



22 September 2011
EMA/CHMP/746483/2011
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Rasitrio

aliskiren / amlodipine / hydrochlorothiazide

On 22 September 2011, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rasitrio, 150 mg/5 mg/12.5 mg, 300 mg/5 mg/12.5 mg, 300 mg/5 mg/25 mg, 300 mg/10 mg/12.5 mg, 300 mg/10 mg/25 mg, film-coated tablets intended for the treatment of essential hypertension as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of aliskiren, amlodipine and hydrochlorothiazide given concurrently at the same dose level as in the combination. The applicant for this medicinal product is Novartis Europharm Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substances in Rasitrio (C09XA54) are aliskiren, amlodipine and hydrochlorothiazide. Aliskiren is a renin-inhibitor, amlodipine is a calcium antagonist and hydrochlorothiazide is a diuretic. Aliskiren inhibits human renin, the enzyme responsible for the conversion of angiotensinogen to angiotensin I. Therefore the final production of the potent vasoconstrictor angiotensin II is inhibited by blocking the renin system at its very origin. Amlodipine inhibits the transmembrane entry of calcium ions into cardiac and vascular smooth muscle causing its relaxation and thus, vasodilation. Hydrochlorothiazide is a thiazide diuretic acting on the renal distal convoluted tubule. Thiazides affect the electrolyte re-absorption mechanisms: directly by increasing sodium and chloride excretion to an approximately equal extent, and indirectly by this diuretic action reducing plasma volume.

The benefits with Rasitrio are its ability to effectively lower the blood pressure achieved by a combination of three antihypertensive agents, each acting on different pathways. The most common side effects are hypotension, dizziness and peripheral oedema.

A pharmacovigilance plan for Rasitrio will be implemented as part of the marketing authorisation.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.



The approved indication is: "Rasitrio is indicated for the treatment of essential hypertension as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of aliskiren, amlodipine and hydrochlorothiazide given concurrently at the same dose level as in the combination."

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Rasitrio and therefore recommends the granting of the marketing authorisation.

Medicinal product no longer authorised