EMA/101161/2015
EMEA/H/C/002073

EPAR summary for the public

Rasilamlo

aliskiren / amlodipine

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

What is Rasilamlo?

Rasilamlo is a medicine that contains the active substances aliskiren and amlodipine. It is available as tablets (150 mg aliskiren and 5 mg amlodipine; 150 mg aliskiren and 10 mg amlodipine; 300 mg aliskiren and 5 mg amlodipine; 300 mg aliskiren and 10 mg amlodipine).

What is Rasilamlo used for?

Rasilamlo is used to treat essential hypertension (high blood pressure) in adults whose blood pressure is not adequately controlled with aliskiren or amlodipine used alone. 'Essential' means that the hypertension has no obvious cause.

The medicine can only be obtained with a prescription.

How is Rasilamlo used?

The patient should take one tablet once a day with a light meal, preferably at the same time each day. The tablet should be swallowed whole with water. It should not be taken together with fruit juice or drinks containing plant extracts such as herbal teas.

The strength of the tablet the patient takes depends on the doses of aliskiren or amlodipine that they received previously. The dose may be adjusted based on the side effects the patient experienced with their previous treatment with aliskiren or amlodipine and also on how the patient responds to treatment with Rasilamlo.

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

Rasilamlo can be used with other antihypertensive medicines, with the exception of 'angiotensin converting enzyme (ACE) inhibitors' or 'angiotensin receptor blockers' (ARBs) in patients with diabetes, or moderate or severe kidney impairment.

How does Rasilamlo work?

Rasilamlo contains two active substances, aliskiren and amlodipine.

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.

Amlodipine is a calcium channel blocker. It blocks special channels on the surface of cells called calcium channels, through which calcium ions normally enter. When calcium ions enter the cells in the muscles of blood vessel walls, this causes contraction. By reducing the flow of calcium into the cells, amlodipine prevents the blood vessel walls from contracting, thus lowering the blood pressure.

How has Rasilamlo been studied?

In three main studies involving 2,212 patients Rasilamlo was compared with aliskiren or amlodipine taken alone for eight or six weeks. The main measure of effectiveness was the change in the average diastolic blood pressure (blood pressure measured between two heartbeats) measured when the patients were seated.

What benefit has Rasilamlo shown during the studies?

Rasilamlo was more effective at controlling essential hypertension than placebo, aliskiren or amlodipine used alone.

In the first study, patients taking Rasilamlo 300/10 mg and 300/5 mg had a fall in their sitting diastolic blood pressure of 13.1 mmHg and 10.5 mmHg, respectively, compared with a fall of 5.8 mmHg in patients taking aliskiren 300 mg.

In the second study the falls in blood pressure were 11.0 mmHg and 9.0 mmHg with Rasilamlo 300/10 mg and 150/10mg, respectively, compared with 7.2mmHg with amlodipine 10 mg.

The third study showed a fall in blood pressure of 8.5 mmHg with Rasilamlo 150/5 mg compared with 8.0 mmHg and 4.8 mmHg with amlodipine 10 mg and 5 mg, respectively.

What is the risk associated with Rasilamlo?

The most common side effects with Rasilamlo are hypotension (low blood pressure) and peripheral oedema (swelling, especially of the ankles and feet). For the full list of all side effects reported with Rasilamlo, see the package leaflet.

Rasilamlo must not be used in people who are hypersensitive (allergic) to aliskiren, amlodipine, to any of the other ingredients of the medicine or other substances derived from dihydropyridine (a group that includes amlodipine). It must not be used in patients with a history of angioedema (swelling beneath the skin) with aliskiren, hereditary angioedema or angioedema of no obvious cause, severe hypotension, shock, narrowing of the aortic heart valve or in patients with heart failure after a heart

attack. It must also not be used in women who are more than three months pregnant or in patients taking medicines containing ciclosporin, itraconazole or other medicines known as 'potent P-glycoprotein inhibitors' (such as quinidine). Rasilamlo in combination with an ACE inhibitor or an ARB must not be used in patients with diabetes, or moderate or severe kidney impairment. Rasilamlo 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.

Why has Rasilamlo been approved?

The CHMP decided that Rasilamlo's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

A risk management plan has been developed to ensure that Rasilamlo is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Rasilamlo, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Rasilamlo

The European Commission granted a marketing authorisation valid throughout the European Union for Rasilamlo on 14 April 2011.

The full EPAR for Rasilamlo 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 Rasilamlo, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2015.