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EPAR summary for the public

Ifirmasta[1]

irbesartan

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

What is Ifirmasta?

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

Ifirmasta is a 'generic medicine'. This means that Ifirmasta 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 Ifirmasta used for?

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

The medicine can only be obtained with a prescription.

How is Ifirmasta used?

The usual recommended dose of Ifirmasta 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.

[1] Previously known as Irbesartan Krka.

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In patients with hypertension and type 2 diabetes, Ifirmasta 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.

How does Ifirmasta work?

The active substance in Ifirmasta, 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 risk caused by high blood pressure, such as having a stroke.

How has Ifirmasta been studied?

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

What are the benefit and risk of Ifirmasta?

Because Ifirmasta is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as those of the reference medicine.

Why has Ifirmasta been approved?

The CHMP concluded that, in accordance with EU requirements, Ifirmasta 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 Ifirmasta be given marketing authorisation.

Other information about Ifirmasta:

The European Commission granted a marketing authorisation valid throughout the EU for Irbesartan Krka on 1 December 2008. The name of the medicine was changed to Ifirmasta on 24 September 2009.

The full EPAR for Ifirmasta 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 Ifirmasta, 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.

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