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Ogluo (*glucagon*)

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

What is Ogluo and what is it used for?

Ogluo is a medicine for treating severe hypoglycaemia (very low levels of glucose in the blood) in patients with diabetes who are at least 2 years old.

Hypoglycaemia can occur when diabetes medicines to reduce blood glucose cause glucose levels to fall too low. In severe cases, patients can faint or become unconscious and they must be treated urgently to raise glucose levels.

Ogluo contains the active substance glucagon.

Ogluo is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance. However, Ogluo is available as a solution for injection while the reference medicine is available as a powder that needs to be dissolved to make up the injection. The reference medicine for Ogluo is GlucaGen.

How is Ogluo used?

Ogluo is available as pre-filled pens and pre-filled syringes each containing 0.5 or 1 mg glucagon. It can only be obtained with a prescription.

Ogluo is injected under the skin into the lower belly, thigh or upper arm. The recommended dose for adults and those weighing at least 25 kg is 1 mg, and for children weighing up to 25 kg the dose is 0.5 mg.

The patient and those in close daily contact with the patient should know how to recognise signs of hypoglycaemia and they should be able to follow instructions in the package leaflet on how to inject Ogluo quickly when needed. The patient must receive medical help right away after injection.

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

How does Ogluo work?

The active substance in Ogluo is a synthetic form of the natural hormone glucagon. In patients with low levels of glucose, the medicine causes the liver to release stored glucose into the bloodstream, so reducing symptoms of hypoglycaemia.

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What benefits of Ogluo have been shown in studies?

In a main study involving 132 adults with type 1 diabetes, participants were given insulin to cause hypoglycaemia on two occasions 7 to 28 days apart. The glucagon injections Ogluo and GlucaGen (the reference medicine) were given under the skin to treat the hypoglycaemia. Participants received both Ogluo and GlucaGen, one on the first occasion and the other on the second. The blood glucose levels of almost all participants rose by an acceptable amount within 30 minutes of treatment (99% of patients treated with Ogluo, and 100% of those treated with GlucaGen). The average time for blood glucose levels to rise to an acceptable level was 14.8 minutes after treatment with Ogluo and 10.4 minutes after GlucaGen.

Two further studies involving a total of 161 adults also found Ogluo to be as effective as another glucagon medicine, Glucagon Emergency Kit (Eli Lilly).

In a study involving 31 children and adolescents aged 2 to 18 years with type 1 diabetes, participants were given insulin to reduce glucose levels to the lower end of the normal range. Treatment with Ogluo was effective at increasing blood glucose levels within 30 minutes. Ogluo was not compared with another medicine in this study.

What are the risks associated with Ogluo?

The most common side effects with Ogluo (which may affect more than 1 in 10 people) are nausea (feeling sick) and vomiting.

Ogluo must not be given to patients with phaeochromocytoma (a tumour of the adrenal gland) because it could cause serious increases in blood pressure.

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

Why is Ogluo authorised in the EU?

Severe hypoglycaemia needs urgent treatment. Ogluo offers a ready-to-use injection which patients' carers can give reliably and easily for emergency treatment of severe hypoglycaemia. Although improvement in blood glucose levels with Ogluo may be delayed by about 4 minutes, preparation of Ogluo injections is quicker compared to injections that need to be made up by dissolving the glucagon powder first. The side effects of Ogluo are manageable.

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

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

The company that markets Ogluo will provide materials, including a video, with information and instructions on the correct way to use the medicine.

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

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

Other information about Ogluo

Ogluo received a marketing authorisation valid throughout the EU on 11 February 2021.

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

This overview was last updated in 02-2021.