



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency starts review of aliskiren-containing medicines following termination of ALTITUDE study

Interim advice while review is ongoing

The European Medicines Agency is reviewing aliskiren-containing medicines, to assess the impact of data coming from the ALTITUDE study on the balance of benefits and risks of these medicines in their approved indication.

Aliskiren-containing medicines are approved for the treatment of essential hypertension. 'Essential' means that there is no obvious cause for high blood pressure.

The Agency's Committee for Medicinal Products for Human Use (CHMP) started the review after it was informed on 19 December 2011 by the marketing authorisation holder of the decision to terminate the ALTITUDE study early. This clinical trial included patients with type 2 diabetes and renal impairment and/or cardiovascular disease. In most patients arterial blood pressure was adequately controlled. The patients included in the trial received aliskiren in addition to either an angiotensin converting enzyme (ACE) inhibitor or an angiotensin receptor blocker (ARB).

Termination of the placebo-controlled phase III trial was recommended by the independent Data Monitoring Committee overseeing the study, because the results showed that there was no benefit with aliskiren and that there were more cases of stroke, renal complications, hyperkalemia and hypotension in patients who received aliskiren compared with patients who received a placebo.

The information available at present is limited. The Committee has asked the company to provide additional analyses to allow the CHMP to assess the impact of the results of the ALTITUDE trial on the overall benefit-risk profile of aliskiren-containing medicines and to determine the need for regulatory action.

Interim advice for doctors and patients

While the review is ongoing the CHMP recommends, as a precautionary measure, that doctors should not prescribe aliskiren-containing medicines to diabetic patients in combination with ACE inhibitors or ARBs.



Doctors should therefore review the treatment of patients taking aliskiren at a routine (non-urgent) appointment, and if patients are diabetic and are also taking ACE inhibitors or ARBs, aliskiren should be stopped and alternative treatments considered.

Patients should not stop any of their treatment before speaking to their doctor, because stopping anti-hypertensive medication without medical supervision can put them at risk. They are advised to discuss their treatment with their doctor at their next scheduled (non-urgent) appointment.

Patients in clinical trials with aliskiren should contact their study site for guidance on their medication.

Further information on the review of aliskiren-containing medicines will be provided when available.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Eight aliskiren-containing medicines are authorised in the European Union since 2007: Rasilamlo, Rasilez, Rasilez HCT, Rasitrio, Riprazo, Riprazo HCT, Sprimeo, Sprimeo HCT. Some of these medicines (Rasilamlo, Rasilez HCT, Rasitrio, Riprazo HCT and Sprimeo HCT) are combinations of aliskiren with other antihypertensive medicines.
3. The review of aliskiren is conducted in the context of a formal review, initiated at the request of the European Commission under Article 20 of Regulation (EC) No 726/2004.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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