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EPAR summary for the public

Irbesartan/Hydrochlorothiazide Teva

irbesartan and hydrochlorothiazide

This is a summary of the European public assessment report (EPAR) for Irbesartan/Hydrochlorothiazide Teva. 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 Irbesartan/Hydrochlorothiazide Teva.

What is Irbesartan/Hydrochlorothiazide Teva?

Irbesartan/Hydrochlorothiazide Teva is a medicine that contains two active substances, irbesartan and hydrochlorothiazide. It is available as tablets (150 mg or 300 mg irbesartan and 12.5 mg hydrochlorothiazide; and 300 mg irbesartan and 25 mg hydrochlorothiazide).

Irbesartan/Hydrochlorothiazide Teva is a 'generic medicine'. This means that Irbesartan/Hydrochlorothiazide Teva is similar to a 'reference medicine' already authorised in the European Union (EU) called CoAprovel. For more information on generic medicines, see the question-and-answer document here.

What is Irbesartan/Hydrochlorothiazide Teva used for?

Irbesartan/Hydrochlorothiazide Teva is used in adults who have essential hypertension (high blood pressure) that is not adequately controlled by 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 Teva used?

Irbesartan/Hydrochlorothiazide Teva is taken by mouth. The dose of Irbesartan/Hydrochlorothiazide Teva to be used depends on the dose of irbesartan or hydrochlorothiazide that the patient was taking

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before. Doses higher than 300 mg irbesartan and 25 mg hydrochlorothiazide once a day are not recommended. Irbesartan/Hydrochlorothiazide Teva may be added to other treatments for hypertension.

How does Irbesartan/Hydrochlorothiazide Teva work?

Irbesartan/Hydrochlorothiazide Teva 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.

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 Teva been studied?

Because Irbesartan/Hydrochlorothiazide Teva is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicine, CoAprovel. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Irbesartan/Hydrochlorothiazide Teva?

Because Irbesartan/Hydrochlorothiazide Teva is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why has Irbesartan/Hydrochlorothiazide Teva been approved?

The CHMP concluded that, in accordance with EU requirements, Irbesartan/Hydrochlorothiazide Teva has been shown to have comparable quality and to be bioequivalent to CoAprovel. Therefore, the CHMP's view was that, as for CoAprovel, the benefit outweighs the identified risk. The Committee recommended that Irbesartan/Hydrochlorothiazide Teva be given marketing authorisation.

Other information about Irbesartan/Hydrochlorothiazide Teva

The European Commission granted a marketing authorisation valid throughout the EU for Irbesartan/Hydrochlorothiazide Teva on 26 November 2009.

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

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

This summary was last updated in 07-2015.