Vivanta®

Sacubitril and Valsartan
Tablet

Description

Vivanta® (sacubitril and valsartan) is a combination of a neprilysin inhibitor and an angiotensin II receptor blocker. Vivanta® is available as film-coated tablets for oral administration, containing 24 mg of sacubitril and 26 mg of valsartan; 49 mg of sacubitril and 51 mg of valsartan; and 97 mg of sacubitril and 103 mg of valsartan.

Indications

Vivanta® 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.

• For the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.

Vivanta® is usually administered in conjunction with other heart failure therapies, in place of an angiotensin-converting enzyme inhibitor (ACEi) or other ARB.

Dosage & Administration

Adult Heart Failure

The recommended starting dose of Vivanta® is 49/51 mg orally twice daily. Double the dose of Vivanta® after 2 to 4 weeks to the target maintenance dose of 97/103 mg twice daily, as tolerated by the patient.

Reduce the starting dose to 24/26 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.

Pediatric Heart Failure

Refer to Table 1 for the recommended dose for pediatric patients aged one year and older. Take the recommended dose orally twice daily. Adjust pediatric patient doses every 2 weeks, as tolerated by the patient.

Table 1: Recommended Dose Titration

Titration Step Dose (twice daily)			
	Starting	Second	Final
Pediatric Patients Less than 40 kg*	1.6 mg/kg	2.3 mg/kg	3.1 mg/kg
Pediatric Patients At least 40 kg, less than 50 kg	24/26 mg	49/51 mg	72/78 mg**
Pediatric Patients At least 50 kg	49/51 mg	72/78 mg**	97/103 mg

* Use of the Oral Suspension recommended in these patients. Recommended mg/kg doses are of the combined amount of both sacubitril and valsartan.

** Doses of 72/78 mg can be achieved using three 24/26 mg tablets.

Contraindications

Vivanta® is contraindicated:

• in patients with hypersensitivity to any component.

• in patients with a history of angioedema related to previous ACEi or ARB therapy.

• with concomitant use of ACEi. Do not administer within 36 hours of switching from or to an ACEi.

• with concomitant use of aliskiren in patients with diabetes.

Warning and precautions

Vivanta® may cause angioedema and must not be used in patients with a known history of angioedema related to previous ACEi or ARB therapy and in patients with hereditary angioedema.

Vivanta® lowers blood pressure and may cause symptomatic hypotension. Closely monitor serum creatinine, and down-titrate or interrupt Vivanta® in patients who develop a clinically significant decrease in renal function. In patients with renal artery stenosis, monitor renal function.

Monitor serum potassium periodically and treat appropriately, especially in patients with risk factors for hyperkalemia such as severe renal impairment, diabetes, hypoaldosteronism, or a high potassium diet. Dosage reduction or interruption of Vivanta® may be required.

Side Effects

The most common side effects are Angioedema, Hypotension, Impaired Renal Function, Hyperkalemia, Cough, Dizziness.

Use in Specific Populations

Pregnancy: Vivanta® can cause fetal harm when administered to a pregnant woman.

Lactation: Not recommended during lactation.

Pediatric Use: Safety and effectiveness have not been established in pediatric patients less than 1 year of age.

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: No dose adjustment is required when administering Vivanta® to patients with mild hepatic impairment (Child-Pugh A classification). Vivanta® is not recommended in patients with severe hepatic impairment, as no studies have been conducted in these patients.

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.

Drug Interactions

Dual Blockade of the Renin-Angiotensin-Aldosterone 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.

Overdose

Limited data are available with regard to overdosage in human subjects with Vivanta®. In healthy volunteers, a single dose of Vivanta® 583 mg sacubitril/617 mg valsartan, and multiple doses of 437 mg sacubitril/463 mg valsartan (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 Vivanta®. Symptomatic treatment should be provided. Vivanta® is unlikely to be removed by hemodialysis because of high protein binding.

Pharmaceutical Precautions

Keep in a dry place and store below 30° C. Protect from moisture and keep out of the reach of children.

Commercial Pack

Vivanta® 50 Tablet: Box containing 10 tablets in 1x10's Alu-Alu form packs. Each film coated tablet contains Sacubitril-Valsartan Sodium Hydrate Complex INN equivalent to Sacubitril 24 mg and Valsartan 26 mg.

Vivanta® 100 Tablet: Box containing 10 tablets in 1x10's Alu-Alu form packs. Each film coated tablet contains Sacubitril-Valsartan Sodium Hydrate Complex INN equivalent to Sacubitril 49 mg and Valsartan 51 mg.

Vivanta® 200 Tablet: Box containing 10 tablets in 1x10's Alu-Alu form packs. Each film coated tablet contains Sacubitril-Valsartan Sodium Hydrate Complex INN equivalent to Sacubitril 97 mg and Valsartan 103 mg.

BEXIMCO PHARMA

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