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Lyumjev[1] (*insulin lispro*)

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

What is Lyumjev and what is it used for?

Lyumjev is a medicine used to control blood glucose (sugar) levels in adults and children aged 1 year and above with diabetes. It contains the active substance insulin lispro.

How is Lyumjev used?

Lyumjev can only be obtained with a prescription. It is given as an injection under the skin of the upper arm, thigh, buttock or belly. It can also be given with an insulin pump. A healthcare professional should explain to the patient how to use the medicine properly.

Because Lyumjev is a fast-acting insulin, it is usually given just before a meal or, if more appropriate, soon after a meal. The dose of Lyumjev is worked out for each patient and depends on the patient's blood glucose level.

In some circumstances, such as when blood acid levels are dangerously high (ketoacidosis), Lyumjev may be given into a vein, under a doctor's supervision.

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

How does Lyumjev work?

In diabetes, patients have high levels of blood glucose either because the body does not produce enough insulin, or the body is unable to use insulin effectively.

The active substance in Lyumjev is a form of insulin that acts faster than regular human insulin or standard insulin lispro medicines because it is absorbed more quickly by the body. It helps control blood glucose levels, thereby alleviating symptoms and reducing the risk of complications of diabetes.

[1] Previously known as Liumjev.

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

What benefits of Lyumjev have been shown in studies

Lyumjev has been shown to be as good at controlling blood glucose as another insulin lispro medicine, Humalog, in four main studies.

Two of the studies involved adults whose diabetes treatment already required injection of mealtime insulin, one involving 1,222 patients with type 1 diabetes (where the body cannot make its own insulin) and one in 673 patients with type 2 diabetes (where the body cannot make enough insulin or cannot use it effectively). The main measure of effectiveness was the HbA1c percentage: lower HbA1c marks well-controlled blood glucose. The average starting HbA1c in both studies was 7.3%. Over 6 months of treatment, patients with type 1 diabetes experienced a fall of 0.13 percentage points in HbA1c with Lyumjev and 0.05 percentage points with Humalog. In patients with type 2 disease, HbA1c fell by 0.38 percentage points with Lyumjev and 0.43 percentage points with Humalog.

The third, smaller, study involved 49 adults whose diabetes was managed with an insulin pump and indicated that both Lyumjev and Humalog were effective in maintaining control of blood sugar in this setting.

A fourth study involving 716 children aged 3 years and above with type 1 diabetes also showed that Lyumjev was at least as effective as Humalog in maintaining control of blood sugar.

What are the risks associated with Lyumjev?

The most common side effect with Lyumjev (which may affect more than 1 in 10 people) is hypoglycaemia (low blood glucose).

Lyumjev must not be given to people whose blood glucose level is already low. Doses may need to be adjusted when it is given with other medicines that reduce blood glucose.

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

Why is Lyumjev authorised in the EU?

Lyumjev has been shown to be effective in controlling blood sugar, and because its action begins faster than existing insulin lispro medicines it was particularly useful in reducing the rise in blood glucose after a meal, although side effects such as low blood sugar might also develop more quickly.

The main studies looked at adults with type 1 and type 2 diabetes as well as children from 3 years of age with type 1 diabetes. The European Medicines Agency noted that these studies were sufficient to show that the medicine will be effective in younger children (from 1 year of age) with type 1 or type 2 diabetes.

The Agency therefore decided that Lyumjev'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 Lyumjev?

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

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

Other information about Lyumjev

Liumjev received a marketing authorisation valid throughout the EU on 24 March 2020.

The name of the medicine was changed to Lyumjev on 21 April 2021.

Further information on Lyumjev can be found on the Agency's website: https://www.ema.europa.eu/en/medicines/human/EPAR/lyumjev-previously-liumjev.

This overview was last updated in 10-2022.