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EPAR summary for the public

Irbesartan Hydrochlorothiazide Zentiva[1]

irbesartan / hydrochlorothiazide

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

What is Irbesartan Hydrochlorothiazide Zentiva?

Irbesartan Hydrochlorothiazide Zentiva 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; 300 mg irbesartan and 25 mg hydrochlorothiazide).

This medicine is the same as CoAprovel, which is already authorised in the European Union (EU). The company that makes CoAprovel has agreed that its scientific data can be used for Irbesartan Hydrochlorothiazide Zentiva.

What is Irbesartan Hydrochlorothiazide Zentiva used for?

Irbesartan Hydrochlorothiazide Zentiva 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 Zentiva used?

The dose of Irbesartan Hydrochlorothiazide Zentiva to be used depends on the dose of irbesartan or hydrochlorothiazide that the patient was taking before. Doses higher than 300 mg irbesartan and

[1] Previously known as Irbesartan Hydrochlorothiazide Winthrop.

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25 mg hydrochlorothiazide once a day are not recommended. Irbesartan Hydrochlorothiazide Zentiva may be added to some other treatments for hypertension.

How does Irbesartan Hydrochlorothiazide Zentiva work?

Irbesartan Hydrochlorothiazide Zentiva 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 Zentiva 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 Zentiva. 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 Zentiva shown during the studies?

Irbesartan Hydrochlorothiazide Zentiva 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 Zentiva?

The most common side effects with Irbesartan Hydrochlorothiazide Zentiva (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 muscles). For the full list of all side effects reported with Irbesartan Hydrochlorothiazide Zentiva, see the package leaflet.

Irbesartan Hydrochlorothiazide Zentiva must not be used in people who are 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 Zentiva 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.

Irbesartan Hydrochlorothiazide Zentiva in combination with aliskiren-containing medicines (used to treat essential hypertension) must not be used in patients with diabetes, or moderate or severe kidney

impairment. Care must be taken when using Irbesartan Hydrochlorothiazide Zentiva 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 Zentiva been approved?

The CHMP decided that Irbesartan Hydrochlorothiazide Zentiva's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Irbesartan Hydrochlorothiazide Zentiva

The European Commission granted a marketing authorisation valid throughout the European Union for Irbesartan Hydrochlorothiazide Winthrop on 19 January 2007. The name of the medicine was changed to Irbesartan Hydrochlorothiazide Zentiva on 6 February 2012.

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

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