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EPAR summary for the public

Rasitrio

aliskiren / amlodipine / hydrochlorothiazide

This is a summary of the European public assessment report (EPAR) for Rasitrio. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Rasitrio.

What is Rasitrio?

Rasitrio is a medicine that contains the active substances aliskiren, amlodipine and hydrochlorothiazide. It is available as tablets in the following strengths: 150 /5/12.5 mg; 300/5/12.5 mg; 300/5/25 mg; 300/10/12.5 mg; and 300/10/25 mg.

What is Rasitrio used for?

Rasitrio is used to treat essential hypertension (high blood pressure) in adults whose blood pressure is already adequately controlled with a combination of aliskiren, amlodipine and hydrochlorothiazide given concurrently at the same dose. 'Essential' means that the hypertension has no obvious cause.

The medicine can only be obtained with a prescription.

How is Rasitrio used?

The patient should take one tablet once a day with a light meal, preferably at the same time each day. The tablet should be swallowed whole with water. It should not be taken together with grapefruit juice.

The strength of the Rasitrio tablet that the patient takes depends on the doses of aliskiren, amlodipine and hydrochlorothiazide that they received previously. Patients should be switched to the fixed combination tablet of Rasitrio that contains the same component doses as previously used individually.



How does Rasitrio work?

Rasitrio contains three active substances, aliskiren, amlodipine, and hydrochlorothiazide.

Aliskiren is a renin inhibitor. It blocks the activity of an enzyme called renin, which is involved in the production of a substance called angiotensin I in the body. Angiotensin I is converted into the hormone angiotensin II, which is a powerful vasoconstrictor (a substance that narrows blood vessels). By blocking the activity of renin, levels of both, angiotensin I and angiotensin II, fall. This causes vasodilation (widening of the blood vessels), so that the blood pressure drops.

Amlodipine is a calcium channel blocker. It blocks special channels on the surface of cells called calcium channels, through which calcium ions normally enter. When calcium ions enter the cells in the muscles of blood vessel walls, this causes contraction. By reducing the flow of calcium into the cells, amlodipine prevents the blood vessel walls from contracting, thus lowering the blood pressure.

Hydrochlorothiazide is a diuretic. It works by increasing urine production, reducing the volume of fluid in the blood and lowering the blood pressure.

The combination of these three active substances reduces blood pressure more than either medicine acting alone.

How has Rasitrio been studied?

In a main study in 1,191 patients with moderate or severe hypertension, Rasitrio combinations containing the three active substances were compared with combinations containing only two active substances: aliskiren plus amlodipine, amlodipine plus hydrochlorothiazide, and aliskiren plus hydrochlorothiazide. The patients were treated for eight weeks. The main measure of effectiveness was the reduction in the average systolic blood pressure (blood pressure when the heart is contracting) measured when the patients were seated.

The company also presented studies showing that the tablet containing all three substances is absorbed in the body in the same way as the separate tablets.

What benefit has Rasitrio shown during the studies?

The Rasitrio combination was more effective than the double combinations at reducing systolic blood pressure. After eight weeks, patients treated with Rasitrio had an average reduction in sitting systolic blood pressure of 37.4 mmHg. Reductions of 28.2 mmHg, 30.6 mmHg and 30.8 mmHg were seen for aliskiren plus hydrochlorothiazide, aliskiren plus amlodipine and amlodipine plus hydrochlorothiazide respectively.

What is the risk associated with Rasitrio?

The most frequent adverse reactions for Rasitrio are hypotension and dizziness. For the full list of all side effects reported with Rasitrio, see the package leaflet.

Rasitrio must not be used in people who are hypersensitive (allergic) to aliskiren, amlodipine, or hydrochlorothiazide, to any of the other ingredients of the medicine or other substances derived from dihydropyridine (a group that includes amlodipine) or sulphonamide (includes hydrochlorothiazide). For the full list of restrictions, see the package leaflet.

Why has Rasitrio been approved?

The main study showed a greater reduction in blood pressure with Rasitrio than with combinations of two active substances. Studies also showed that the active substances in Rasitrio are absorbed in the body in the same way as the active substances when given as separate tablets. The CHMP noted that taking the three active substances in one tablet, as opposed to taking separate tablets, may lead to better compliance with treatment.

The Committee therefore decided that Rasitrio's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Rasitrio

The European Commission granted a marketing authorisation valid throughout the European Union for Rasitrio on 22 November 2011.

The full EPAR for Rasitrio can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports](http://ema.europa.eu/Find%20medicine/Human%20medicines/European%20Public%20Assessment%20Reports). For more information about treatment with Rasitrio, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2012.

Medicinal product no longer authorised