EMA/807106/2011
EMEA/H/C/002517

EPAR summary for the public

Ipreziv

azilsartan medoxomil

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

What is Ipreziv?

Ipreziv is a medicine that contains the active substance azilsartan medoxomil. It is available as tablets (20 mg, 40 and 80 mg).

What is Ipreziv used for?

Ipreziv is used in adults who have essential hypertension (high blood pressure). 'Essential' means that the hypertension has no obvious cause.

The medicine can only be obtained with a prescription.

How is Ipreziv used?

Ipreziv is taken by mouth and the usual recommended dose is 40 mg once a day. If the blood pressure is not sufficiently controlled, the dose can be increased to 80 mg, or another medicine for hypertension, such as chlortalidone or hydrochlorothiazide, can be added.

How does Ipreziv work?

The active substance in Ipreziv, azilsartan medoxomil, 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, azilsartan medoxomil stops the hormone from having an effect,

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

therefore allowing the blood vessels to widen. This allows the blood pressure to fall towards normal, thus reducing the risks associated with high blood pressure, such as having a stroke.

How has Ipreziv been studied?

The effects of Ipreziv were first tested in experimental models before being studied in humans.

Eight main studies involving over 6,000 patients with essential hypertension were carried out with Ipreziv.

Five studies investigated the effects of Ipreziv taken alone, comparing it with placebo (a dummy treatment) or with other antihypertensive medicines (ramipril, valsartan and olmesartan medoxomil). The patients in these studies had mild to moderate hypertension.

Three studies investigated the effects of Ipreziv in combination with other antihypertensive medicines (chlortalidone, amlodipine, and hydrochlorothiazide). The patients in the combination studies had moderate to severe hypertension.

The studies lasted between six and 56 weeks and the main measure of effectiveness was the change in the systolic blood pressure (blood pressure when the heart is contracting).

What benefit has Ipreziv shown during the studies?

Ipreziv on its own was more effective than placebo. In the two studies with Ipreziv taken alone compared with placebo, patients had an average fall in systolic blood pressure of about 13.5 mmHg on Ipreziv 40 mg and a fall of about 14.5 mmHg on Ipreziv 80 mg after 6 weeks. This compares with a fall of 0.3 to 1.4 mmHg in the patients taking placebo.

When Ipreziv alone was compared with other medicines, 80 mg of Ipreziv was more effective in lowering blood pressure than the highest approved dose of valsartan (320 mg) and olmesartan medoxomil (40 mg). Ipreziv 40 and 80 mg was also more effective than ramipril (10 mg).

The studies also showed that Ipreziv, when taken in combination with other medicines, can produce additional decreases in blood pressure compared with when these medicines are taken without Ipreziv.

What is the risk associated with Ipreziv?

Side effects with Ipreziv are generally mild or moderate, with the most common side effect being dizziness. For the full list of all side effects reported with Ipreziv, see the package leaflet.

Ipreziv must not be used in people who are hypersensitive (allergic) to azilsartan medoxomil or 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 also not recommended.

Why has Ipreziv been approved?

The CHMP concluded that Ipreziv belongs to an established class of medicines in the treatment of hypertension and its risks are similar to others within this class. The Committee decided that the benefits of Ipreziv are greater than its risks in patients with essential hypertension and recommended that it be given marketing authorisation.

Other information about Ipreziv

The European Commission granted a marketing authorisation valid throughout the European Union for Ipreziv on 07 December 2011.

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

This summary was last updated in 10-2011.