

Information For the User
Sacubitril 49 mg + Valsartan 51 mg tablet

Sacustep 100 Tablet

Composition:

Each film-coated bilayered tablet contains:

Sacubitril – 49 mg

Valsartan – 51 mg

Excipients – q.s.

Description:

Sacustep 100 Tablet is a fixed-dose combination of Sacubitril and Valsartan, classified as an angiotensin receptor neprilysin inhibitor (ARNI). This formulation is indicated for the treatment of chronic heart failure with reduced ejection fraction (HFrEF), offering improved survival and reduced hospitalization compared to traditional therapies. Sacubitril enhances the levels of beneficial natriuretic peptides, while Valsartan counteracts the harmful effects of the renin-angiotensin-aldosterone system (RAAS).

Indications:

Chronic heart failure (NYHA Class II–IV) with reduced ejection fraction

Alternative to ACE inhibitors or ARBs in stable symptomatic heart failure patients

Used to reduce cardiovascular mortality and morbidity

Mechanism of Action:

Sacubitril is a neprilysin inhibitor that prevents the degradation of natriuretic peptides, bradykinin, and other vasoactive peptides. This leads to vasodilation, natriuresis, diuresis, and inhibition of cardiac remodeling.

Valsartan blocks the angiotensin II type 1 (AT1) receptor, reducing vasoconstriction, sodium retention, and aldosterone secretion. Together, the combination improves hemodynamics and delays progression of heart failure.

Dosage and Administration:

Recommended dose: One tablet twice daily (Sacubitril 49 mg + Valsartan 51 mg)

Patients should be stabilized on lower doses before up-titration to Sacustep 100

Administer orally, with or without food

Ensure a 36-hour washout period after discontinuing ACE inhibitors before initiating therapy

Side Effects:

Dizziness, hypotension

Hyperkalemia

Renal function impairment

Cough

Rare: Angioedema

Precautions:

Not to be used with ACE inhibitors or in patients with a history of angioedema

Monitor blood pressure, renal function, and potassium levels regularly

Contraindicated during pregnancy and lactation
Use with caution in patients with hepatic or renal impairment

Storage:

Store below 25°C in a dry place
Protect from direct sunlight and moisture
Keep out of reach of children

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,
Panchkula-134113

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