EMA/494300/2021
EMEA/H/C/002178

Incresync (*alogliptin/pioglitazone*)

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

What is Incresync and what is it used for?

Incresync is a diabetes medicine containing the active substances alogliptin and pioglitazone. It is used as an addition to diet and exercise in adults with type 2 diabetes to improve the control of glucose (sugar) levels in the blood:

- in patients who are not satisfactorily controlled with pioglitazone alone, and who cannot be treated with metformin (another diabetes medicine);
- together with metformin in patients who are not satisfactorily controlled with a combination of pioglitazone and metformin.

Incresync can also be used to replace separate alogliptin and pioglitazone tablets in adults who are already being treated with this combination.

How is Incresync used?

Incresync is available as tablets and can only be obtained with a prescription. It is taken by mouth once daily. The recommended dose depends on the patient's current treatment for diabetes. For more information about using Incresync, see the package leaflet or contact your doctor or pharmacist.

How does Incresync 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 in which the body is unable to use insulin effectively. The active substances in Incresync, alogliptin and pioglitazone, work in different ways to help correct this.

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 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. Alogliptin is licensed in the EU as Vipidia.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Pioglitazone makes cells (fat, muscle and liver) more sensitive to insulin, which means that the body makes better use of the insulin it produces. Pioglitazone is authorised in the EU as Actos and associated names.

As a result of the action of both active substances, glucose levels in the blood are reduced, which helps to control type 2 diabetes.

What benefits of Incresync have been shown in studies?

Incresync has been investigated in two main studies involving 1,296 patients with type 2 diabetes that was not well controlled by previous treatment. One of the studies compared the effects of alogliptin with placebo (a dummy treatment) when used as an add-on to existing treatment with pioglitazone, with or without metformin or another diabetes medicine. In the other study, the effects of adding alogliptin to existing treatment with pioglitazone and metformin were compared with increasing the doses of pioglitazone. In both 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 in the first study and 52 weeks in the second study.

Both studies showed that the combination of the active substances in Incresync could produce a small but clinically relevant improvement in HbA1c. When alogliptin was added to pioglitazone, the improvement was a reduction of HbA1c of 0.47% at an alogliptin dose of 12.5 mg and 0.61% at an alogliptin dose of 25 mg. Incresync was at least as effective as pioglitazone and metformin in reducing HbA1c.

What are the risks associated with Incresync?

The most common side effects with Incresync (which may affect up to 1 in 10 people) are upper respiratory tract infections (nose and throat infections), sinusitis (inflammation of the sinuses), headache, nausea (feeling sick), dyspepsia (heartburn), abdominal pain (tummy ache), pruritus (itching), myalgia (muscle pain), peripheral oedema (swelling in arms and legs) and weight gain. For the full list of side effects of Incresync, see the package leaflet.

Incresync 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 dipeptidyl-peptidase-4 (DPP-4) inhibitor. It must also not be used in patients who have or have ever had heart failure or bladder cancer, those with reduced liver function, diabetic ketoacidosis (a serious condition that can occur in diabetes), or blood in the urine that has not been properly investigated. For the full list of restrictions, see the package leaflet.

Why is Incresync authorised in the EU?

The European Medicines Agency decided that Incresync's benefits are greater than its risks and it can be authorised for use in the EU. The Agency considered that adding alogliptin to existing treatment with pioglitazone with or without metformin had shown to produce modest but clinically relevant improvements in HbA1c. The Agency therefore considered that the combination of alogliptin and pioglitazone in Incresync is of benefit to patients. Incresync's safety profile was consistent with that seen with the individual components.

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

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

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

Other information about Incresync

Incresync received a marketing authorisation valid throughout the EU on 19 September 2013.

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

This overview was last updated in 09-2021.