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EPAR summary for the public

Jardiance

empagliflozin

This is a summary of the European public assessment report (EPAR) for Jardiance. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Jardiance.

For practical information about using Jardiance, patients should read the package leaflet or contact their doctor or pharmacist.

What is Jardiance and what is it used for?

Jardiance is a diabetes medicine used with diet and exercise to treat adults whose type 2 diabetes is not satisfactorily controlled.

Jardiance can be used on its own in patients who cannot take metformin (another diabetes medicine). It can also be used as an 'add-on' to other diabetes medicines.

Jardiance contains the active substance empagliflozin.

How is Jardiance used?

Jardiance is available as tablets (10 and 25 mg) and can only be obtained with a prescription. The recommended starting dose is 10 mg once a day, which can be increased if necessary to 25 mg daily in suitable patients.

If Jardiance is used in combination with insulin or sulphonylureas (medicines that make the body produce insulin), the doses of these may need to be reduced to decrease the risk of hypoglycaemia (low blood sugar levels). Because Jardiance relies on the working of the kidneys for its effect, treatment with this medicine is not recommended in patients with moderately or severely impaired kidney function. For further information, see the package leaflet.

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How does Jardiance work?

Type 2 diabetes is a disease in which the body does not make enough insulin to control the level of glucose (sugar) in the blood or when the body is unable to use insulin effectively. This leads to high levels of glucose in the blood.

The active substance in Jardiance, empagliflozin, works by blocking a protein in the kidneys called sodium-glucose co-transporter 2 (SGLT2). As blood is filtered by the kidneys, SGLT2 stops glucose in the bloodstream from being passed out into the urine. By blocking the action of SGLT2, empagliflozin causes more glucose to be removed via the kidney, through the urine, thereby reducing the levels of glucose in the blood.

What benefits of Jardiance have been shown in studies?

A beneficial effect of Jardiance on blood glucose has been shown in four main studies involving over 2,700 patients. Jardiance was compared with placebo (a dummy treatment) when used alone or added to treatment with other diabetes medicines (metformin, pioglitazone, or metformin plus either pioglitazone or another type of diabetes medicine called a sulphonylurea). The main measure of effectiveness was the change in the level of a substance in the blood called glycosylated haemoglobin (HbA1c), which gives an indication of how well the blood glucose is controlled, after 24 weeks of treatment. When blood sugar levels decrease, HbA1C levels also decrease.

All the studies showed a modest but clinically meaningful decrease in HbA1c with Jardiance compared with placebo: in the study investigating use of Jardiance without other medicines, the reduction in HbA1c was 0.74% more than placebo with the 10 mg dose and 0.85% more than placebo with the 25 mg dose. Modest but clinically meaningful reductions in HbA1c were also seen when Jardiance was added to other medicines. In addition, the results indicated that Jardiance treatment was associated with a beneficial fall in body weight and blood pressure.

Supportive evidence was provided from a further six studies. Some of these were continuations of the main studies, and suggested that the benefits of the medicine continued with longer therapy. There was also supportive evidence suggesting benefit when the medicine was combined with insulin.

Another main study showed that adding Jardiance to usual treatment reduced adverse cardiovascular (heart and blood vessels) effects. The study involved patients with type 2 diabetes who already had cardiovascular disease (such as angina, heart attack and stroke). The main measure of effectiveness was the occurrence of one of three major cardiovascular events: stroke, heart attack or death caused by cardiovascular disease. On average, patients in the study were followed up for 3.1 years. In those receiving Jardiance, cardiovascular events occurred in 10.5% (490 out of 4,687) of patients compared with 12.1% (282 out of 2,333) of patients receiving placebo.

What are the risks associated with Jardiance?

The most common side effect with Jardiance (which may affect more than 1 in 10 people) is hypoglycaemia (low blood sugar) when the medicine is taken with a sulphonylurea or insulin. For the full list of all side effects and restrictions with Jardiance, see the package leaflet.

Why is Jardiance approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Jardiance's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP

concluded that Jardiance was shown to be effective in lowering blood glucose levels in patients with type 2 diabetes, when given alone or in combination with other diabetes medicines with different mechanisms of action. Jardiance was also shown to reduce cardiovascular events in patients with type 2 diabetes who already had cardiovascular disease. In addition, beneficial reductions in weight and blood pressure were seen in patients treated with Jardiance. However, the blood glucose lowering effects of the medicine are lower in patients with kidney impairment, and the CHMP recommended that the medicine not be used in some patients, depending on their kidney function. Regarding safety, overall the side effects were considered manageable.

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

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

Other information about Jardiance

The European Commission granted a marketing authorisation valid throughout the European Union for Jardiance on 22 May 2014.

The full EPAR and risk management plan summary for Jardiance 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 Jardiance, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2017.