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Suliqua (*insulin glargine / lixisenatide*)

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

What is Suliqua and what is it used for?

Suliqua is a medicine that is used together with metformin (another diabetes medicine), with or without SGLT-2 inhibitors (other diabetes medicines), for the treatment of adults with type 2 diabetes. It is used with appropriate diet and exercise to improve control of blood glucose (sugar) when the diabetes is not satisfactorily controlled.

The active substances in Suliqua are insulin glargine and lixisenatide.

How is Suliqua used?

Suliqua is available as pre-filled disposable pens in two different strengths and can only be obtained with a prescription. It is given by injection under the skin of the belly, the thigh or the upper arm.

Suliqua is given once a day up to 1 hour before a meal, preferably at the same time each day. Before Suliqua is started, the patient's insulin and diabetes medicines other than metformin and SGLT-2 inhibitors should be stopped. The dose is adjusted individually for each patient according to the patient's blood glucose.

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

How does Suliqua work?

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

One of the active substances in Suliqua, insulin glargine, is a replacement insulin that acts in the same way as the body's own insulin and helps glucose enter cells from the blood, thereby controlling the level of glucose in the blood. Insulin glargine reaches the bloodstream more slowly than human insulin after an injection and its action therefore lasts longer.

The other active substance in Suliqua, lixisenatide, belongs to the class of medicines known as GLP-1 agonists. It 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 to control blood glucose levels.

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By controlling the level of blood glucose, the symptoms and complications of diabetes are reduced.

What benefits of Suliqua have been shown in studies?

Suliqua was effective at controlling blood glucose in three main studies in patients with type 2 diabetes. The main measure of effectiveness in all three studies was the change in the blood levels of a substance called glycosylated haemoglobin (HbA1c). HbA1c gives an indication of how well blood glucose is controlled: a reduction in HbA1c levels indicates improved control of blood glucose levels. The first two studies looked at the change in HbA1c after 30 weeks, and the third study looked at the change after 26 weeks.

The first study involved 1,170 patients whose blood glucose was not adequately controlled by metformin with or without another diabetes medicine taken by mouth. After stopping their diabetes medicines given by mouth except metformin, patients were given Suliqua or one of its two components, insulin glargine or lixisenatide. Results showed that Suliqua is more effective at controlling blood glucose levels than either component: average HbA1c at the start of the study was 8.1%, which fell after 30 weeks of treatment to 6.5% in the group using Suliqua, compared with 6.8% in the group using insulin glargine and 7.3% in the group using lixisenatide.

The second study involved 736 patients whose blood glucose was not adequately controlled by a long-acting insulin such as insulin glargine with or without one or two other diabetes medicines taken by mouth. After stopping all diabetes medicines given by mouth except metformin, patients were given either Suliqua or insulin glargine. Average HbA1c was 8.1% before patients started taking Suliqua or insulin glargine. After 30 weeks of treatment, average HbA1c fell to 6.9% in the group taking Suliqua and to 7.5% in patients receiving insulin glargine.

The third study involved 514 patients whose blood glucose was not adequately controlled by metformin (alone or with other diabetes medicines taken by mouth) in combination with a diabetes medicine belonging to the class of GLP-1 agonists. Half of the patients were switched from their GLP-1 agonist medicine to Suliqua. After 26 weeks of treatment, average HbA1c dropped from 7.7% to 6.7% in the group treated with Suliqua and from 7.8% to 7.4% in the group that continued using a GLP-1 agonist.

What are the risks associated with Suliqua?

The most common side effect with Suliqua (which may affect more than 1 in 10 people) is hypoglycaemia (low blood glucose); problems with the digestive system are common and include diarrhoea, vomiting and nausea (feeling sick). For the full list of all side effects and restrictions with Suliqua, see the package leaflet.

Why is Suliqua authorised in the EU?

The European Medicines Agency (EMA) decided that Suliqua's benefits are greater than its risks and recommended that it be approved for use in the EU.

The Agency concluded that combination treatment with a long-acting insulin and a GLP-1 agonist such as Suliqua is an important option for patients with type 2 diabetes who are eligible for insulin or who need intensive insulin therapy. In these patients, Suliqua was effective at controlling glucose levels and reduced the risk of problems linked to intensive insulin therapy such as hypoglycaemia and weight gain. In terms of safety there were no new safety concerns with the combination of insulin glargine and lixisenatide in Suliqua compared with the components used separately.

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

The company that markets Suliqua will provide educational materials for healthcare professionals and patients, explaining how to use the medicine safely, so as to reduce the risk of medication errors.

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

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

Other information about Suliqua

Suliqua received a marketing authorisation valid throughout the EU on 11 January 2017.

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

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