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Press Office

Press release

European Medicines Agency recommends new contraindications and warnings for aliskiren-containing medicines

Combination of aliskiren with 'ACE' inhibitors and 'ARBs' no longer recommended for patients; contraindication in patients with diabetes or kidney problems

The European Medicines Agency finalised a review of aliskiren-containing medicines, recommending that these medicines should be contraindicated in patients with diabetes or moderate to severe renal impairment who take angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs). In addition, the Agency recommended the inclusion of a warning that the combination of aliskiren and ACE inhibitor or ARB is not recommended in all other patients because adverse outcomes cannot be excluded.

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

Advice for doctors and patients

Doctors should stop prescribing aliskiren-containing medicines to patients with diabetes (type 1 or type 2) or with moderate to severe kidney impairment who are also taking an ACE inhibitor or ARB, and should consider alternative antihypertensive treatment as necessary.

For all other patients receiving aliskiren-containing medicines in combination with an ACE inhibitor or an ARB, the balance of benefits and risks of continuing treatment should be considered carefully.

Patients should discuss their treatment with their doctor at their next scheduled (non-urgent) appointment. They 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.

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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

The recommendations follow a review of all available safety data by the Agency's Committee for Medicinal Products for Human Use (CHMP). The review was started in December 2011 after the Agency was informed by the marketing authorisation holder of the decision to terminate the ALTITUDE study early. This placebo-controlled phase III 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 ACE inhibitor or an ARB.

Although the information available at the time was limited, the CHMP gave interim recommendations in December 2011, advising doctors that they should not prescribe aliskiren-containing medicines to diabetic patients in combination with ACE inhibitors or ARBs.

Since then further data and analyses from the ALTITUDE study, alongside all data from other studies and spontaneous reports of suspected adverse drug reactions, have become available and were reviewed by the CHMP. The data suggest a risk of adverse outcomes (hypotension, syncope, stroke, hyperkalaemia and changes in renal function, including acute renal failure) when aliskiren is combined with ACE inhibitors or ARBs, especially in diabetic patients and those with impaired renal function. Although less evidence is available for other patient groups, adverse outcomes cannot be excluded and therefore the CHMP no longer recommends the use of this combination.

Healthcare professionals in the European Union will receive a letter shortly to inform them of the changes to the prescribing information for aliskiren-containing medicines.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. A European Commission decision on this opinion will be issued in due course.
3. Eight aliskiren-containing medicines are authorised in the European Union (EU) since 2007: Rasilamlo, Rasilez, Rasilez HCT, Rasitrio, Riprazo, Riprazo HCT, Sprimeo and Sprimeo HCT. Some of these medicines (Rasilamlo, Rasilez HCT, Rasitrio, Riprazo HCT and Sprimeo HCT) are combinations of aliskiren with other antihypertensive medicines. Aliskiren-containing medicines are available as tablets and marketed in all EU Member States, except Estonia, Latvia, Lithuania and Romania.
4. 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.
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu