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Forxiga (*dapagliflozin*)

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

What is Forxiga and what is it used for?

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

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

In heart failure, Forxiga is used in adults who have symptoms of the disease and reduced ejection fraction (a measure of how well the heart pumps blood). Heart failure is the inability of the heart to pump enough blood around the body.

In chronic kidney disease, Forxiga is used in adults with reduced kidney function.

Forxiga contains the active substance dapagliflozin.

How is Forxiga used?

Forxiga 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 of Forxiga is 10 mg once a day.

For type 2 diabetes, if Forxiga is used with insulin or medicines that help the body produce insulin, the doses of these medicines may need to be reduced to prevent hypoglycaemia (low blood sugar levels).

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

How does Forxiga work?

The active substance in Forxiga, dapagliflozin, 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

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passing glucose from the blood into the urine. Patients with diabetes have high levels of glucose in the blood. By blocking the action of SGLT2, dapagliflozin causes the kidney to pass more glucose into the urine, thereby reducing the levels of glucose in the blood.

Blocking the action of SGLT2 also supports heart function in patients with heart failure and kidney function in patients with chronic kidney disease, regardless of having diabetes. Dapagliflozin's actions increase the elimination of salt and water in the urine. This decreases the overall blood volume, reducing the effort needed for the heart to pump blood, thereby improving its function in patients with heart failure.

What benefits of Forxiga have been shown in studies?

Diabetes

Forxiga was found effective in several studies in patients with type 2 diabetes. The main measure of effectiveness was the level of glycosylated haemoglobin (HbA1c), which gives an indication of how well blood glucose is controlled.

In two studies involving 840 adults with type 2 diabetes, Forxiga, when used alone, decreased HbA1c levels by 0.66 percentage points more than placebo (a dummy treatment) after 24 weeks. In four other studies involving 2,370 adults, adding Forxiga to other diabetes medicines decreased HbA1c levels by 0.54–0.68 percentage points more than adding placebo after 24 weeks.

In a study involving 814 adults with type 2 diabetes, Forxiga used in combination with metformin was at least as effective as a sulphonylurea (another type of diabetes medicines) used with metformin. Both combinations reduced HbA1c levels by 0.52 percentage points after 52 weeks.

A long-term study, involving over 17,000 adults with type 2 diabetes, looked at the effects of dapagliflozin on cardiovascular (heart and circulation) disease. The study indicated that dapagliflozin's effects were in line with those of other diabetes medicines that also work by blocking SGLT2.

The effects of Forxiga in combination with metformin and/or insulin were also investigated in a study involving 72 children and young adults between 10 and 24 years of age with type 2 diabetes. Although HbA1c levels decreased in patients treated with Forxiga compared with those given placebo, the results of the study alone were not robust enough to demonstrate the effect of Forxiga in children. However, these results and additional data on the disease in children and data on how the medicine is absorbed, modified and removed from the body in children compared with adults support that Forxiga works in the same way in children and in adults.

Heart failure

Forxiga was effective at reducing the risk of death, hospitalisation or urgent medical visit due to heart failure in a main study involving 4,744 adult patients with heart failure with reduced ejection fraction. Forxiga was compared with placebo, both added to patients' usual heart failure treatment. The rate of death and hospitalisation or urgent medical visit per 100 patient-years was 11.6 in the Forxiga group compared with 15.6 in the placebo group; the risk was 26% lower with Forxiga than with placebo.

Chronic kidney disease

Forxiga was effective in treating adult patients with chronic kidney disease based on a study involving 4,304 patients. When Forxiga was added to the patients' usual treatment for chronic kidney disease, the proportion of patients that experienced a decline in kidney function, severe kidney disease or death was 9.2% in the Forxiga group compared with 14.5% in the placebo group; the risk was 39% lower with Forxiga than with placebo.

What are the risks associated with Forxiga?

The most common side effect with Forxiga in patients with type 2 diabetes (which may affect more than 1 in 10 people) is hypoglycaemia (low blood sugar levels) when used in combination with a sulphonylurea or insulin. Overall, common side effects (which may affect up to 1 in 10 people) include genital infections, dizziness, rash, back pain, dysuria (painful urination) and polyuria (increase in urine production).

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

Why is Forxiga authorised in the EU?

The European Medicines Agency considered that Forxiga was effective for treating type 2 diabetes in adults and children from 10 years of age when given alone or in combination with other diabetes medicines which work in different ways. In addition, beneficial reductions in weight and blood pressure occurred in patients treated with Forxiga. In heart failure, Forxiga can reduce the risk of death or serious complications in patients with heart failure with reduced ejection fraction. In patients with chronic kidney disease Forxiga can reduce the risk of kidney function decline or death due to kidney or heart problems, when added to the patient's usual treatment.

Forxiga's common side effects were related to raised levels of sugar in the urine, such as increased genital and, to a smaller degree, urinary infection, and are considered manageable.

The Agency concluded that the benefits of Forxiga outweigh its risks and recommended that it be granted marketing authorisation.

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

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

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

Other information about Forxiga

Forxiga received a marketing authorisation valid throughout the EU on 11 November 2012.

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

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

This overview was last updated in 11-2021.