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Baqsimi (*glucagon*)

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

What is Baqsimi and what is it used for?

Baqsimi is a medicine used to treat severe hypoglycaemia (very low blood glucose levels) in adults, adolescents, and children aged 4 years or older who have diabetes.

Hypoglycaemia can occur in people with diabetes when treatments to control blood glucose cause the levels of glucose to become too low. In severe cases, it can make patients faint or become unconscious and must therefore be treated immediately.

Baqsimi contains the active substance glucagon.

How is Baqsimi used?

Baqsimi is available as a powder to be given into the nose. The tip of the container is inserted into one nostril and the plunger then is used to deliver the medicine.

Most of the time Baqsimi is given by the patient's family members or friends. These people will need to know in advance what to do if the patient has symptoms of hypoglycaemia. After giving the dose, they should call for medical help right away.

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

How does Baqsimi work?

The active substance in Baqsimi is a synthetic form of the natural hormone glucagon, which counterbalances the effects of insulin. In patients with low levels of glucose, the medicine causes the liver to release its stored glucose into the bloodstream, thereby reducing symptoms of hypoglycaemia.

What benefits of Baqsimi have been shown in studies?

Baqsimi has been shown to effectively treat hypoglycaemia in three main studies. The first study involved 83 adults with type 1 or type 2 diabetes who were given insulin to cause hypoglycaemia and then treated with either Baqsimi or an intramuscular (into a muscle) injection of glucagon. The blood glucose levels of almost all participants rose to acceptable levels within 30 minutes of treatment (99%

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of patients treated with Baqsimi, and 100% of those treated with intramuscular glucagon). These results were confirmed in a similar study conducted in 70 adults with type 1 diabetes. In this second study, blood glucose levels rose to acceptable levels within 30 minutes of treatment in all participants given either Baqsimi or intramuscular glucagon.

The third study involved 48 children and adolescents between 4 and 17 years of age with type 1 diabetes who were given insulin to lower their blood glucose levels. Blood glucose levels of all participants rose to acceptable levels within 30 minutes of treatment with either Baqsimi or intramuscular glucagon.

What are the risks associated with Baqsimi?

The most common side effects with Baqsimi (which may affect more than 1 in 10 people) are watery eyes, irritation in the nose and throat, nausea (feeling sick), headache and vomiting.

Baqsimi 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 Baqsimi, see the package leaflet.

Why is Baqsimi authorised in the EU?

The European Medicines Agency decided that Baqsimi's benefits are greater than its risks and it can be authorised for use in the EU. Severe hypoglycaemia requires emergency treatment and there has been a need for a ready-to-use device that can be easily used. In studies, Baqsimi, which is given into the nose, was as effective as intramuscular injection in treating hypoglycaemia. The safety profile was similar for both methods and considered acceptable.

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

The company that markets Baqsimi will provide educational materials for doctors, patients and caregivers with information on how to use the medicine safely and how to identify and report side effects. The company should also provide a demonstration kit including a training device to healthcare professionals who will prescribe Baqsimi as well as patients or carers if they request it.

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

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

Other information about Baqsimi

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