

# Summary Public Assessment Report

## Empagliflozin Reddy (empagliflozin)

**SE/H/2773/001-002/DC**

# Summary Public Assessment Report

Empagliflozin Reddy  
empagliflozin

Film-coated tablet, 10 mg, 25 mg

This is a summary of the public assessment report (PAR) for Empagliflozin Reddy. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

## **What is Empagliflozin Reddy and what is it used for?**

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Jardiance.

Empagliflozin Reddy is used for type 2 diabetes mellitus

- Empagliflozin Reddy is used to treat type 2 diabetes in adults and children aged 10 years and older that cannot be controlled by diet and exercise alone.
- Empagliflozin Reddy can be used without other medicines in patients who cannot take metformin (another diabetes medicine).
- Empagliflozin Reddy can also be used with other medicines for the treatment of diabetes. These may be medicines taken by mouth or given by injection such as insulin.

This medicine can also help prevent heart disease in patients with type 2 diabetes mellitus.

It is important that you continue with your diet and exercise plan as told by your doctor, pharmacist or nurse.

## **Heart failure**

- Empagliflozin Reddy is used to treat heart failure in adult patients with symptoms due to impaired heart function.

## **Chronic kidney disease**

- Empagliflozin Reddy is used to treat chronic kidney disease in adult patients.

## **How does Empagliflozin Reddy work?**

Empagliflozin Reddy works by blocking the SGLT2 protein in your kidneys. This causes blood sugar (glucose) to be removed in your urine. Thereby Empagliflozin Reddy lowers the amount of sugar in your blood.

## **How is Empagliflozin Reddy used?**

The pharmaceutical form is film-coated tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

## **What benefits of Empagliflozin Reddy have been shown in studies?**

Because the product is a generic medicine, studies have been limited to tests to determine that it is bioequivalent to the reference medicine, Jardiance. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

**What are the possible side effects from Empagliflozin Reddy?**

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

**Why is Empagliflozin Reddy approved?**

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Jardiance, the benefits are greater than its risks and recommended that it can be approved for use.

**What measures are being taken to ensure the safe and effective use of Empagliflozin Reddy?**

A risk management plan has been developed to ensure that the product 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, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well. For more details, please see the full PAR for Empagliflozin Reddy on the following website: [MRI - Home](#).

**Other information about Empagliflozin Reddy**

The full PAR for Empagliflozin Reddy can be found on the following website: [MRI - Home](#). For more information about treatment with Empagliflozin Reddy, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-06.