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Jeraygo (*aprocitentan*)

An overview of Jeraygo and why it is authorised in the EU

What is Jeraygo and what is it used for?

Jeraygo is a medicine used to treat hypertension (high blood pressure) in adults whose blood pressure cannot be adequately controlled by at least three other medicines (so-called resistant hypertension).

Jeraygo contains the active substance aprocitentan.

How is Jeraygo used?

Jeraygo can only be obtained with a prescription. The medicine is available as tablets to be taken by mouth once a day.

For more information about using Jeraygo, see the package leaflet or contact your doctor or pharmacist.

How does Jeraygo work?

The active substance in Jeraygo, aprocitentan, works by preventing the hormone endothelin from attaching to its receptors (targets). This hormone is involved in the tightening of blood vessels and is thought to play a role in hypertension. By blocking endothelin's action, Jeraygo helps the blood vessels to relax, lowering the blood pressure.

What benefits of Jeraygo have been shown in studies?

A main study showed that Jeraygo is more effective than placebo (a dummy treatment) at reducing blood pressure in people with resistant hypertension.

The study involved 730 people whose blood pressure was not controlled enough despite the use of at least 3 medicines to treat hypertension. About 1 in 5 patients involved in the study also had severe kidney problems. After 4 weeks of treatment, patients receiving Jeraygo had an average decrease in their sitting systolic blood pressure (SiSBP) of around 15 mmHg (when using either a high or low dose of Jeraygo) compared with an average decrease of around 12 mmHg for those who received placebo.

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What are the risks associated with Jeraygo?

For the full list of side effects and restrictions with Jeraygo, see the package leaflet.

The most common side effects with Jeraygo which may affect more than 1 in 10 people include oedema (fluid retention), such as swollen ankles, feet or legs . A decrease in the levels of haemoglobin (the protein in red blood cells that carries oxygen around the body) may occur in up to 1 in 10 people.

Jeraygo must not be used during pregnancy or in women who can have children and are not using reliable contraception; it must also not be used by women who are breastfeeding.

Jeraygo must not be used by patients with severe liver problems.

Why is Jeraygo authorised in the EU?

People with hypertension are at higher risk of cardiovascular diseases (problems affecting the heart and blood circulation). Jeraygo has been shown to decrease blood pressure in people with resistant hypertension. This effect is expected to reduce the risk of cardiovascular problems in these patients. Jeraygo was also shown to be effective in patients with resistant hypertension who had severe kidney problems; this is considered an advantage as these patients have limited options for the treatment of their hypertension.

Overall, the side effects of Jeraygo are manageable. The European Medicines Agency noted that oedema can occur with Jeraygo and this may increase the risk of cardiovascular problems; however, measures are in place to reduce the risk of oedema occurring, including the recommendation to increase the dose with caution.

The Agency therefore decided that Jeraygo's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Jeraygo?

The company that markets Jeraygo must provide a card to patients using Jeraygo, reminding them that the medicine must not be used during pregnancy and breastfeeding or in people with severe liver problems.

The company must also carry out a long-term safety study to further look into the risk of oedema and potential cardiovascular problems.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Jeraygo have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Jeraygo are continuously monitored. Suspected side effects reported with Jeraygo are carefully evaluated and any necessary action taken to protect patients.

Other information about Jeraygo

Jeraygo received a marketing authorisation valid throughout the EU on 27-06-2024.

Further information on Jeraygo can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/jeraygo.

This overview was last updated in 06-2024.