European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

IRBESARTAN BMS

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Irbesartan BMS?

Irbesartan BMS is a medicine that contains the active substance irbesartan. It is available as white, oval tablets (75, 150 and 300 mg).
This medicine is the same as Karvea, which is already authorised in the European Union (EU). The company that makes Karvea has agreed that its scientific data can be used for Irbesartan BMS.

What is Irbesartan BMS used for?

Irbesartan BMS is used in patients who have essential hypertension (high blood pressure). 'Essential' means that the hypertension has no obvious cause. Irbesartan BMS is also used to treat kidney disease in patients with hypertension and type 2 diabetes (non-insulin-dependent diabetes). Irbesartan BMS is not recommended for use in patients below 18 years of age, because of a lack of information on safety and effectiveness in this age group.
The medicine can only be obtained with a prescription.

How is Irbesartan BMS used?

Irbesartan BMS is taken by mouth, with or without food. The usual recommended dose 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, Irbesartan BMS is added to other treatments for hypertension. Treatment is started at 150 mg once a day and is usually increased to 300 mg once a day.

How does Irbesartan BMS work?

The active substance in Irbesartan BMS, 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.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

How has Irbesartan BMS been studied?
Irbesartan BMS was originally studied in 11 trials for its effects on blood pressure. Irbesartan BMS 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, Irbesartan BMS was studied in two large studies involving a total of 2,326 patients with type 2 diabetes. Irbesartan BMS 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 Irbesartan BMS 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, Irbesartan BMS was compared with placebo and with amlodipine.

What benefit has Irbesartan BMS shown during the studies?
In the blood pressure studies, Irbesartan BMS 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, Irbesartan BMS was more effective than placebo at reducing the risk of developing kidney damage as measured by protein excretion. In the second kidney disease study, Irbesartan BMS reduced the relative risk of a doubling of blood creatinine levels, needing a kidney transplant or dialysis, 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 Irbesartan BMS?
The most common side effects with Irbesartan BMS (seen in more than 1 and 10 patients in 100) are dizziness, nausea (feeling sick) or vomiting, fatigue (tiredness) and increases in blood creatine kinase levels (an enzyme found in muscles). In addition, more than 1 patient in 100 with type 2 diabetes and kidney disease has the following side effects: hyperkalaemia (high blood potassium levels), orthostatic dizziness (dizziness when standing up), orthostatic hypotension (low blood pressure when standing up) and musculoskeletal (joint) pain. For the full list of all side effects reported with Irbesartan BMS, see the Package Leaflet.
Irbesartan BMS should not be used in people who may be 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.

Why has Irbesartan BMS been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Irbesartan BMS's benefits are greater than its risks for the treatment of essential hypertension and of renal disease in patients with hypertension and type 2 diabetes mellitus. The Committee recommended that Irbesartan BMS be given marketing authorisation.

Other information about Irbesartan BMS:
The European Commission granted a marketing authorisation valid throughout the EU for Irbesartan BMS to Bristol-Myers Squibb Pharma EEIG on 19 January 2007.

The full EPAR for Irbesartan BMS is available here.

This summary was last updated in 03-2009.