetes

Precautions

- Signs and symptoms of angioedema and hypotension should be observed
- Renal function and potassium level should be monitored in susceptible patients

Use in specific populations

Pregnancy: Sacubitril/Valsartan can cause fetal harm when administered to a pregnant woman
Lactation: Drug should be discontinued during lactation
Pediatric use: Safety and effectiveness in pediatric patients have not been established
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 not recommended

Drug Interactions

Dual blockade of the renin-angiotensin system: Should not be used with an ACEi, aliskiren in patients with diabetes, and use with an ARB should be avoided
Potassium-sparing diuretics: Serum potassium level may be increased
NSAIDs: Risk of renal impairment may be increased
Lithium: Increased risk of lithium toxicity

Overdosage

Limited data are available with regard to overdosage in human subjects with Sacubitril and Valsartan. In healthy volunteers, a single dose of sacubitril/valsartan 1200 mg, and multiple doses of sacubitril/valsartan 900 mg (14 days) have been studied and were well tolerated.
Hypotension is the most likely result of overdosage due to the blood pressure lowering effects of Sacubitril and Valsartan. Symptomatic treatment should be provided. The drug is unlikely to be removed by hemodialysis because of high protein binding.

Storage condition

Do not store above 30 ^{0}C. Keep away from light and out of the reach of children.

Commercial pack

Sabitar™ 50: Each box contains 3 blister strips of 10 tablets.
Sabitar™ 100: Each box contains 2 blister strips of 10 tablets.
Sabitar™ 200: Each box contains 1 blister strip of 10 tablets.

Manufactured by
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