LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Vildagliptin Accord

(vildagliptin)

SE/H/1962/01/DC

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vildagliptin

Tablet, 50 mg

This is a summary of the public assessment report (PAR) for Vildagliptin Accord. It explains how Vildagliptin Accord 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 Vildagliptin Accord.

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

What is Vildagliptin Accord and what is it used for?

Vildagliptin Accord is a 'generic medicine'. This means that Vildagliptin Accord is similar to a 'reference medicine' already authorised in the European Union (EU) called Galvus. Vildagliptin Accord can be used to treat adult patients with type 2 diabetes when diabetes cannot be controlled by diet and exercise alone.

How does Vildagliptin Accord work?

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. Vildagliptin Accord works by making the pancreas produce more insulin and less glucagon. This helps to control the blood sugar level.

How is Vildagliptin Accord used?

The pharmaceutical form of Vildagliptin Accord 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 in Sweden.

What benefits of Vildagliptin Accord have been shown in studies?

No additional studies were needed as Vildagliptin Accord is a generic medicine considered to be similar to the reference medicine, Galvus.

What are the possible side effects of Vildagliptin Accord?

Because Vildagliptin Accord 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 restrictions, see the package leaflet.

Why is Vildagliptin Accord approved?

It was concluded that, in accordance with EU requirements, Vildagliptin Accord has been shown to have comparable quality and similar 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 Vildagliptin Accord?

A risk management plan has been developed to ensure that Vildagliptin Accord 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 Vildagliptin Accord, 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 Vildagliptin Accord

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

This summary was last updated in 2020-08.