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EPAR summary for the public

Suliqua

insulin glargine / lixisenatide

This is a summary of the European public assessment report (EPAR) for Suliqua. 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 Suliqua.

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

What is Suliqua and what is it used for?

Suliqua is a medicine that is used together with metformin (another diabetes medicine) for the treatment of adults with type 2 diabetes. It is used when blood glucose (sugar) levels are not satisfactorily controlled by metformin alone or by a combination of metformin and another medicine (either another glucose-lowering medicine taken by mouth or a long-acting insulin).

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 as an injection under the skin of the belly, the thigh or the upper arm.

Suliqua is given once a day, preferably at the same time each day. Before Suliqua is started the patient's insulin and diabetes medicines other than metformin must be stopped. The dose is adjusted individually for each patient, and the patient's blood glucose should be regularly tested to find the lowest effective dose.

For further information, see the package leaflet.

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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 enters the bloodstream more slowly than human insulin after an injection and its action is therefore longer lasting.

The other active substance in Suliqua, lixisenatide, belongs to the class of diabetes 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 with the control of blood glucose levels.

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

What benefits of Suliqua have been shown in studies?

Suliqua has been shown to be effective at controlling blood glucose in two main studies involving 1,906 patients with type 2 diabetes. In both studies, the main measure of effectiveness was the change after 30 weeks of treatment in the level in the blood of a substance called glycosylated haemoglobin (HbA1c), which gives an indication of how well blood glucose is controlled.

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. Upon entering the study, all patients had to stop their other diabetes medicines and were given Suliqua or insulin glargine or lixisenatide, all with metformin. Results showed that Suliqua is more effective at controlling blood glucose levels than either components: 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. A reduction in HbA1c levels means an improvement in the control of blood sugar levels.

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. Patients who entered the study, had to stop all medicines given by mouth except metformin and were then 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.

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 approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Suliqua's benefits are greater than its risks and recommended that it be approved for use in the EU.

The CHMP concluded that combination treatments with a long-acting insulin and a GLP-1 agonist such as Suliqua are an important treatment option for patients 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.

Other information about Suliqua

The European Commission granted a marketing authorisation valid throughout the European Union for Suliqua on 11 January 2017.

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

This summary was last updated in 12-2016.