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Galvus (*vildagliptin*)

An overview of Galvus and why it is authorised in the EU

What is Galvus and what is it used for?

Galvus is a diabetes medicine that is used together with diet and exercise to control the blood glucose (sugar) in adults with type 2 diabetes. It is used alone when metformin (another diabetes medicine) is not suitable, or together with other diabetes medicines, including insulin, when these medicines do not provide adequate control of the blood glucose.

Galvus contains the active substance vildagliptin.

How is Galvus used?

Galvus can only be obtained with a prescription and is available as 50-mg tablets. The recommended dose of Galvus is:

- one tablet in the morning and another in the evening (100 mg per day) when used alone, with metformin, with a thiazolidinedione, with metformin plus a sulphonylurea, or with insulin (with or without metformin);
- one tablet in the morning (50 mg per day) when taken with a sulphonylurea. A lower dose of the sulphonylurea may also be considered to reduce the risk of hypoglycaemia (low blood glucose levels).

In patients with moderate or severe kidney problems, the recommended dose is 50 mg once daily.

Because vildagliptin has been associated with liver problems, the doctor should carry out tests to check the patient's liver function before treatment with Galvus and at regular intervals during treatment.

For more information about using Galvus, see the package leaflet or contact your doctor or pharmacist.

How does Galvus work?

Type 2 diabetes is a disease in which the pancreas does not make enough insulin to control the level of glucose in the blood or when the body is unable to use insulin effectively. The active substance in Galvus, 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 blocking the breakdown of incretin hormones in the blood, vildagliptin

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prolongs their action, stimulating 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.

What benefits of Galvus have been shown in studies?

Galvus on its own or as an add-on treatment has been studied in 11 main studies involving a total of over 6,000 patients with type 2 diabetes and insufficient control of blood glucose levels. In all studies, the main measure of effectiveness was the change in blood levels of a substance called glycosylated haemoglobin (HbA1c), which gives an indication of how well blood glucose is controlled.

Galvus was effective at reducing levels of HbA1c but was less effective than metformin, rosiglitazone (a thiazolidinedione) or gliclazide (a sulphonylurea). In a study comparing Galvus with metformin, significantly better results were seen with metformin: a reduction in HbA1c of 1.5 percentage points after 52 weeks compared with a reduction of around 1 percentage point in patients treated with Galvus.

When used as an add-on to metformin and to pioglitazone (a thiazolidinedione), Galvus reduced HbA1c levels by 0.8 to 1.0 percentage points. When used with glimepiride (a sulphonylurea), Galvus caused a reduction of around 0.6 percentage points. In contrast, patients adding placebo to their existing treatment showed smaller changes in HbA1c levels, ranging from a fall of 0.3 to a rise of 0.2 percentage points.

As an add-on to metformin plus glimepiride, Galvus reduced HbA1c levels by 1 percentage point, compared with a reduction of 0.3 percentage points in patients taking placebo.

Finally, when used as an add-on to insulin treatment, Galvus caused a greater reduction in HbA1c levels than adding placebo, but the size of this effect in one study was small, possibly due to the fact that the study included long-term patients who were less likely to show improvement. However, in another study, the size of this effect was significant. Patients taking Galvus in addition to insulin, with or without metformin, had a reduction in HbA1c levels of 0.77 percentage points, compared with 0.05 percentage points in patients taking placebo in addition to insulin.

What are the risks associated with Galvus?

The most common side effect with Galvus (which may affect up to 1 in 10 people) is dizziness. For the full list of all side effects reported with the medicine, including side effects occurring when it is taken with other diabetes medicines, see the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Galvus authorised in the EU?

Studies have shown Galvus to be effective as add-on to metformin, a thiazolidinedione or a sulphonylurea (dual therapy), a sulphonylurea and metformin (triple therapy) or insulin with or without metformin. Galvus on its own has also been shown to be effective in reducing blood glucose but less so than metformin. The medicine should therefore only be used on its own in patients for whom metformin is inappropriate either because of side effects occurring with metformin or because they have a condition that makes metformin unsuitable for them. The side effects of Galvus were mostly mild and resolved over time.

The European Medicines Agency decided that Galvus' benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Galvus?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Galvus have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Galvus are continuously monitored. Suspected side effects reported with the medicine are carefully evaluated and any necessary action taken to protect patients.

Other information about Galvus

Galvus received a marketing authorisation valid throughout the EU on 26 September 2007.

Further information on Galvus can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/galvus.

This overview was last updated in 06-2021.