



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/515960/2018
EMA/H/C/000964

Rasilez HCT (*aliskiren / hydrochlorothiazide*)

An overview of Rasilez HCT and why it is authorised in the EU

What is Rasilez HCT and what is it used for?

Rasilez HCT is a medicine used to treat essential hypertension (high blood pressure) in adults. 'Essential' means that no specific cause for the hypertension can be found.

Rasilez HCT is used in patients whose blood pressure is not adequately controlled by aliskiren or hydrochlorothiazide taken alone. It can also be used in patients whose blood pressure is adequately controlled with aliskiren and hydrochlorothiazide taken as separate tablets, to replace the same doses of the two active substances.

The medicine contains the active substances aliskiren and hydrochlorothiazide.

How is Rasilez HCT used?

Rasilez HCT can only be obtained with a prescription and it is available as tablets (150 mg/12.5 mg; 150 mg/25 mg; 300 mg /12.5 mg; 300 mg/25 mg). The recommended dose of Rasilez HCT is one tablet per day. The dose depends on the doses of aliskiren or hydrochlorothiazide that the patient was taking before.

Patients previously taking only aliskiren or hydrochlorothiazide may need to take the two substances as separate tablets and adjust the doses before switching to Rasilez HCT. After two to four weeks of taking Rasilez HCT, the dose can be increased in patients whose blood pressure remains uncontrolled.

In patients already adequately controlled with the two active substances, the dose of Rasilez HCT must contain the same doses of aliskiren and hydrochlorothiazide that the patient was taking before.

Rasilez HCT should not be taken together with fruit juice or drinks containing plant extracts such as herbal teas. For more information about using Rasilez HCT, see the package leaflet or contact your doctor or pharmacist.

How does Rasilez HCT work?

The two active substances in Rasilez HCT, aliskiren and hydrochlorothiazide, work in different ways to reduce blood pressure.



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. 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.

Hydrochlorothiazide is a diuretic, which is another type of treatment for hypertension. It works by increasing urine output, reducing the amount of fluid in the blood and reducing blood pressure.

The combination of the two active substances has an additive effect, reducing the blood pressure more than either medicine alone. By lowering blood pressure, the risk caused by high blood pressure, such as having a stroke, is reduced.

What benefits of Rasilez HCT have been shown in studies?

Aliskiren on its own has been authorised in the EU since August 2007 as Rasilez, Sprimeo and Riprazo. The company presented information used in the assessment of aliskiren and from the published literature to support its application for Rasilez HCT, as well as information from additional studies.

Overall, the company presented the results of nine main studies involving a total of almost 9,000 patients with essential hypertension. Most studies involved patients with mild to moderate hypertension and one involved patients with severe hypertension. The studies compared the combination of aliskiren and hydrochlorothiazide with placebo (a dummy treatment), with aliskiren or hydrochlorothiazide taken alone, or with other medicines for hypertension (valsartan, irbesartan, lisinopril or amlodipine). The studies lasted for between 8 weeks and a year, and the main measure of effectiveness was the change in blood pressure either during the resting phase of the heartbeat (diastolic) or when the chambers of the heart were contracting (systolic).

Results showed that Rasilez HCT was more effective than placebo in reducing blood pressure. In patients whose blood pressure was not adequately controlled on either aliskiren or hydrochlorothiazide alone, switching to the combination resulted in greater falls in blood pressure than remaining on one active substance alone.

Three additional studies showed that the active substances were absorbed in the body in the same way when taken as separate tablets and as Rasilez HCT.

What are the risks associated with Rasilez HCT?

The most common side effect with Rasilez HCT (which may affect between 1 and 10 patients in 100) is diarrhoea. Other common side effects (which may affect more than 1 in 10 patients) that have been observed with hydrochlorothiazide alone are hypokalaemia (low blood potassium levels) and increases in blood cholesterol and triglyceride (a type of fat) levels. For the full list of all side effects reported with Rasilez HCT, see the package leaflet.

Rasilez HCT must not be used in patients who have had angioedema (swelling under the skin) with aliskiren, hereditary angioedema or angioedema of no obvious cause, who have anuria (a condition in which a patient cannot make or pass urine), severe kidney or liver impairment, or whose blood potassium levels are too low or blood calcium levels are too high. It must not be taken with ciclosporin, itraconazole or other medicines known as 'potent P-glycoprotein inhibitors' (such as quinidine). It must not be used in women who are more than three months pregnant. Its use during the first three months of pregnancy is not recommended. Rasilez HCT in combination with an 'angiotensin converting enzyme (ACE) inhibitors' or 'angiotensin receptor blockers' (ARBs) must not be used in patients with diabetes,

or moderate or severe kidney impairment. Rasilez HCT 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 is Rasilez HCT authorised in the EU?

The European Medicines Agency decided that Rasilez HCT's benefits are greater than its risks and it can be authorised for use in the EU. The medicine has been shown to reduce blood pressure more than each active substance alone. Taking the two active substances in one tablet is expected to help patients to stick to their treatment. Side effects are similar to those of the two active substances.

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

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

As for all medicines, data on the use of Rasilez HCT are continuously monitored. Side effects reported with Rasilez HCT are carefully evaluated and any necessary action taken to protect patients.

Other information about Rasilez HCT

Rasilez HCT received a marketing authorisation valid throughout the EU on 16 January 2009.

Further information on Rasilez HCT can be found on the Agency's website: ema.europa.eu/Find/medicine/Human_medicines/European_Public_Assessment_Reports.

This overview was last updated in 07-2018.