EMA/62491/2026
EMEA/H/C/006158

Bysumlog (*insulin lispro*)

A plain-language overview of Bysumlog and why it is authorised in the EU

What is Bysumlog and what is it used for?

Bysumlog is a medicine used to control blood glucose (sugar) levels in adults and children with diabetes who need insulin.

Bysumlog contains the active substance insulin lispro and is a biological medicine. It is a 'biosimilar medicine'; this means that Bysumlog is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Bysumlog is Humalog. For more information on biosimilar medicines, see here.

How is Bysumlog used?

Bysumlog can only be obtained with a prescription. It is given as an injection under the skin of the upper arm, thigh, buttock or abdomen (belly). Patients can inject themselves with this medicine if they have been trained appropriately.

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

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

How does Bysumlog 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.

Bysumlog is a replacement insulin that is very similar to the insulin made by the body. The active substance in Bysumlog, insulin lispro, is a form of insulin that acts faster than naturally produced human insulin because it is absorbed more quickly by the body. It helps control blood glucose levels, thereby improving symptoms and reducing the risk of complications of diabetes.

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What benefits of Bysumlog have been shown in studies?

Laboratory studies comparing Bysumlog with Humalog have shown that the active substance in Bysumlog is highly similar to that in Humalog in terms of structure, purity and biological activity. Studies have also shown that giving Bysumlog produces similar levels of the active substance in the body to those seen with Humalog.

Based on the data accumulated on biosimilars of insulin medicines, studies on the effectiveness of insulin lispro carried out with Humalog do not need to be repeated for Bysumlog.

Studies carried out with Bysumlog are described in more detail in the medicine's assessment report.

What are the side effects and restrictions with Bysumlog?

The safety of Bysumlog has been evaluated and, based on all the studies carried out, the side effects of the medicine are considered to be comparable to those of Humalog.

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

Bysumlog may cause hypoglycaemia (low blood glucose levels) and must not be given to patients whose blood glucose is already low.

Why is Bysumlog authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Bysumlog has a highly similar structure, purity and biological activity to Humalog and is distributed in the body in the same way.

Based on these data, and those accumulated on insulin biosimilars, Bysumlog is expected to have the same effects as Humalog in its authorised uses.

Therefore, the Agency's view was that, as for Humalog, the benefits of Bysumlog outweigh the identified risks and it can be authorised for use in the EU.

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

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

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

Other information about Bysumlog

Bysumlog received a marketing authorisation valid throughout the EU on 06 May 2026.

Further information on Bysumlog, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/bysumlog.

For information about the availability of this medicine in your country, contact your national competent authority.

This overview was last updated in 05-2026.