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EPAR summary for the public

CoAprovel

irbesartan / hydrochlorothiazide

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

What is CoAprovel?

CoAprovel 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).

What is CoAprovel used for?

CoAprovel 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 CoAprovel used?

The dose of CoAprovel 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. CoAprovel may be added to some other treatments for hypertension.

How does CoAprovel work?

CoAprovel contains two active substances, irbesartan and hydrochlorothiazide.

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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 CoAprovel been studied?

Irbesartan on its own has been approved in the European Union (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 CoAprovel. 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 CoAprovel shown during the studies?

CoAprovel 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 CoAprovel?

The most common side effects with CoAprovel (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 CoAprovel, see the package leaflet.

CoAprovel 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. CoAprovel 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.

CoAprovel 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 CoAprovel 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 CoAprovel been approved?

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

Other information about CoAprovel

The European Commission granted a marketing authorisation valid throughout the EU for CoAprovel on 15 October 1998.

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

This summary was last updated in 07-2013.