

Information For the User
Sacubitril 98 mg + Valsartan 102 mg tablet

Sacustep 200 Tablet

Brand Name: Sacustep 200 Tablet

Composition:

Each film-coated tablet contains:

Sacubitril 98 mg

Valsartan 102 mg

Therapeutic Indication:

Indicated for the treatment of heart failure with reduced ejection fraction (HFrEF)

Helps in reducing cardiovascular mortality, hospitalization due to heart failure, and improving symptoms of heart failure

Mechanism of Action:

Sacubitril is a neprilysin inhibitor that increases levels of natriuretic peptides, leading to vasodilation, natriuresis, and inhibition of pathological growth in the heart

Valsartan is an angiotensin II receptor blocker (ARB) that inhibits the binding of angiotensin II to AT1 receptors, causing vasodilation and reduction in aldosterone-mediated sodium and water retention

The combination (ARNI – angiotensin receptor neprilysin inhibitor) provides synergistic effects to reduce cardiac load and improve heart failure outcomes

Dosage & Administration:

Usual adult dose: one tablet twice daily or as directed by the physician

Take consistently with or without food

Do not abruptly discontinue therapy

Adjust dose based on blood pressure, renal function, and tolerability

Contraindications:

Hypersensitivity to Sacubitril, Valsartan, or any component of the formulation

History of angioedema related to ACE inhibitors or ARBs

Concomitant use with ACE inhibitors or within 36 hours of switching from ACE inhibitor therapy

Pregnancy and lactation

Severe hepatic impairment or biliary obstruction

Warnings & Precautions:

Monitor blood pressure, renal function, and serum electrolytes regularly

Use with caution in patients with hypotension, renal impairment, or hyperkalemia

Discontinue immediately if pregnancy occurs

May cause dizziness, hypotension, or hyperkalemia

Side Effects:

Common: hypotension, dizziness, hyperkalemia, fatigue

Less common: cough, renal impairment, headache

Rare: angioedema, severe hypersensitivity reactions, liver enzyme elevations

Storage:

Store in a cool, dry, and dark place below 25°C
Protect from moisture and light
Keep out of reach of children

Packaging:

Sacustep 200 Tablet is available in blister or strip packs

Schedule:

Schedule H Prescription Drug – To be sold by retail on the prescription of a registered medical practitioner only

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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