

Summary Public Assessment Report

Rytoggi (dapagliflozin, metformin hydrochloride)

SE/H/2621/01-02/DC

Summary Public Assessment Report

Rytoggi
dapagliflozin, metformin hydrochloride

Film-coated tablet, 5 mg/850 mg, 5 mg/1000 mg

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

The product is used to treat diabetes:

- This medicine is taken in combination with diet and exercise.
- This medicine is used if your diabetes cannot be controlled with other medicines used to treat diabetes.
- Your doctor may ask you to take this medicine on its own or together with other medicines to treat diabetes. This may be another medicine taken by mouth and/or a medicine given by injection, such as insulin or a GLP-1 receptor agonist (helps your body to increase the production of insulin when your blood sugar is high).
- If you are already taking both dapagliflozin and metformin as single tablets, your doctor may ask you to switch to this medicine. To avoid overdose, do not continue taking dapagliflozin and metformin tablets, if you are taking [Product Name].

It is important to continue to follow the advice on diet and exercise given to you by your doctor, pharmacist or nurse.

How does Rytoggi work?

This medicine contains two different substances called dapagliflozin and metformin. Both belong to a group of medicines called oral anti-diabetics. These are medicines taken by mouth for diabetes.

Rytoggi is used for a type of diabetes called "type 2 diabetes" in adult patients (aged 18 years and older) and usually occurs when you are older. If you have type 2 diabetes, your pancreas does not make enough insulin or your body is not able to use the insulin it produces properly. This leads to a high level of sugar (glucose) in your blood.

- Dapagliflozin works by removing excess sugar from your body via your urine and lowers the amount of sugar in your blood. It can also help prevent heart disease.
- Metformin works mainly by inhibiting glucose production in the liver.

How is Rytoggi 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 Rytoggi 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, Xigduo. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Rytoggi?

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 Rytoggi 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 Xigduo, 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 Rytoggi?

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 Rytoggi

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

This summary was last updated in 2026-03.