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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 1 year or older who have diabetes.

Hypoglycaemia can occur in people with diabetes when treatments to control blood glucose (sugar), such as insulin, cause it to become too low. In some cases hypoglycaemia can be severe, causing patients to faint or become unconscious. In such cases it needs to be treated immediately using a medicine that quickly raises blood sugar.

Baqsimi contains the active substance glucagon.

How is Baqsimi used?

Baqsimi can only be obtained with a prescription. It is available as a powder in a single-use nasal device designed to deliver one dose of Baqsimi into the nose.

The tip of the container is inserted into one nostril and the plunger is then used to deliver the medicine.

Baqsimi is usually given to the patient by someone they know, such as a family member, work colleague or friend. These people need to know in advance what to do if the patient has symptoms of hypoglycaemia. After giving Baqsimi, they should call for medical help right away.

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 naturally occurring hormone glucagon, which counterbalances the effects of insulin. In patients with low levels of glucose, glucagon causes the liver to release its stored glucose into the bloodstream. This increases blood levels of glucose thereby reducing symptoms of hypoglycaemia.

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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 injection of glucagon into a muscle. The blood glucose levels of almost all participants rose to acceptable levels within 30 minutes of treatment (99% 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 aged between 4 and 17 years 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.

Data from the third study was evaluated to determine how a single dose of Baqsimi would affect blood glucose levels in children aged 1 to 17 years. Based on this data, it was concluded that a single dose of Baqsimi would increase blood glucose to acceptable levels in almost 100% of children. Furthermore, more than 97% of children would be expected to achieve these levels within 15 minutes of using Baqsimi.

A fourth study involved 7 children aged from 1 to less than 4 years of age who had fasted overnight, so their blood glucose levels were lower than normal. In all 7 children, blood glucose levels rose to acceptable levels within 30 minutes of receiving a single dose of Baqsimi.

What are the risks associated with Baqsimi?

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

The most common side effects with Baqsimi (which may affect more than 1 in 10 people) include 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 can cause serious increases in blood pressure.

Why is Baqsimi authorised in the EU?

Severe hypoglycaemia requires emergency treatment and there has been a need for a ready-to-use device that is easy to use. In studies, Baqsimi, which is given into the nose, was as effective as injections into a muscle to treat hypoglycaemia. The safety profile was similar for both methods and considered acceptable.

The European Medicines Agency therefore decided that Baqsimi'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 Baqsimi?

The company that markets Baqsimi will provide educational materials for doctors, patients and caregivers, including information on how to use the medicine safely and how to identify and report side effects. The company will also provide a demonstration kit with 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

Baqsimi received a marketing authorisation valid throughout the EU on the 16 December 2019.

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

This overview was last updated in 08-2025.