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EPAR summary for the public

Karvea

irbesartan

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

What is Karvea?

Karvea is a medicine that contains the active substance irbesartan. It is available as tablets (75, 150 and 300 mg).

What is Karvea used for?

Karvea is used in adults who have essential hypertension (high blood pressure). 'Essential' means that the hypertension has no obvious cause. Karvea is also used to treat kidney disease in adults with hypertension and type 2 diabetes (non-insulin-dependent diabetes).

The medicine can only be obtained with a prescription.

How is Karvea used?

The usual recommended dose of Karvea is 150 mg once a day. If the blood pressure is not sufficiently controlled, the dose can be increased to 300 mg a day or other medicines for hypertension can be added, such as hydrochlorothiazide. A starting dose of 75 mg can be used in patients receiving haemodialysis (a blood clearance technique) or in patients over 75 years of age.

In patients with hypertension and type 2 diabetes, Karvea is added to some other treatments for hypertension. Treatment is started at 150 mg once a day and is usually increased to 300 mg once a day.

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How does Karvea work?

The active substance in Karvea, irbesartan, 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, irbesartan stops the hormone having an effect, allowing the blood vessels to widen. This allows the blood pressure to drop, reducing the risks associated with high blood pressure, such as having a stroke.

How has Karvea been studied?

Karvea was originally studied in 11 trials for its effects on blood pressure. Karvea was compared with placebo (a dummy treatment) in 712 patients and with other medicines for hypertension (atenolol, enalapril or amlodipine) in 823 patients. Its use in combination with hydrochlorothiazide was also examined in 1,736 patients. The main measure of effectiveness was the reduction in diastolic blood pressure (the blood pressure measured between two heartbeats).

For the treatment of kidney disease, Karvea was studied in two large studies involving a total of 2,326 patients with type 2 diabetes. Karvea was used for two years or more. One study looked at markers of kidney damage by measuring whether the kidneys were releasing the protein albumin into the urine. The second study looked at whether Karvea increased the time taken until the patients' blood creatinine levels had doubled (a marker of kidney disease), until they needed a kidney transplant or dialysis, or until they died. In this study, Karvea was compared with placebo and with amlodipine.

What benefit has Karvea shown during the studies?

In the blood pressure studies, Karvea was more effective than placebo at reducing diastolic blood pressure and had similar effects to the other medicines for hypertension. When used with hydrochlorothiazide, the effects of the two medicines were additive.

In the first kidney disease study, Karvea was more effective than placebo at reducing the risk of developing kidney damage as measured by protein excretion. In the second kidney disease study, Karvea reduced the relative risk of a doubling of blood creatinine levels, needing a kidney transplant, or death during the study by 20% in comparison with placebo. There was a 23% relative risk reduction compared with amlodipine. The main benefit was on the effect on blood creatinine levels.

What is the risk associated with Karvea?

The most common side effect with Karvea (seen in more than 1 patient in 10) is hyperkalaemia (high blood potassium levels). For the full list of all side effects reported with Karvea, see the Package Leaflet.

Karvea must not be used in people who are hypersensitive (allergic) to irbesartan 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 not recommended. Karvea in combination with aliskiren-containing medicines (used to treat essential hypertension) must not be used in patients with diabetes, or moderate or severe kidney impairment.

Why has Karvea been approved?

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

Other information about Karvea

The European Commission granted a marketing authorisation valid throughout the European Union for Karvea on 27 August 1997.

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

This summary was last updated in 07-2013.