LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Daforbis
(dapagliflozin)

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Summary Public Assessment Report

Daforbis
dapagliflozin

Film-coated tablet, 5 mg, 10 mg

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

The product is used in the treatment of:

- **Type 2 diabetes**
  - in adults and children aged 10 years and older.
  - if your type 2 diabetes cannot be controlled with diet and exercise.
  - Daforbis can be used 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 to you by your 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 Daforbis work?

Daforbis 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 your kidney. By blocking this protein, blood sugar (glucose), salt (sodium) and water are removed from your body via the urine.

How is Daforbis 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 Daforbis 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 Daforbis?

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 Daforbis 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 Daforbis?

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 Daforbis

The full PAR for Daforbis can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Daforbis, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2023-07.