EMA/288275/2015
EMEA/H/C/000775

EPAR summary for the public

Imprida

amlodipine / valsartan

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

What is Imprida?

Imprida is a medicine that contains two active substances, amlodipine and valsartan. It is available as tablets (5 mg amlodipine and 80 mg valsartan; 5 mg amlodipine and 160 mg valsartan; 10 mg amlodipine and 160 mg valsartan).

What is Imprida used for?

Imprida is used in patients who have essential hypertension (high blood pressure) that is not adequately controlled on either amlodipine or valsartan taken alone. 'Essential' means that the hypertension has no obvious cause.

The medicine can only be obtained with a prescription

How is Imprida used?

Imprida is taken by mouth as one tablet once a day with some water. The dose of Imprida to be used depends on the doses of amlodipine or valsartan that the patient was taking before. The patient may need to take separate tablets or capsules before switching to the combination tablet.

How does Imprida work?

Imprida contains two active substances, amlodipine and valsartan. Both are anti-hypertensive medicines that have been available separately in the European Union (EU) since the mid-1990s. They

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

work in similar ways to reduce blood pressure by allowing the blood vessels to relax. By lowering the blood pressure, the risks associated with by high blood pressure, such as having a stroke, are reduced.

Amlodipine is a calcium channel blocker. It blocks special channels on the surface of cells called calcium channels, through which calcium ions normally enter the cells. 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 cells from contracting and this helps the blood vessels to relax.

Valsartan is an 'angiotensin II receptor antagonist', which means that it blocks the action of a hormone in the body called angiotensin II. Angiotensin II is a powerful vasoconstrictor (a substance that narrows blood vessels). By blocking the receptors to which angiotensin II normally attaches, valsartan stops the hormone having an effect, allowing the blood vessels to widen.

How has Imprida been studied?

Because amlodipine and valsartan have been used for many years, the company presented information on the two substances from earlier studies and the scientific literature, as well as new studies that used a combination of the two active substances.

Five main studies involving nearly 5,200 patients, mostly with mild to moderate hypertension, were carried out. Two studies (involving almost 3,200 patients) compared amlodipine, valsartan or a combination of both substances with placebo (a dummy treatment). Two studies (involving 1,891 patients) compared the combination in patients whose hypertension was not adequately controlled with either 10 mg amlodipine or 160 mg valsartan. The fifth, smaller study compared the combination with lisinopril and hydrochlorothiazide (another combination used to treat hypertension) in 130 patients with severe hypertension. In all studies, the main measure of effectiveness was the reduction in diastolic blood pressure (the blood pressure measured between two heartbeats). The blood pressure was measured in 'millimetres of mercury' (mmHg).

The company also presented evidence that the levels of amlodipine and valsartan in the blood were the same in people taking Imprida and people taking the separate medicines.

What benefit has Imprida shown during the studies?

The combination of amlodipine and valsartan was more effective at reducing blood pressure than placebo or either valsartan or amlodipine taken alone. In the studies comparing the combination in patients who were already taking either amlodipine or valsartan, the blood pressure in patients taking valsartan alone had fallen by 6.6 mmHg after eight weeks, compared with 9.6 and 11.4 mmHg in the patients adding 5 or 10 mg amlodipine, respectively. Patients taking amlodipine alone had a fall of 10.0 mmHg, compared with 11.8 mmHg in the patients adding 160 mg valsartan.

What is the risk associated with Imprida?

The most common side effects with Imprida (seen in between 1 and 10 patients in 100) are headache, nasopharyngitis (inflammation of the nose and throat), influenza (flu), hypokalaemia (low blood potassium levels), various types of oedema (swelling), fatigue (tiredness), flushing (reddening), asthenia (weakness) and hot flushes. For the full list of all side effects reported with Imprida, see the package leaflet.

Imprida must not be used in patients who are hypersensitive (allergic) to amlodipine or other medicines in the 'dihydropyridine derivatives' class, to valsartan, or to any of the other ingredients. 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. Imprida must not be used in patients who have severe liver or bile problems, patients with certain heart problems and patients with severe hypotension (low blood pressure). Imprida must also not be used in combination with aliskiren-containing medicines (also used to treat essential hypertension) in patients with type 2 diabetes or in patients with moderate or severe kidney impairment. For the full list of restrictions, see the package leaflet.

Why has Imprida been approved?

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

Other information about Imprida

The European Commission granted a marketing authorisation valid throughout the EU for Imprida on 17 January 2007.

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

This summary was last updated in 05-2015.