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# Edistride (*dapagliflozin*)

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

## What is Edistride and what is it used for?

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

In type 2 diabetes, Edistride 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 chronic heart failure (inability of the heart to pump enough blood around the body), Edistride is used in adults who have symptoms of the disease. Edistride is also used in adults with chronic kidney disease.

Edistride contains the active substance dapagliflozin.

## How is Edistride used?

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

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

For type 2 diabetes, if Edistride 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 Edistride, see the package leaflet or contact your doctor or pharmacist.

## How does Edistride work?

The active substance in Edistride, 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 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, 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 chronic 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 Edistride have been shown in studies?

### Type 2 diabetes

Edistride 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, Edistride, 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 over 2,300 adults, adding Edistride 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, Edistride 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 Edistride 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 Edistride compared with those given placebo, the results of the study alone were not robust enough to demonstrate the effect of Edistride 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 Edistride works in the same way in children and in adults.

### Heart failure

Edistride was effective at reducing the risk of death, hospitalisation or urgent medical visit due to heart failure in two main studies involving about 4,700 and 6,200 adult patients with heart failure. In these studies, Edistride was compared with placebo, both added to the patients' usual treatment for heart failure.

The first study involved patients with heart failure with reduced ejection fraction (when the muscle of the heart is not pumping blood as well as normal). The rate of death and hospitalisation or urgent medical visit per 100 patient years was 11.6 in the Edistride group compared with 15.6 in the placebo group; the risk was 26% lower with Edistride than with placebo.

The second study involved patients with heart failure without reduced ejection fraction. The rate of death, hospitalisation or urgent medical visit per 100 patient years was 7.8 in the Edistride group compared with 9.6 in the placebo group; the risk was 18% lower with Edistride than with placebo.

**Chronic kidney disease**

Edistride was effective in treating adult patients with chronic kidney disease based on a study involving over 4,300 patients. When Edistride was added to 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% among those taking Edistride, compared with 14.5% among those taking placebo; the risk was 39% lower with Edistride than with placebo.

## What are the risks associated with Edistride?

The most common side effect with Edistride 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.

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

## Why is Edistride authorised in the EU?

The European Medicines Agency considered that Edistride 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 Edistride. In heart failure, Edistride can reduce the risk of death or serious complications in patients with heart failure. In patients with chronic kidney disease Edistride can reduce the risk of kidney function decline or death due to kidney or heart problems, when added to the patient's usual treatment.

Edistride'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 Edistride outweigh its risks and recommended that it be granted marketing authorisation.

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

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

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

## Other information about Edistride

Edistride received a marketing authorisation valid throughout the EU on 9 November 2015. This authorisation was based on the authorisation granted for Forxiga in 2012.

Further information on Edistride can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Edistride.

This overview was last updated in 01-2023.