EMA/402904/2016
EMEA/H/C/000780

EPAR summary for the public

Rasilez

aliskiren

This is a summary of the European public assessment report (EPAR) for Rasilez. 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 Rasilez.

What is Rasilez?

Rasilez is a medicine that contains the active substance aliskiren. It is available as tablets (150 and 300 mg).

What is Rasilez used for?

Rasilez is used to treat essential hypertension (high blood pressure) in adults. 'Essential' means that the hypertension has no obvious cause.

The medicine can only be obtained with a prescription.

How is Rasilez used?

The recommended dose of Rasilez is 150 mg once a day. Rasilez may be taken alone or in combination with other medicines for hypertension, with the exception of 'angiotensin converting enzyme (ACE) inhibitors' or 'angiotensin receptor blockers' (ARBs) in patients with diabetes, or moderate or severe kidney impairment. Rasilez should not be taken together with fruit juice or drinks containing plant extracts such as herbal teas. The dose of Rasilez may be increased to 300 mg once a day in patients whose blood pressure is not adequately controlled.

How does Rasilez work?

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 called angiotensin I in the body.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Angiotensin I is converted into the hormone angiotensin II, which is a powerful vasoconstrictor (a substance that 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. This may reduce the risks associated with high blood pressure, such as having a stroke.

How has Rasilez been studied?

Rasilez has been studied in 14 main studies involving over 10,000 patients with essential hypertension. Thirteen of the studies included patients with mild to moderate hypertension, and one included patients with severe hypertension. In five of the studies, the effects of Rasilez taken alone were compared with those of placebo (a dummy treatment). Rasilez, taken alone or in combination with other medicines, was also compared with other medicines for hypertension. Combination studies looked at Rasilez used with an ACE inhibitor (ramipril), an ARB (valsartan), a beta-blocker (atenolol), a calcium-channel blocker (amlodipine) and a diuretic (hydrochlorothiazide). The studies lasted between six and 52 weeks and the main measure of effectiveness was the change in blood pressure during either the resting phase of the heartbeat ('diastolic') or when the chambers of the heart were contracting ('systolic'). The blood pressure was measured in 'millimetres of mercury' (mmHg).

What benefit has Rasilez shown during the studies?

Rasilez on its own was more effective than placebo and as effective as comparator treatments in reducing blood pressure. When the results of the five studies comparing Rasilez taken alone with placebo were looked at together, patients aged under 65 years had an average fall in diastolic blood pressure of 9.0 mmHg after eight weeks of taking 150 mg Rasilez, from an average of 99.4 mmHg at the start of the study. This was compared with a fall of 5.8 mmHg from 99.3 mmHg in the patients taking placebo.

Larger falls were seen in patients aged 65 years or over and those taking higher doses of Rasilez. Rasilez also reduced blood pressure in patients with diabetes and patients who were overweight. The medicine's effects were maintained for up to a year in two of the studies.

The studies with Rasilez taken in combination with other medicines showed additional decreases in blood pressure compared with the decreases produced by these medicines alone.

What is the risk associated with Rasilez?

The most common side effects with Rasilez (seen in between 1 and 10 patients in 100) are dizziness, diarrhoea, arthralgia (joint pain) and hyperkalaemia (high blood potassium levels). For the full list of all side effects reported with Rasilez, see the package leaflet.

Rasilez must not be used in patients who have had angioedema (swelling under the skin) with aliskiren, hereditary angioedema or angioedema of no obvious cause, or in women who are more than three months pregnant. Its use during the first three months of pregnancy and in women planning to become pregnant is not recommended. Rasilez must also not be taken with ciclosporin, itraconazole or other medicines known as 'potent P-glycoprotein inhibitors' (such as quinidine). Rasilez in combination with an ACE inhibitor or an ARB must not be used in patients with diabetes, or moderate or severe kidney impairment. Rasilez is for use in adults only; it must not be used in children aged less than 2 years and is not recommended for older children. For the full list of restrictions, see the package leaflet.

Why has Rasilez been approved?

The CHMP noted that Rasilez is effective in reducing blood pressure when used alone or in combination. The CHMP therefore decided that the benefits of Rasilez are greater than its risks and recommended that it be given marketing authorisation. However, in February 2012, following the review of a study called ALTITUDE, the CHMP recommended that Rasilez should not be used together with an ACE inhibitor or ARB in patients with diabetes or with moderate or severe kidney impairment because of an increase in the risk of cardiovascular and kidney problems.

What measures are being taken to ensure the safe and effective use of Rasilez?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Rasilez have also been included in the summary of product characteristics and the package leaflet.

Other information about Rasilez

The European Commission granted a marketing authorisation valid throughout the European Union for Rasilez on 22 August 2007.

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

This summary was last updated in 06-2016.