EMA/701116/2017
EMEA/H/C/006279

Kyinsu (*insulin icodec / semaglutide*)

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

What is Kyinsu and what is it used for?

Kyinsu is a medicine used for the treatment of type 2 diabetes. It is used in adults whose diabetes is not sufficiently controlled with basal insulin (a slow-acting type of insulin) or a GLP-1 receptor agonist, a medicine that acts like the GLP-1 hormone. Kyinsu is used together with diet, exercise and diabetes medicines taken by mouth.

Kyinsu contains the active substances insulin icodec and semaglutide.

How is Kyinsu used?

Kyinsu is available as prefilled pens. It is given once a week as an injection under the skin, in the thigh, the upper arm, or belly. Patients can inject themselves with Kyinsu if they have been trained appropriately.

Before starting Kyinsu, treatment with an insulin medicine or GLP-1 receptor agonist should be stopped. When switching to Kyinsu, the patient's blood glucose will be regularly tested and the doctor will adjust the dose to the patient's needs.

Kyinsu can only be obtained with a prescription. For more information about using Kyinsu, see the package leaflet or contact your doctor or pharmacist.

How does Kyinsu work?

Type 2 diabetes is a disease in which the body does not produce enough insulin to control the level of blood glucose or the body is unable to use insulin effectively.

Kyinsu contains two active substances: insulin icodec and semaglutide which both help control the level of blood glucose. Insulin icodec acts in the same way as the naturally produced insulin, but it works for a longer time.

Semaglutide, a GLP-1 receptor agonist, acts in the same way as GLP-1 (a hormone produced in the gut) by increasing the amount of insulin that the pancreas releases in response to food. This helps with the control of blood glucose levels.

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What benefits of Kyinsu have been shown in studies?

Weekly injections of Kyinsu have been shown to improve the control of blood glucose in three main studies involving over 2,600 adults with type 2 diabetes that was not satisfactorily controlled either with basal insulin or with a GLP-1 receptor agonist.

The main measure of effectiveness for all three studies was the levels of a substance in the blood called glycosylated haemoglobin (HbA1c) which indicate how well the blood glucose is controlled. A reduction in HbA1c levels indicates improved blood glucose control.

- The first study involved 1,291 adults whose blood glucose levels were not sufficiently controlled with daily basal insulin. They received either Kyinsu or insulin icodec with or without other diabetes medicines given orally. After one year of treatment, the average reduction in HbA1c was 1.55 percentage points with Kyinsu compared with 0.89 with insulin icodec. In addition, treatment with Kyinsu was associated with weight loss.
- The second study involved 683 adults whose blood glucose levels were not sufficiently controlled with a GLP-1 receptor agonist. They received either Kyinsu or semaglutide with or without oral antidiabetic medicines. After one year, Kyinsu lowered patients' HbA1c levels on average by 1.35 percentage points compared with 0.90 for those who received semaglutide. In this study, people treated with Kyinsu gained weight while those on semaglutide lost weight.
- The third study involved 679 adults whose blood glucose levels were not sufficiently controlled with daily basal insulin. They received either Kyinsu or insulin glargine and insulin aspart, two other types of insulin medicines, with or without oral antidiabetic medicines. Kyinsu lowered HbA1c levels by 1.47 percentage points on average compared with 1.40 for those who received insulin glargine and insulin aspart. In addition, treatment with Kyinsu was associated with weight loss.

What are the risks associated with Kyinsu?

For the full list of side effects and restrictions with Kyinsu, see the package leaflet.

The most common side effects with Kyinsu (which may affect more than 1 in 10 people) include hypoglycaemia (low blood glucose levels) and gastrointestinal adverse reactions (stomach and gut problems), including nausea and diarrhoea.

Why is Kyinsu authorised in the EU?

Combining basal insulin with a GLP-1 receptor agonist offers an effective treatment option in patients with type 2 diabetes previously treated with basal insulin, providing improved glycaemic control with less weight gain and a lower risk of hypoglycaemia compared to intensifying insulin treatment. Kyinsu has been shown to improve blood glucose control in adults with type 2 diabetes who were not sufficiently controlled with insulin, with the added benefit of weight loss. In patients not sufficiently controlled with a GLP-1 receptor agonist, Kyinsu also improved blood glucose control, although it was associated with weight gain, in contrast to the weight loss typically seen with GLP-1 receptor agonists alone.

The availability of both active substances in a single injection is considered convenient and may support better adherence to treatment.

The side effects of Kyinsu are in line with those seen with the individual active substances, and include hypoglycaemia and gastrointestinal problems which are known to be associated with GLP-1 receptor agonists and are generally transient.

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

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

The company that markets Kyinsu will have to provide an educational guide to all patients treated with the medicine to reduce the risk of medication errors. The guide will contain information and instructions to avoid dosing errors and mix-ups with other injectable diabetes treatments when switching to once weekly Kyinsu.

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

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

Other information about Kyinsu

Kyinsu received a marketing authorisation valid throughout the EU on 24 November 2025.

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

This overview was last updated in 11-2025.