European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

IRBESARTAN HYDROCHLOROTHIAZIDE 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 Hydrochlorothiazide BMS?

Irbesartan Hydrochlorothiazide BMS is a medicine that contains two active substances, irbesartan and hydrochlorothiazide. It is available as oval tablets (peach: 150 mg or 300 mg irbesartan and 12.5 mg hydrochlorothiazide; pink: 300 mg irbesartan and 25 mg hydrochlorothiazide).
This medicine is the same as Karvezide, which is already authorised in the European Union (EU). The company that makes Karvezide has agreed that its scientific data can be used for Irbesartan Hydrochlorothiazide BMS.

What is Irbesartan Hydrochlorothiazide BMS used for?

Irbesartan Hydrochlorothiazide BMS is used in adults who have essential hypertension (high blood pressure) that is not adequately controlled on irbesartan or hydrochlorothiazide alone. 'Essential' means that the hypertension has no obvious cause.
The medicine can only be obtained with a prescription.

How is Irbesartan Hydrochlorothiazide BMS used?

Irbesartan Hydrochlorothiazide BMS is taken by mouth, with or without food. The dose of Irbesartan Hydrochlorothiazide BMS to be used depends on the dose of irbesartan or hydrochlorothiazide that the patient was taking before. Doses higher than 300 mg irbesartan and 25 mg hydrochlorothiazide once a day are not recommended. Irbesartan Hydrochlorothiazide BMS may be added to other treatments for hypertension.

How does Irbesartan Hydrochlorothiazide BMS work?

Irbesartan Hydrochlorothiazide BMS contains two active substances, irbesartan and hydrochlorothiazide.
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.
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 lowering the blood pressure.

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The combination of the two active substances has an additive effect, reducing the blood pressure more than either medicine alone. By lowering the blood pressure, the risks associated with high blood pressure, such as having a stroke, are reduced.

How has Irbesartan Hydrochlorothiazide BMS been studied?
Irbesartan on its own has been approved in the EU since 1997 under the names Karvea and Aprovel. It can be used with hydrochlorothiazide to treat hypertension. The studies of Karvea/Aprovel used with hydrochlorothiazide as separate tablets were used to support the use of Irbesartan Hydrochlorothiazide BMS. Further studies were also carried out with doses of 300 mg irbesartan in combination with 25 mg hydrochlorothiazide. The main measure of effectiveness was the reduction in diastolic blood pressure (the blood pressure measured between two heartbeats).

What benefit has Irbesartan Hydrochlorothiazide BMS shown during the studies?
Irbesartan Hydrochlorothiazide BMS was more effective than placebo (a dummy treatment) and than hydrochlorothiazide alone in reducing diastolic blood pressure. Increasing the dose to 300 mg irbesartan and 25 mg hydrochlorothiazide may give a further decrease in blood pressure.

What is the risk associated with Irbesartan Hydrochlorothiazide BMS?
The most common side effects with Irbesartan Hydrochlorothiazide BMS (seen in between 1 and 10 patients in 100) are dizziness, nausea (feeling sick) or vomiting, abnormal urination, fatigue (tiredness), and increases in blood urea nitrogen (BUN, a breakdown product of protein), creatinine (a breakdown product of muscle) and creatine kinase (an enzyme found in muscle). For the full list of all side effects reported with Irbesartan Hydrochlorothiazide BMS, see the Package Leaflet.
Irbesartan Hydrochlorothiazide BMS should not be used in people who may be hypersensitive (allergic) to irbesartan, hydrochlorothiazide, sulfonamides, 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. Irbesartan Hydrochlorothiazide BMS must also not be used in patients who have severe liver, kidney or bile problems, blood potassium levels that are too low or blood calcium levels that are too high.
Care must be taken when using Irbesartan Hydrochlorothiazide BMS with other medicines that have an effect on blood potassium levels. The full list of these medicines is given in the Package Leaflet.

Why has Irbesartan Hydrochlorothiazide BMS been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Irbesartan Hydrochlorothiazide BMS's benefits are greater than its risks for the treatment of essential hypertension in adult patients whose blood pressure is not adequately controlled on irbesartan or hydrochlorothiazide alone. The Committee recommended that Irbesartan Hydrochlorothiazide BMS be given marketing authorisation.

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

The full EPAR for Irbesartan Hydrochlorothiazide BMS is available here.

This summary was last updated in 04-2009.