LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Vandetva
(vildagliptin)

SE/H/2067/01/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

Vandetva
vildagliptin

Tablet, 50 mg

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

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

What is Vandetva and what is it used for?

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

Vandetva 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. It can be used in the following ways:

- on its own (monotherapy) in patients whose diabetes is not sufficiently controlled by diet and exercise and who cannot take metformin;
- together with metformin, a thiazolidinedione or a sulphonylurea (dual therapy) when the patient's diabetes is insufficiently controlled by this other medicine taken alone, but it is only used in combination with a sulphonylurea in patients who cannot take metformin;
- together with a sulphonylurea and metformin (triple therapy) in patients whose diabetes is not sufficiently controlled by these medicines plus diet and exercise.

How does Vandetva work?

The active substance of Vildagliptin STADA 50 mg tablets, vildagliptin, belongs to a group of medicines called "oral antidiabetics".

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 a rise in blood sugar levels. The pancreas makes both of these substances.

Vildagliptin STADA works by making the pancreas produce more insulin and less glucagon. This helps to control blood sugar levels. The active substance in Vandetva, vildagliptin, is a dipeptidyl-peptidase-4 (DPP-4) inhibitor. It works by blocking the breakdown of 'incretin' hormones in the body. These hormones are released after a meal and stimulate the pancreas to produce insulin. By increasing levels of incretin hormones in the blood, vildagliptin stimulates the pancreas to produce more insulin when blood glucose levels are high. Vildagliptin does not work when the blood glucose is low. Vildagliptin also reduces the

amount of glucose made by the liver, by increasing insulin levels and decreasing the levels of the hormone glucagon. Together, these processes reduce blood glucose levels and help to control type-2 diabetes. This medicine has been shown to reduce blood sugar, which may help to prevent complications from diabetes.

How is Vandetva used?

The pharmaceutical form of Vandetva 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 Vandetva have been shown in studies?

Because Vandetva 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 Vandetva?

Because Vandetva 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 Vandetva approved?

It was concluded that, in accordance with EU requirements, Vandetva 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 Vandetva?

A risk management plan has been developed to ensure that Vandetva 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 Vandetva, 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 Vandetva

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

This summary was last updated in 2021-06.