EMA/474704/2013
EMEA/H/C/002182

EPAR summary for the public

Vipidia

alogliptin

This is a summary of the European public assessment report (EPAR) for Vipidia. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Vipidia.

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

What is Vipidia and what is it used for?

Vipidia is a diabetes medicine that contains the active substance alogliptin. It is used, together with diet and exercise, as an addition to other diabetes medicines in adults with type 2 diabetes, to control their blood glucose (sugar) level.

How is Vipidia used?

Vipidia is available as tablets (6.25, 12.5 and 25 mg) and can only be obtained with a prescription. The recommended dose is 25 mg taken by mouth once daily, in combination with other diabetes medicines as prescribed by a doctor. When Vipidia is added to a sulphonylurea (a type of diabetes medicine) or insulin, the doctor may need to lower the dose of these medicines to reduce the risk of hypoglycaemia (low blood sugar level). In patients with reduced kidney function, the daily dose of Vipidia should be reduced. For further information, see the package leaflet.

How does Vipidia 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 Vipidia, alogliptin, 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, alogliptin prolongs their action in stimulating the pancreas to produce more insulin when blood

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

glucose levels are high. Alogliptin does not work when the blood glucose is low. Alogliptin 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 Vipidia have been shown in studies?

Vipidia has been studied in seven main studies involving 5,675 adults with type 2 diabetes. Five of the studies compared Vipidia with placebo (a dummy treatment), when used alone or added to other diabetes medicines, in patients in whom previous treatment had failed. In two other studies, Vipidia was compared with the diabetes medicines glipizide and pioglitazone in patients who were already taking metformin.

In all of the studies, the main measure of effectiveness was the change in the level of glycosylated haemoglobin (HbA1c), which is the percentage of haemoglobin in the blood that has glucose attached. HbA1c levels give an indication of how well the blood glucose is controlled. HbA1c levels were measured after 26 weeks when Vipidia was used alone or added to other diabetes medicines, and after 52 weeks when Vipidia was compared with glipizide or pioglitazone.

In all studies Vipidia led to a decrease in HbA1c indicating that blood glucose levels had been reduced. When used alone or in combination with other anti-diabetes medicines, Vipidia reduced HbA1c levels by 0.48–0.61% more than placebo. Vipidia was as least as affective as pioglitazone in lowering HbA1c when added to metformin, but the study comparing Vipidia with glipizide was not conclusive.

What are the risks associated with Vipidia?

The most common side effect with Vipidia (which may affect up to 1 in 10 people) is pruritus (itching). For the full list of all side effects reported with Vipidia, see the package leaflet.

Vipidia must not be used in patients who are hypersensitive (allergic) to the active substances or any of the ingredients or who have had serious allergic reactions to any DPP 4 inhibitor.

Why is Vipidia approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that Vipidia's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP considered that the effects of Vipidia on HbA1c levels were similar to those of other DPP-4 inhibitors and were modest but clinically relevant. Regarding its safety, Vipidia's safety profile was consistent with that seen with other DPP-4 inhibitors.

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

A risk management plan has been developed to ensure that Vipidia 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 Vipidia, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Vipidia

The European Commission granted a marketing authorisation valid throughout the European Union for Vipidia on 19 September 2013.

The full EPAR for Vipidia can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Vipidia, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2013.