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EPAR summary for the public

Sprimeo HCT

aliskiren / hydrochlorothiazide

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

What is Sprimeo HCT?

Sprimeo HCT is a medicine that contains the active substances aliskiren and hydrochlorothiazide. It is available as tablets (150 mg aliskiren and 12.5 mg hydrochlorothiazide; 150 mg aliskiren and 25 mg hydrochlorothiazide; 300 mg aliskiren and 12.5 mg hydrochlorothiazide; 300 mg aliskiren and 25 mg hydrochlorothiazide).

What is Sprimeo HCT used for?

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

Sprimeo 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 can only be obtained with a prescription.

How is Sprimeo HCT used?

The recommended dose of Sprimeo HCT is one tablet per day. 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

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HCT. The dose depends on the doses of aliskiren and/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 Sprimeo HCT. After two to four weeks of taking Sprimeo 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 Sprimeo HCT must contain the same doses of aliskiren and hydrochlorothiazide that the patient was taking before.

How does Sprimeo HCT work?

Sprimeo HCT contains two active substances, aliskiren and hydrochlorothiazide.

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.

How has Sprimeo HCT been studied?

Aliskiren on its own has been authorised in the European Union (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 Sprimeo 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 eight 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).

Three additional studies were carried out to show that the active substances were absorbed in the body in the same way when they taken as separate tablets and as Sprimeo HCT.

What benefit has Sprimeo HCT shown during the studies?

Sprimeo 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.

What is the risk associated with Sprimeo HCT?

The most common side effect with Sprimeo HCT (seen in between 1 and 10 patients in 100) is diarrhoea. For the full list of all side effects reported with Sprimeo HCT, see the package leaflet.

Sprimeo HCT must not be used in people who are hypersensitive (allergic) to aliskiren, hydrochlorothiazide, any of the other ingredients or sulfonamides. 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, who have 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 or breast-feeding. Its use during the first three months of pregnancy is not recommended. Sprimeo 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.

Why has Sprimeo HCT been approved?

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

Other information about Sprimeo HCT

The European Commission granted a marketing authorisation valid throughout the European Union for Sprimeo HCT on 23 June 2011. This authorisation was based on the authorisation of Rasilez HCT in 2009 ('informed consent').

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

This summary was last updated in 04-2012.