

Summary Public Assessment Report

Dalmevin (vildagliptin)

SE/H/1613/01/DC

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Dalmevin
(vildagliptin)

Tablet 50 mg

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

For practical information about using Dalmevin, patients should read the package leaflet or contact their doctor or pharmacist.

What is Dalmevin and what is it used for?

Dalmevin is a 'generic medicine'. This means that Dalmevin is similar to a 'reference medicine' already authorised in the European Union (EU) called Galvus.

The active substance of Dalmevin, vildagliptin, belongs to a group of medicines called "oral antidiabetics".

Dalmevin is used to treat adult patients with type 2 diabetes. It is used when diabetes cannot be controlled by diet and exercise alone. It helps to control the level of sugar in the blood. Your doctor will prescribe Dalmevin either alone or together with certain other antidiabetic medicines which you will already be taking, if these have not proved sufficiently effective to control diabetes.

Type 2 diabetes develops if the body does not make enough insulin or if the insulin that the body makes does not work as well as it should. It can also develop if the body produces too much glucagon.

Insulin is a substance which helps to lower the level of sugar in the blood, especially after meals. Glucagon is a substance which triggers the production of sugar by the liver, causing the blood sugar level to rise. The pancreas makes both of these substances.

How does Dalmevin work?

Dalmevin works by making the pancreas produce more insulin and less glucagon. This helps to control the blood sugar level. This medicine has been shown to reduce blood sugar, which may help to prevent complications from your diabetes. Even though you are now starting a medicine for your diabetes, it is important that you continue to follow the diet and/or exercise which has been recommended for you.

How is Dalmevin used?

The pharmaceutical form of Dalmevin is 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.

What benefits of Dalmevin have been shown in studies?

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

What are the possible side effects of Dalmevin?

Because Dalmevin is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Dalmevin approved?

It was concluded that, in accordance with EU requirements, Dalmevin has been shown to have comparable quality and to be bioequivalent to the reference medicine Galvus. Therefore, the Medical Products Agency in Sweden decided that, as for Galvus, 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 Dalmevin?

A risk management plan has been developed to ensure that Dalmevin 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 for Dalmevin, 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 Dalmevin

The marketing authorisation for Dalmevin was granted on 2017-07-20 in Sweden.

The full PAR for Dalmevin can be found on the following website:
<http://mri.medagencies.org/Human/>. For more information about treatment with Dalmevin, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2017-09.