Cardovan Plus®

Valsartan USP and Hydrochlorothiazide BP Film Coated Tablet

DESCRIPTION

Cardovan Plus® is a combined preparation of Valsartan and Hydrochlorothiazide. Valsartan, an orally active, specific angiotensin II receptor blocker (ARB) acting on the AT1 receptor subtype, and hydrochlorothiazide, a diuretic. 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. Valsartan blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 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 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. Hydrochlorothiazide is a thiazide diuretic. Thiazides affect the renal tubular mechanisms of electrolyte reabsorption, directly increasing excretion of sodium and chloride in approximately equivalent amounts. Indirectly, the diuretic action of hydrochlorothiazide reduces plasma volume, with consequent increases in plasma renin activity, increases in aldosterone secretion, increases in urinary potassium loss, and decreases in serum potassium. The renin-aldosterone link is mediated by angiotensin II, so co-administration of an angiotensin II receptor antagonist tends to reverse the potassium loss associated with these diuretics. The mechanism of the antihypertensive effect of thiazides is unknown.

INDICATIONS

Cardovan Plus® is indicated for the treatment of hypertension, to lower blood pressure:

- In patients not adequately controlled with monotherapy.
- As initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals.

Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

DOSAGE AND ADMINISTRATION

General considerations:

- Maximum effects within 2 to 4 weeks after dose change
- Renal impairment: Not recommended for patients with severe renal impairment (creatinine clearance ≤30 mL/min)
- This combination may be administered with or without food.

Hypertension:

- **Add-on therapy or Initial therapy:** Initiate with 160/12.5 mg. Titrate upwards as needed to a maximum dose of 320/25 mg. One tablet daily
- **Replacement therapy:** May be substituted for titrated components

CONTRAINDICATIONS

- Anuria
- Hypersensitivity to any sulfonamide-derived drugs

SIDE EFFECTS

- Headache
- Dizziness
- Fatigue

PRECAUTIONS AND WARNINGS

- Avoid fetal or neonatal exposure
- Symptomatic hypotension with volume- and/or salt-depletion. Correct volume-depletion prior to administration. Not recommended as initial therapy in volume-depleted patients
- Use with caution in patients with impaired hepatic or renal function
- Observe for signs of fluid or electrolyte imbalance
- Thiazide diuretics may cause an exacerbation or activation of systemic lupus erythematosus
- Hydrochlorothiazide has been associated with acute angle-closure glaucoma

USE IN PREGNANCY AND LACTATION

Pregnancy Category D. Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. Resulting oligohydramnios cab be failure, and death. When pregnancy is detected, discontinue **Cardovan Plus®** as soon as possible. Intrauterine exposure to thiazide diuretics is associated with fetal or neonatal jaundice. thrombocytopenia, and possible other adverse reactions that have occurred in adults.

Nursing Mother: Drug or nursing should be discontinued.

PHARMACEUTICAL PRECAUTIONS

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

PACKAGING

Cardovan Plus® 80/12.5 Tablet : Box containing 3 strips of 10 tablets each. Each tablet contains Valsartan USP 80 mg and Hydrochlorothiazide BP 12.5 mg.

Cardovan Plus® 160/12.5 Tablet : Box containing 3 strips of 10 tablets each. Each tablet contains Valsartan USP 160 mg and Hydrochlorothiazide BP 12.5 mg.

SK+F
Manufactured by
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PM04814 V01