

Summary Public Assessment Report

Dapagliflozin Reddy (dapagliflozin propanediol monohydrate)

SE/H/2560/01-02/DC

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Dapagliflozin Reddy
dapagliflozin propanediol monohydrate

film-coated tablet, 5 mg, 10 mg

This is a summary of the public assessment report (PAR) for Dapagliflozin 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 Dapagliflozin 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 Forxiga.

Dapagliflozin Reddy contains the active substance dapagliflozin. It belongs to a group of medicines called "sodium glucose co-transporter-2 (SGLT2) inhibitors". They work by blocking the SGLT2 protein in the kidney. By blocking this protein, blood sugar (glucose), salt (sodium) and water are removed from the body via the urine.

The product is used in the treatment of:

Type 2 diabetes

- in adults and children aged 10 years and older.
- if the type 2 diabetes cannot be controlled with diet and exercise.
- on its own or together with other medicines to treat diabetes.
- It is important to continue to follow the advice on diet and exercise given by the doctor, pharmacist or nurse.

Heart failure

- in adults (aged 18 years and older) when the heart does not pump blood as well as it should.

Chronic kidney disease

- in adults with reduced kidney function.

How does Dapagliflozin Reddy work?

In type 2 diabetes the body does not make enough insulin or is not able to use the insulin it makes properly. This leads to a high level of sugar (glucose) in the blood. This can lead to serious problems like heart or kidney disease, blindness, and poor circulation in arms and legs.

Dapagliflozin Reddy works by removing excess glucose from the body. It can also help prevent heart disease.

The type of heart failure that occurs when the heart does not pump blood to the lungs and the rest of the body as well as it should, can lead to serious medical problems and need for hospital care.

The most common symptoms of heart failure are feeling breathless, feeling tired or very tired all the time, and ankle swelling. Dapagliflozin Reddy helps protect the heart from getting worse and improves the symptoms. It can lower the need to go to hospital and can help some patients to live longer.

In chronic kidney disease, the kidneys may gradually lose their function. This means they would not be able to clean and filter the blood the way they should. Loss of kidney function can lead to serious medical problems and need for hospital care.

Dapagliflozin Reddy helps protect the kidneys from losing their function, helping some patients to even live longer.

How is Dapagliflozin 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 Dapagliflozin Reddy have been shown in studies?

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

What are the possible side effects from Dapagliflozin Reddy?

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

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Dapagliflozin 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 Forxiga, 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 Dapagliflozin 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.

Other information about Dapagliflozin Reddy

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

This summary was last updated in 2025-11.