Valmor™

Sacubitril & Valsartan Tablet

COMPOSITION

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

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

PHARMACOLOGY

Valmor™ (Sacubitril & Valsartan) is a combination of Neprilysin inhibitor Sacubitril and Angiotensin II Receptor Blocker (ARB) Valsartan. The drug inhibits Neprilysin through the active metabolite of Sacubitril and blocks AT_1 receptor through Valsartan. The cardiovascular and renal effects of this combination in heart failure patients are attributed to the increased level of natriuretic peptide, and the simultaneous inhibition of the effects of Angiotensin II by Valsartan.

INDICATIONS

Indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure and reduced ejection fraction.

DOSAGE & ADMINISTRATION

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

A starting dose of 24/26 mg (Sacubitril/Valsartan) twice-daily is recommended for:

- Patients not currently taking an Angiotensin Converting Enzyme (ACE) inhibitor 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

Dose should be doubled after 2 to 4 weeks to the target maintenance dose of 97/103 mg (Sacubitril/Valsartan) twice-daily, as tolerated by the patient.

CONTRAINDICATIONS

Sacubitril and Valsartan is contraindicated:

- In patients with hypersensitivity to any component
- 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

USE IN PREGNANCY & LACTATION

Sacubitril and Valsartan can cause fetal harm when administered to a pregnant woman. There is no information regarding the presence of Sacubitril and Valsartan in human milk, the effects on the breastfed infant, or the effects on milk production. Because of the potential for serious adverse reactions from exposure to Sacubitril and Valsartan, nursing woman are not recommended to breast feed during treatment with Sacubitril and Valsartan.

WARNING AND PRECAUTIONS

Sacubitril and Valsartan may cause angioedema. If angioedema occurs, the product should be discontinued immediately. The product lowers blood pressure and may cause symptomatic hypotension. In elderly patients or with compromised renal function, concomitant use of NSAIDs, including COX-2 inhibitors with Sacubitril and Valsartan may result in worsening of renal function, including possible acute renal failure.

DRUG INTERACTIONS

Concurrent use with Potassium-Sparing diuretics (e.g. Spironolactone, Triamterene, Amiloride), Potassium Supplements or salt substitutes containing Potassium may lead to increase in serum Potassium.

STORAGE CONDITIONS

Store below 30°C. Protect from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Valmor™ 50 Tablet: Each box contains 10 Tablets in alu-alu blister pack.

Valmor™ 100 Tablet: Each box contains 10 Tablets in alu-alu blister pack.

Manufactured by

SQUARE

SQUARE

PHARMACEUTICALS LTD.

BANGLADESH