EMA/307646/2024
EMEA/H/C/006214

Zegalogue (*dasiglucagon*)

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

What is Zegalogue and what is it used for?

Zegalogue is used for treating severe hypoglycaemia (low blood glucose levels) in adults and children from 6 years of age who have diabetes mellitus.

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

Zegalogue contains the active substance dasiglucagon.

How is Zegalogue used?

Zegalogue is given by injection under the skin in the lower abdomen, buttocks, thigh or outer upper arm as soon as signs of severe hypoglycaemia are recognised. If there is no response, an additional dose from another device may be given after 15 minutes.

Patients and their caregivers should receive information about the signs and symptoms of severe hypoglycaemia. As severe hypoglycaemia requires the help of others, the patient should be instructed to inform those around them about Zegalogue and how to use it.

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

How does Zegalogue work?

The active substance in Zegalogue works in a similar way to a natural hormone in the body called glucagon. In patients with low levels of blood glucose, the medicine causes the liver to release stored glucose into the bloodstream, thereby reducing symptoms of hypoglycaemia.

What benefits of Zegalogue have been shown in studies?

Three main studies showed that Zegalogue was effective at restoring blood glucose levels in patients with type 1 diabetes whose blood glucose levels were very low after insulin treatment.

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

In the first study in 168 adults, patients who had Zegalogue recovered in 10 minutes while those given placebo recovered in 40 minutes. There were similar results in a second study in 44 adults where patients who had Zegalogue recovered in 10 minutes while those who had placebo recovered after 35 minutes.

The third study involved 41 children from 6 years of age. In this study, patients who had Zegalogue also recovered in 10 minutes, while those on placebo recovered after 30 minutes.

What are the risks associated with Zegalogue?

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

The most common side effects with Zegalogue (which may affect more than 1 in 10 people) include nausea (feeling sick) and vomiting. Another common side effect which may affect up to 1 in 10 people is headache.

Zegalogue must not be used in patients with phaeocromocytoma (a tumour in the adrenal glands).

Why is Zegalogue authorised in the EU?

The main studies showed that Zegalogue was effective at restoring blood glucose levels in people with hypoglycaemia caused by insulin treatment. The side effects are considered acceptable. The European Medicines Agency therefore decided that Zegalogue ’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 Zegalogue?

The company that markets Zegalogue will provide healthcare professionals, patients and caregivers with educational materials, a leaflet and an instructional video, on how to use the medicine.

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

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

Other information about Zegalogue

Zegalogue received a marketing authorisation valid throughout the EU on 24 July 2024.

Further information on Zegalogue can be found on the Agency’s website: ema.europa.eu/medicines/human/EPAR/zegalogue

This overview was last updated in July 2024.