EMA/760451/2012
EMEA/H/C/001050

**EPAR summary for the public**

# Icandra

## Vildagliptin / metformin hydrochloride

This is a summary of the European public assessment report (EPAR) for Icandra. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Icandra.

## What is Icandra?

Icandra is a medicine that contains the active substances vildagliptin and metformin hydrochloride. It is available as tablets (50 mg/850 mg and 50 mg/1,000 mg).

This medicine is the same as Eucreas, which is already authorised in the European Union (EU). The company that makes Eucreas has agreed that its scientific data can be used for Icandra.

## What is Icandra used for?

Icandra is used to treat adults with type 2 diabetes. It is used in the following ways:

- in patients whose disease is insufficiently controlled with the maximum tolerated dose of metformin taken alone;
- in patients who are already taking the combination of vildagliptin and metformin as separate tablets;
- in combination with a sulphonylurea (another type of anti-diabetes medicine) together with diet and exercise, in patients whose diabetes is not satisfactorily controlled on metformin and a sulphonylurea.
- in combination with insulin together with diet and exercise, in patients whose diabetes is insufficiently controlled with insulin at a stable dose and metformin.

The medicine can only be obtained with a prescription.

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## How is Icandra used?

The recommended dose of Icandra is one tablet twice a day, with one tablet taken in the morning and one in the evening. The choice of tablet strength to start with depends on the patient's current treatment and the expected effects of Icandra, but it is recommended to provide a dose of metformin similar to the dose already being taken. Patients already taking vildagliptin and metformin should switch to Icandra containing the same amounts of each active substance. Doses of vildagliptin above 100 mg are not recommended.

Taking Icandra with or just after food may reduce any stomach problems caused by metformin. Icandra should not be used in patients who have moderate or severe problems with their kidneys or who have problems with their liver. Elderly patients taking Icandra should have their kidney function monitored regularly.

## How does Icandra work?

Type 2 diabetes is a disease in which the pancreas does not make enough insulin to control the level of glucose (sugar) in the blood or when the body is unable to use insulin effectively. Icandra contains two active substances, which each have a different mode of action. Vildagliptin, which is a dipeptidyl peptidase 4 (DPP-4) inhibitor, 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. Metformin works mainly by inhibiting glucose production and reducing its absorption in the gut. As a result of the action of both substances, the blood glucose is reduced and this helps to control type 2 diabetes.

## How has Icandra been studied?

Vildagliptin on its own was approved by the EU in September 2007 under the name Galvus, and metformin has been available in the EU since 1959. Vildagliptin can be used with metformin in type 2 diabetes patients who are not satisfactorily controlled on metformin alone. The studies with Galvus as an add-on to metformin, metformin and a sulphonylurea, or metformin and insulin have been used to support the use of Icandra in the same indications. The studies compared Galvus with placebo and measured the levels of a substance in the blood called glycosylated haemoglobin (HbA1c), which gives an indication of how well the blood glucose is controlled.

The applicant also presented the results of two studies showing that the active substances in the two strengths of Icandra were absorbed in the body in the same way as when they were taken as separate tablets.

## What benefit has Icandra shown during the studies?

Vildagliptin has been shown to be more effective than placebo (a dummy treatment) at reducing HbA1c levels when it was added to metformin. Patients adding vildagliptin had a fall in HbA1c levels of 0.88 percentage points after 24 weeks from a starting level of 8.38%. In contrast, patients adding placebo had smaller changes in HbA1c levels, with a rise of 0.23 percentage points from a starting level of 8.3%. In other studies, vildagliptin in combination with metformin has been shown to be more effective than placebo when used with a sulphonylurea or insulin.

## What is the risk associated with Icandra?

The most common side effects with Icandra (seen in more than 1 patient in 10) are nausea (feeling sick), vomiting, diarrhoea, abdominal (tummy) pain and loss of appetite. For the full list of all side effects reported with Icandra, see the package leaflet.

Icandra should not be used in people who may be hypersensitive (allergic) to vildagliptin, metformin or any of the other ingredients. It must not be used in patients who have diabetic ketoacidosis (high levels of ketones and acids in the blood), diabetic pre-coma, problems with their kidneys or liver, conditions that may affect the kidneys, or a disease that causes a reduced supply of oxygen to the tissues such as failure of the heart or lungs or a recent heart attack. It must also not be used in patients with alcohol intoxication (excessive alcohol consumption) or alcoholism, or during breast-feeding. For the full list of restrictions, see the package leaflet.

## Why has Icandra been approved?

The CHMP concluded that vildagliptin taken with metformin reduces blood glucose levels and the combination of the two active substances in one tablet may help patients to stick to their treatment. The CHMP also noted that the combination of vildagliptin and metformin was effective as an add-on to a sulphonylurea or insulin. Therefore, the Committee decided that the benefits of Icandra are greater than its risks and recommended that it be given marketing authorisation.

## Other information about Icandra

The European Commission granted a marketing authorisation valid throughout the European Union for Vildagliptin/Metformin Hydrochloride on 1 December 2008. The name of the medicine was changed to Icandra on 6 February 2009.

The full EPAR for Icandra 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 Icandra, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2012.