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Dapagliflozin Viatris (*dapagliflozin*)

An overview of Dapagliflozin Viatris and why it is authorised in the EU

What is Dapagliflozin Viatris and what is it used for?

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

In type 2 diabetes, Dapagliflozin Viatris 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), Dapagliflozin Viatris is used in adults who have symptoms of the disease and reduced ejection fraction (a measure of how well the heart pumps blood).

Dapagliflozin Viatris is also used in adults with chronic kidney disease.

Dapagliflozin Viatris is a 'generic medicine'. This means that Dapagliflozin Viatris contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Forxiga. For more information on generic medicines, see the question-and-answer document here.

Dapagliflozin Viatris contains the active substance dapagliflozin.

How is Dapagliflozin Viatris used?

Dapagliflozin Viatris 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 Dapagliflozin Viatris is 10 mg once a day.

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

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How does Dapagliflozin Viatris work?

The active substance in Dapagliflozin Viatris, 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 blood. By blocking the action of SGLT2, dapagliflozin 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 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 removal 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 and also preserving kidney function.

How has Dapagliflozin Viatris been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Forxiga, and do not need to be repeated for Dapagliflozin Viatris.

As for every medicine, the company provided studies on the quality of Dapagliflozin Viatris. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Dapagliflozin Viatris ?

Because Dapagliflozin Viatris is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Dapagliflozin Viatris authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Dapagliflozin Viatris has been shown to have comparable quality and to be bioequivalent to Forxiga. Therefore, the Agency's view was that, as for Forxiga, the benefits of Dapagliflozin Viatris outweigh the identified risks and it can be authorised for use in the EU.

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

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

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

Other information about Dapagliflozin Viatris

Dapagliflozin Viatris received a marketing authorisation valid throughout the EU on 24 March 2023.

Further information on Dapagliflozin Viatris can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/dapagliflozin-viatris. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 03-2023.