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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 with diet and exercise to treat adults whose type 2 diabetes is not adequately controlled. It can be used on its own in patients who cannot take metformin (another treatment for diabetes). It can also be used as an 'add-on' to other diabetes medicines.

Jardiance is also used in adults to treat symptoms of long-term heart failure (a condition in which the heart does not pump blood to the body as well as it should).

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.

For diabetes, 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).

For heart failure, the recommended dose is 10 mg once a day.

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

How does Jardiance work?

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

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

causes more glucose to be removed via the kidney, through the urine, thereby reducing the levels of glucose in the blood.

Empagliflozin also helps the body to remove sodium. This lowers blood pressure and makes it easier for the heart to pump 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 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.

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 who were given either Jardiance or placebo. In the first study, of the patients taking Jardiance for around 14 months, 19.4% (361 out of 1,863) were hospitalised for heart failure or died of cardiovascular causes, compared with 24.7% (462 out of 1,867) of those who were taking placebo. In the second study, 13.8% (415 out of 2,997) of patients taking 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 patients who received 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 sulphonylurea or insulin, and reduced amounts of fluids in the body when used to treat heart failure. For the full list of side effects and restrictions with Jardiance, see the package leaflet.

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 diabetes. 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.

The blood glucose lowering effects of the medicine are lower in patients with kidney problems, and the EMA recommended that the medicine not be used in some patients, depending on their kidney function.

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 02-2022.