European Medicines Agency
Press office

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PRESS RELEASE

European Medicines Agency recommends new contraindication and warning for Rasilez and other aliskiren medicines

The European Medicines Agency (EMEA) has recommended adding a contra-indication to the Product Information for aliskiren, stating that it must not be used in patients who have experienced angioedema (swelling of the tissues beneath the skin) when taking aliskiren in the past. The Agency also recommended the inclusion of a warning, stating that patients who develop signs of angioedema should stop treatment and seek medical attention.

Aliskiren is authorised for the treatment of essential hypertension (high blood pressure with no identifiable cause). It has been authorised in the European Union (EU) since August 2007 as Rasilez, Enviage, Sprimeo, Tekturna and Riprazo.

Angioedema is characterised by swelling of the skin, the tissues below the skin and the moist body surfaces such as the lining of the mouth and throat. It can develop rapidly and in rare cases can be dangerous if it affects the throat, because it can lead to obstruction of the airway.

Cases of angioedema or similar reactions were reported with aliskiren-containing medicines. Following assessment of all available evidence, the EMEA's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of aliskiren-containing medicines in the treatment of essential hypertension continue to outweigh their risks, but that angioedema can occur as a rare and serious side effect with these medicines.

The Committee is therefore recommending that:

- healthcare professionals should not prescribe any aliskiren-containing medicines for patients who have developed angioedema with the aliskiren-containing medicine in the past;
- any patients who develop signs of angioedema should stop aliskiren treatment promptly and seek medical attention.

The EMEA's recommendation has been sent to the European Commission for the adoption of a legally binding decision.

Aliskiren is also authorised in combination with hydrochlorothiazide as Rasilez HCT. The Product Information for this medicine already contains this contraindication and warning.

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Notes:

1. The active substance in Rasilez, aliskiren, is a renin inhibitor. It blocks the activity of a human enzyme called renin, which is involved in the production of a substance, angiotensin I, in the body. Angiotensin I is converted into the hormone angiotensin II, which is a powerful vasoconstrictor (it narrows blood vessels). By blocking the production of angiotensin I, levels of both angiotensin I and angiotensin II fall. This causes vasodilation (widening of the blood vessels), so that the blood pressure drops and the potential risk of damage caused by high blood pressure may be reduced.
2. In the EU, Rasilez is marketed in Austria, Belgium, Cyprus, Denmark, Finland, Greece, Germany, Ireland, Iceland, Luxembourg, Malta, Norway, the Netherlands, Poland, Spain, Slovakia, Sweden and the United Kingdom. The other aliskiren-containing medicines have not been launched.

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3. More information about Rasilez is available in the European public assessment report here: http://www.emea.europa.eu/humandocs/Humans/EPAR/rasilez/rasilez.htm
4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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