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EPAR summary for the public

Sprimeo

aliskiren

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

What is Sprimeo?

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

What is Sprimeo used for?

Sprimeo 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 Sprimeo used?

The recommended dose of Sprimeo is 150 mg once a day. Sprimeo 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. It should be taken with a light meal preferably at the same time each day, but grapefruit juice should not be taken together with Sprimeo. The dose of Sprimeo may be increased to 300 mg once a day in patients whose blood pressure is not adequately controlled.

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How does Sprimeo work?

The active substance in Sprimeo, 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. This may reduce the risks associated with high blood pressure, such as having a stroke.

How has Sprimeo been studied?

Sprimeo 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 Sprimeo taken alone were compared with those of placebo (a dummy treatment). Sprimeo, taken alone or in combination with other medicines, was also compared with other medicines for hypertension. Combination studies looked at Sprimeo 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 Sprimeo shown during the studies?

Sprimeo 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 Sprimeo 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 Sprimeo, 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 Sprimeo. Sprimeo 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 Sprimeo 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 Sprimeo?

The most common side effects with Sprimeo (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 Sprimeo, see the package leaflet.

Sprimeo must not be used by people who are hypersensitive (allergic) to aliskiren or any of the other ingredients. It 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. Sprimeo must also not be taken with ciclosporin, itraconazole or other medicines known as 'potent P-glycoprotein inhibitors' (such as quinidine). Sprimeo in

combination with an ACE inhibitor or an ARB must not be used in patients with diabetes, or moderate or severe kidney impairment.

Why has Sprimeo been approved?

The CHMP noted that Sprimeo is effective in reducing blood pressure when used alone or in combination. The CHMP therefore decided that the benefits of Sprimeo 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 Sprimeo 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.

Other information about Sprimeo

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

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

This summary was last updated in 04-2012.