

Co-Disys®

Valsartan & Amlodipine tablet



Composition

Co-Disys® 80/5: Each film coated tablet contains Valsartan USP 80 mg & Amlodipine Besylate BP 6.93 mg equivalent to Amlodipine 5 mg.

Co-Disys® 160/5: Each film coated tablet contains Valsartan USP 160 mg & Amlodipine Besylate BP 6.93 mg equivalent to Amlodipine 5 mg.

Co-Disys® 160/10: Each film coated tablet contains Valsartan USP 160 mg & Amlodipine Besylate BP 13.86 mg equivalent to Amlodipine 10 mg.

Description

Co-Disys® is a fixed combination of amlodipine and valsartan. Amlodipine is a dihydropyridine calcium channel blocker that inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. Experimental data suggest that amlodipine binds to both dihydropyridine and nondihydropyridine binding sites. The contractile processes of cardiac muscle and vascular smooth muscle are dependent upon the movement of extracellular calcium ions into these cells through specific ion channels. Amlodipine inhibits calcium ion influx across cell membranes selectively, with a greater effect on vascular smooth muscle cells than on cardiac muscle cells. Amlodipine is a peripheral arterial vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and reduction in blood pressure.

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. By blocking the action of angiotensin, valsartan dilates the blood vessels and reduces blood pressure. Valsartan has much (about 20,000-fold) greater affinity for the AT₁ receptor than for the AT₂ receptor.

Indications

Co-Disys® is indicated for the treatment of hypertension. Co-Disys® may be used in patients whose blood pressure is not adequately controlled on either monotherapy. Co-Disys® may also be used as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals.

Dosage and Administration

Amlodipine is an effective treatment of hypertension in once daily doses of 2.5 mg to-10 mg while valsartan is effective in doses of 80 mg to-320 mg. The majority of the antihypertensive effect is attained within 2 weeks after initiation of therapy or a change in dose. The dosage can be increased after 1 to 2 weeks of therapy to a maximum of 10 mg amlodipine and 320 mg valsartan daily as needed to control blood pressure. Co-Disys® may be administered with or without food. Co-Disys® may be administered with other antihypertensive agents.

Elderly patients: Because of decreased clearance of amlodipine, therapy should usually be initiated at 2.5 mg.

Renal impairment: No initial dosage adjustment is required for patients with mild or moderate renal impairment. Dosages should be titrated slowly in patients with severe renal impairment.

Hepatic impairment: No initial dosage adjustment is required for patients with mild or moderate liver insufficiency. Titrate slowly in patients with hepatic

impairment.

Contraindications

Co-Disys® is contraindicated in patients with hypersensitivity to the active substances, to dihydropyridine derivatives, or to any of the excipients; Severe hepatic impairment, biliary cirrhosis or cholestasis; Severe renal impairment and patients undergoing dialysis; Second and third trimesters of pregnancy.

Adverse Effects

The most common adverse effects include peripheral edema, headache, vertigo, nasopharyngitis and dizziness.

Use in pregnancy & lactation

Co-Disys®, like other drugs that act on the renin angiotensin system, can cause fetal and neonatal morbidity and death when used during the second or third trimester of pregnancy. The use of Angiotensin II Receptor Antagonists is not recommended during the first trimester of pregnancy and contraindicated during the second and third trimesters of pregnancy.

It is not known whether amlodipine or valsartan are excreted in human milk. In the absence of this information, it is recommended that nursing be discontinued while Co-Disys® is administered.

Drug Interactions

Interaction linked to amlodipine: A study in elderly patients has shown that diltiazem inhibits the metabolism of amlodipine, probably via CYP3A4 (plasma concentration increases by approximately 50% and the effect of amlodipine is increased). The possibility that more potent inhibitors of CYP3A4 (i.e. ketoconazole, itraconazole, ritonavir) may increase the plasma concentration of amlodipine to a greater extent than diltiazem cannot be excluded. Co-administration with CYP3A4 inducers (anticonvulsant agents e.g. carbamazepine, phenobarbital, phenytoin, fosphenytoin and primidone, rifampicin, *Hypericum perforatum*) may lead to reduced plasma concentrations of amlodipine.

Interaction linked to Valsartan: Concomitant use with lithium or potassium sparing diuretics is not recommended.

Pack

Co-Disys® 80/5: Each box contains 30 tablets in Alu-Alu blister pack.

Co-Disys® 160/5: Each box contains 30 tablets in Alu-Alu blister pack.

Co-Disys® 160/10: Each box contains 30 tablets in Alu-Alu blister pack.

Storage

Store in a cool and dry place below 30 C. Protect from light.

Medicine: Keep out of reach of children.



Manufactured by
Healthcare Pharmaceuticals Ltd.
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