European Medicines Agency

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Irbesartan Teva
irbesartan

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 for the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Irbesartan Teva?
Irbesartan Teva is a medicine that contains the active substance irbesartan. It is available as white tablets (75, 150 and 300 mg).
Irbesartan Teva is a 'generic medicine'. This means that Irbesartan Teva is similar to a 'reference medicine' already authorised in the European Union (EU) called Aprovel. For more information on generic medicines, see the question-and-answer document here.

What is Irbesartan Teva used for?
Irbesartan Teva is used in patients who have essential hypertension (high blood pressure). 'Essential' means that the hypertension has no obvious cause. Irbesartan Teva is also used to treat kidney disease in patients with hypertension and type 2 diabetes (non-insulin-dependent diabetes). Irbesartan Teva 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 Teva used?
Irbesartan Teva 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 Teva 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 Teva work?
The active substance in Irbesartan Teva, 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 Teva been studied?
Because Irbesartan Teva is a generic medicine, studies have been limited to tests to determine that it is bioequivalent to the reference medicine, Aprovel. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefit and risk of Irbesartan Teva?
Because Irbesartan Teva is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as the reference medicine.

Why has Irbesartan Teva been approved?
The Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Irbesartan Teva has been shown to have comparable quality and to be bioequivalent to Aprovel. Therefore, the CHMP's view was that, as for Aprovel, the benefit outweighs the identified risk. The Committee recommended that Irbesartan Teva be given marketing authorisation.

Other information about Irbesartan Teva:
The European Commission granted a marketing authorisation valid throughout the European Union for Irbesartan Teva to Teva Pharma B.V. on 30 October 2009.

The full EPAR for Irbesartan Teva can be found here.
The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 08-2009.