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Awiqli (*insulin icodec*)

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

What is Awiqli and what is it used for?

Awiqli is a medicine used to treat adults with diabetes. It contains the active substance insulin icodec, a long-acting insulin.

How is Awiqli used?

Awiqli can only be obtained with a prescription. It is given as an injection under the skin of the belly, thigh or upper arm once a week, on the same day each week. The dose is adjusted based on the patient's blood glucose level, which should be tested regularly.

In patients with type 1 diabetes mellitus, Awiqli must be combined with short-acting insulin to cover mealtime insulin requirements.

In patients with type 2 diabetes mellitus, Awiqli can be given alone or in combination with other diabetes medicines, including short-acting insulin.

When switching patients from another long-acting insulin, the first dose of Awiqli can be increased by 50% to get faster control of blood sugar. For patients with type 1 diabetes mellitus the first dose of Awiqli should always be increased by 50%.

For more information about using Awiqli, see the package leaflet or contact your healthcare provider.

How does Awiqli work?

Diabetes is a disease in which blood glucose is high, either because the body cannot produce insulin (type 1 diabetes) or because the body does not make enough insulin or cannot use it effectively (type 2 diabetes). The replacement insulin in Awiqli acts in the same way as the body's own insulin and helps glucose enter cells from the blood. This controls the level of blood glucose and reduces the symptoms and complications of diabetes. In the bloodstream, insulin icodec binds to a protein called albumin which makes it stay longer in the body, prolonging its action.

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What benefits of Awiqli have been shown in studies?

Awiqli was shown to be effective at controlling blood glucose in five studies in adults with type-2 diabetes and one study in adults with type-1 diabetes.

The main measure of effectiveness was the change in the level of glycosylated haemoglobin (HbA1c), which is the percentage of haemoglobin in the blood that has glucose attached to it. Reduced HbA1c levels indicate an improvement in the control of blood glucose.

For type-2 diabetes the studies involved over 3,500 adults who were either never treated with insulin before or previously received another long-acting insulin alone or a long-acting and short-acting insulin together. Patients either received Awiqli or insulin degludec or insulin glargine. Awiqli led to a decrease in the level of HbA1c. The level achieved with Awiqli after 26 weeks of treatment was similar to that seen with daily insulin degludec or insulin glargine.

For type 1 diabetes Awiqli was studied in one main study in 582 adults who had been treated with multiple daily insulin injections. People either received once weekly Awiqli or daily insulin degludec, in addition to short-acting insulin. After 26 weeks of treatment, HbA1c levels fell by an average of 0.47 percentage point in patients given Awiqli, compared with 0.51 points in those taking insulin degludec. After 52 weeks, the effect had diminished at 0.37 percentage points for Awiqli, compared with 0.54 points in those taking insulin degludec. Awiqli was therefore shown to be at least as effective as insulin degludec in patients with type-1 diabetes.

What are the risks associated with Awiqli?

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

The most common side effects with Awiqli (which may affect more than 1 in 10 people) include hypoglycaemia (low blood glucose levels). In patients with type 1 diabetes, hypoglycaemic events are more common compared to daily basal insulin.

Why is Awiqli authorised in the EU?

Studies showed that once-weekly Awiqli lowered blood glucose in patients with type 1 and type 2 diabetes. At the time of approval, available long-acting insulin treatments had to be administered once or twice daily. Awiqli only requires one injection each week and may be more convenient for certain patients.

For type 1 diabetes, there are concerns about the higher risk of hypoglycaemia compared to daily long-acting insulin. People with type 1 diabetes should therefore only be started on Awiqli if there are clear benefits of a weekly treatment.

Side effects were considered manageable with hypoglycaemia being the most common side effect.

The European Medicines Agency therefore decided that Awiqli'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 Awiqli?

The company that markets Awiqli will issue educational materials for patients with detailed information on how to avoid errors and mix-ups when switching from daily long-acting insulin.

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

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

Other information about Awiqli

Awiqli received a marketing authorisation valid throughout the EU on 17 May 2024.

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

This overview was last updated in 05-2024.