



EUROPEAN MEDICINES AGENCY  
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## EPAR summary for the public

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# 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 that contains the active substance empagliflozin. It is used in adults with type 2 diabetes to control their blood glucose (sugar) level.

Jardiance can be used on its own in patients with type 2 diabetes whose blood glucose levels are not satisfactorily controlled on diet and exercise alone and who cannot take metformin (another diabetes medicine).

Jardiance can also be used as an 'add-on' to other diabetes medicines, including insulin, when these medicines together with exercise and diet are not providing adequate control of the diabetes.

### 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 medicines that make the body produce insulin, their doses 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 some patients, such as those aged above 85 years or with moderately or severely impaired kidney function. For further information, see the package leaflet.



## 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 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). SGLT2 is a protein that absorbs glucose back from the urine into the bloodstream as the blood is filtered in the kidneys. By blocking the action of SGLT2, Jardiance causes more glucose to be removed via 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 10 or 25 mg once a day 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 sulfonylurea). 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.

All the studies showed a modest but clinically meaningful improvement 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 for longer, 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.

## 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 sulfonylurea 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. In addition, beneficial reductions in weight and blood pressure were seen in patients treated with Jardiance. However, the benefits of the medicine are lower in patients with renal 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?**

A risk management plan has been developed to ensure that Jardiance is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Jardiance, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the [summary of the risk management plan](#).

## **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](http://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 05-2014.