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Jardiance (*empagliflozin*)

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

What is Jardiance and what is it used for?

Jardiance is a medicine used to treat type 2 diabetes, chronic (long-term) heart failure and chronic kidney disease.

In type 2 diabetes, Jardiance is used in adults and children aged 10 years and above whose condition is not controlled well enough. It is used with appropriate diet and exercise in patients who cannot take metformin (another treatment for diabetes). It can also be used as an 'add-on' treatment to other diabetes medicines.

In chronic heart failure (a condition in which the heart does not pump blood around the body as well as it should), Jardiance is used in adults to treat symptoms of the disease. Jardiance is also used in adults with chronic kidney disease.

Jardiance contains the active substance empagliflozin.

How is Jardiance used?

Jardiance is available as tablets and can only be obtained with a prescription.

For type 2 diabetes, heart failure and chronic kidney disease, the recommended dose is 10 mg once a day.

For type 2 diabetes, the dose may be increased in suitable patients; if Jardiance is used in combination with insulin or medicines that make the body produce insulin, the doses of these medicines may need to be reduced to decrease the risk of hypoglycaemia (low blood sugar levels).

For more information about using Jardiance, see the package leaflet or contact your healthcare provider.

How does Jardiance work?

The active substance in Jardiance, empagliflozin, blocks the action of a protein in the kidneys called sodium-glucose co-transporter 2 (SGLT2). As blood is filtered by the kidneys, SGLT2 stops the kidneys passing glucose from the blood into the urine. Patients with diabetes have high levels of glucose in the

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blood. By blocking the action of SGLT2, empagliflozin causes the kidneys to pass more glucose into the urine, thereby reducing the levels of glucose in the blood.

Blocking the action of SGLT2 also increases the removal of salt and water in the urine. This decreases the overall blood volume, reducing the effort needed for the heart to pump blood. This improves heart function in patients with heart failure and also preserves kidney function in patients with chronic kidney disease, regardless of having diabetes.

What benefits of Jardiance have been shown in studies?

Type 2 diabetes

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 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 harmful 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.

Jardiance was also effective in a study involving 158 children and adolescents aged 10 years and older. After 26 weeks of treatment, HbA1c levels fell by around 0.17 percentage points in those treated with Jardiance compared with a rise of around 0.68 percentage points in those who took placebo.

Heart failure

In the treatment of heart failure, irrespective of diabetes, a beneficial effect of Jardiance was shown in two studies involving 3,730 and 5,988 patients, respectively, who were given either Jardiance or placebo.

In the first study, 19.4% (361 out of 1,863) of patients who took Jardiance for around 14 months were hospitalised for heart failure or died of cardiovascular causes, compared with 24.7% (462 out of 1,867) of those who took placebo.

In the second study, 13.8% (415 out of 2,997) of patients who took Jardiance for around 23 months were hospitalised for heart failure or died of cardiovascular causes, compared with 17.1% (511 out of 2,991) of those who took placebo.

Chronic kidney disease

Jardiance was effective in treating adult patients with chronic kidney disease, irrespective of whether they had diabetes, based on a study involving over 6,600 patients. When Jardiance was added to their usual treatment for chronic kidney disease, 13.1% (432 out of 3,304) of patients taking Jardiance experienced worsening of their kidney function or died because of heart or kidney problems compared with 16.9% (558 out of 3,305) of those taking placebo; the risk was 28% lower with Jardiance than with placebo.

What are the risks associated with Jardiance?

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

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 sulphonylurea or insulin (other treatments for type 2 diabetes), and reduced amounts of fluids in the body when used to treat heart failure.

Why is Jardiance authorised in the EU?

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 and patients who suffered from long-term heart failure irrespective of whether they had diabetes. In patients with chronic kidney disease, irrespective of having diabetes, Jardiance was also shown to reduce the risk of kidney function decline or death due to kidney or heart problems, when added to the patient's usual treatment. In addition, beneficial reductions in weight and blood pressure were seen in patients treated with Jardiance. Regarding safety, overall the side effects were considered manageable.

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

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.

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

Other information about Jardiance

Jardiance received a marketing authorisation valid throughout the EU on 22 May 2014.

Further information on Jardiance can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/jardiance.

This overview was last updated in 12-2023.