

Product: Irbesartan + Amlodipine (Aprovasc)

Strengths: 150 mg/5 mg Film-Coated Tab (DR-XY45509), 300 mg/5 mg Film-Coated Tab (DR-XY45507), 300 mg/10 mg Film-Coated Tab (DR-XY45508)

Presentation: Alu/White Opaque PVC/PE/PVDC blister pack x 14's (Box of 28's)

I: Treatment of essential hypertension. Indicated in patients whose blood pressure is not adequately controlled on Irbesartan or Amlodipine monotherapy

D: Recommended is one tab per day. Should be administered in patients whose BP is not adequately controlled on monotherapy with Irbesartan or Amlodipine or for continuation of therapy for patients receiving the drug as separate tabs. Max. recommended dose is 300mg/10 mg per day. No dosage adjustment is necessary for the elderly and/or patients with impaired renal function. Safety and efficacy in children has not been established. Administer with caution in patients with hepatic insufficiency. Can be used with or without food.

C: Hypersensitivity to irbesartan, amlodipine, dihydropyridines or to any formulation component; Shock (including cardiogenic shock); Obstruction of the left ventricular outflow tract; Unstable angina (excluding Prinzmetal's angina); Hemodynamically unstable heart failure following an acute myocardial infarction; Severe hypotension; Pregnancy and Lactation. Do NOT co-administer with medications containing aliskiren in patients with diabetes or with moderate to severe renal impairment (GFR <60mL/min/1.73m²). Do NOT co-administer with ACE Inhibitors in patients with diabetic nephropathy.

W: Symptomatic hypotension may occur in patients with ACE Inhibitors, with intensive treatment on diuretics and/or salt restriction, or in hemodialysis. Can cause hypoglycemia in patients treated for diabetes. Fetal or Neonatal morbidity and mortality. Patients with heart failure, hepatic impairment, or renal failure. The dose must be increased carefully in elderly patients. Safety and efficacy of this drug in hypertensive crisis has not been established.

P: Dual blockade of the RAAS with the combination of Aprovasc with ACE Inhibitors or with Aliskiren is not recommended. The use of Aprovasc in patients with or with a history of psoriasis should be weighed carefully as it may exacerbate the condition. Safety and efficacy in pediatric patients have not been established. Renal function should be monitored in patients receiving periodic treatment with Irbesartan and NSAIDs. The concomitant use of ARBs and CCBs may reduce renal lithium clearance and increase of serum levels that may reach toxic levels thus should be monitored in patients who are receiving Aprovasc. Amlodipine may have a mild or moderate effect on the ability to drive and use machines.

Int: Use of Aprovasc in combination with ACE inhibitors is contraindicated in patients with diabetic nephropathy and is not recommended. Irbesartan has the potential to inhibit OATP1B1 thus it may be necessary to adjust the dose in antidiabetic treatment such as repaglinide. The concomitant use of Irbesartan with potassium-sparing diuretics, potassium supplements, potassium-containing salt substitutes, or other medications that may increase kalaemia with Irbesartan therefore requiring close monitoring. The administration of Aprovasc with grapefruit juice is not recommended as in some patients it may result to an increase in the blood pressure lowering the effects of the drug. When using amlodipine and sildenafil in combination, each agent independently exerts its own blood pressure reductive effect. Concomitant use of amlodipine with inhibitors or inducers of CYP3A4 may give rise to variations of plasma concentrations of amlodipine exposure thus clinical monitoring and dose adjustment may be necessary. Aprovasc is contraindicated in lactation.

AE: Dizziness, Headache, Drowsiness, Nausea or Vomiting, Fatigue, edema, Palpitations, Flushing, Fatigue, Visual disturbances (including diplopia), Altered bowel habits (including diarrhea and constipation), Dyspepsia, Abdominal pain, Asthenia

PK: Irbesartan is an orally active agent and does not require biotransformation for its activity. After oral administration, Irbesartan is rapidly and completely absorbed. Peak plasma concentrations occurs from 1.5 to 2 hours after oral administration. Food does not affect the bioavailability of Irbesartan. After oral administration of therapeutic doses, amlodipine is well absorbed, with maximum blood levels between 6 to 12 hours after dose administration. The volume of distribution is approximately 21 L/Kg. In vitro studies have shown approximately 97.5% circulating amlodipine is bound to plasma proteins. Absorption of amlodipine is not affected by food intake.

PD: Irbesartan and Amlodipine, provide an addition of antihypertensive effects when administered concomitantly. Both the AT1 receptor blocker and the calcium channel antagonist decrease blood pressure by reducing the peripheral resistance. Irbesartan is a specific antagonist of angiotensin II receptors (AT1 subtype) and does not require metabolic activation for its action. It blocks the potent vasoconstriction and aldosterone -secreting effects produced by angiotensin II, by selective antagonism of angiotensin II receptors (AT1 subtype) localized in vascular smooth muscle cells and in the adrenal cortex. The effect on the decrease in blood pressure by Irbesartan becomes apparent after the first dose and is present in an important way for 1-2 weeks; the maximum effect occurs in 4-6 weeks. Amlodipine is a calcium dihydropyridine antagonist (calcium ion antagonist or slow-channel blocker) that inhibits the entry of calcium ions and the transmembrane influx of these ions into both the cardiac smooth muscle and the vascular smooth muscle. Amlodipine antihypertensive action mechanism is due to a direct relaxing effect on the vascular smooth muscle. The precise mechanism by which amlodipine alleviates angina symptoms has not been determined, however, amlodipine reduces the total ischemic burden through the following two actions: dilation of the peripheral arterioles which reduces the total peripheral resistance against which the heart works, and dilation of the main coronary arterioles and coronary arterioles which increases the oxygen supply to the myocardium in patients with coronary artery spasm.

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