

# Cardovan<sup>®</sup>

Valsartan USP Film Coated Tablet

## DESCRIPTION

**Cardovan<sup>®</sup>** is a preparation of Valsartan. Valsartan is a nonpeptide, orally active, and specific angiotensin II receptor blocker acting on the AT<sub>1</sub> receptor subtype. Angiotensin II is formed from angiotensin I in a reaction catalyzed by angiotensin-converting enzyme (ACE, kininase II). Angiotensin II is the principal pressor agent of the renin-angiotensin system, with effects that include vasoconstriction, stimulation of synthesis and release of aldosterone, cardiac stimulation, and renal reabsorption of sodium. **Cardovan<sup>®</sup>** blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT<sub>1</sub> receptor in many tissues, such as vascular smooth muscle and the adrenal gland. Its action is therefore independent of the pathways for angiotensin II synthesis. Blockade of the renin-angiotensin system with ACE inhibitors, which inhibit the biosynthesis of angiotensin II from angiotensin I, is widely used in the treatment of hypertension. ACE inhibitors also inhibit the degradation of bradykinin, a reaction also catalyzed by ACE. Because Valsartan does not inhibit ACE (kininase II), it does not affect the response to bradykinin. Whether this difference has clinical relevance is not yet known. Valsartan does not bind to or block other hormone receptors or ion channels known to be important in cardiovascular regulation. Blockade of the angiotensin II receptor inhibits the negative regulatory feedback of angiotensin II on renin secretion, but the resulting increased plasma renin activity and angiotensin II circulating levels do not overcome the effect of Valsartan on blood pressure.

## INDICATIONS

- ▶ Treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.
- ▶ Treatment of heart failure (NYHA class II-IV); Valsartan significantly reduces hospitalization for heart failure.
- ▶ Reduction of cardiovascular mortality in clinically stable patients with left ventricular failure or left ventricular dysfunction following myocardial infarction.

## DOSAGE AND ADMINISTRATION

Indication	Starting Dose	Dose Range
Adult Hypertension	80 or 160 mg once daily	80-320 mg once daily
Pediatric Hypertension (6-16 years)	1.3 mg/kg once daily (up to 40 mg total)	1.3-2.7 mg/kg once daily (up to 40-160 mg total)
Heart Failure	40 mg twice daily	40-160 mg twice daily
Post-Myocardial infarction	20 mg twice daily	20-160 mg twice daily

## CONTRAINDICATIONS

Known hypersensitivity to any component. Do not coadminister Aliskiren with Valsartan in patient with diabetes.

## SIDE EFFECTS

Headache, dizziness, viral infection, fatigue and abdominal pain.

## PRECAUTIONS & WARNINGS

- ▶ Observe for signs and symptoms of hypotension
- ▶ Monitor renal function and potassium in susceptible patients

## DRUG INTERACTIONS

- ▶ Potassium sparing diuretics, potassium supplements or salt substitutes may lead to increases in serum potassium, and in heart failure patients, increases in serum creatinine
- ▶ NSAID use may lead to increased risk of renal impairment and loss of antihypertensive effect

## USE IN PREGNANCY & LACTATION

Pregnancy Category D. When pregnancy is detected, Valsartan should be discontinued as soon as possible. It is not known whether Valsartan is excreted in human milk. Valsartan was excreted in the milk of lactating rats; however, animal breast milk drug levels may not accurately reflect human breast milk levels. Because many drugs are excreted into human milk and because of the potential for adverse reactions in nursing infants from Valsartan, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

## PHARMACEUTICAL PRECAUTIONS

Keep away from light and wet place. Keep out of reach of children.

## PACKAGING

**Cardovan® 80 Tablet** : Box containing 3 strips of 10 tablets each. Each tablet contains Valsartan USP 80 mg.

**Cardovan® 160 Tablet** : Box containing 3 strips of 10 tablets each. Each tablet contains Valsartan USP 160 mg.

# SK+F

Manufactured by

**ESKAYEF PHARMACEUTICALS LIMITED**

TONGI, GAZIPUR, BANGLADESH

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PM04688 V01