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EPAR summary for the public

Insulin lispro Sanofi

insulin lispro

This is a summary of the European public assessment report (EPAR) for Insulin lispro Sanofi. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Insulin lispro Sanofi.

For practical information about using Insulin lispro Sanofi, patients should read the package leaflet or contact their doctor or pharmacist.

What is Insulin lispro Sanofi and what is it used for?

Insulin lispro Sanofi is a medicine used to control blood glucose (sugar) levels in adults and children with diabetes who need insulin. It contains the active substance insulin lispro.

Insulin lispro Sanofi is a 'biosimilar medicine'. This means that it is highly similar to a biological medicine (also known as the 'reference medicine') that is already authorised in the European Union (EU). The reference medicine for Insulin lispro Sanofi is Humalog 100 U/ml solution. For more information on biosimilar medicines, see here.

How is Insulin lispro Sanofi used?

Insulin lispro Sanofi is given as an injection under the skin in the upper arm, thigh, buttock or belly. It can also be given with an infusion pump. In some circumstances, such as when blood acid levels are dangerously high (ketoacidosis), the medicine may be given into a vein.

Because Insulin lispro Sanofi is a fast-acting insulin, it is usually given shortly before a meal and, when necessary, soon after a meal. The dose of Insulin lispro Sanofi is worked out for each patient and depends on the patient's blood glucose level. The doctor should instruct the patient on how to use the medicine properly.

The medicine can only be obtained with a prescription. For further information, see the package leaflet.

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How does Insulin lispro Sanofi 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 Insulin lispro Sanofi is a form of insulin which is absorbed more quickly by the body than human regular insulin, and can therefore act faster. It helps control blood glucose levels, thereby alleviating symptoms and reducing the risk of complications of diabetes.

What benefits of Insulin lispro Sanofi have been shown in studies?

Laboratory studies comparing Insulin lispro Sanofi with the reference medicine Humalog have shown that the active substance in Insulin lispro Sanofi is highly similar in terms of structure, purity and biological activity to that of Humalog. In addition, studies have shown that both medicines produce similar levels of the active substance in the body.

Two further studies in a total of 1,012 patients compared Insulin lispro Sanofi with Humalog and found them to be similarly effective at reducing blood levels of a substance called glycosylated haemoglobin (HbA1c), which gives an indication of how well blood glucose levels are controlled over time. In one study, in patients with type 1 diabetes, HbA1c reduced by 0.44 and 0.46 percentage points with Insulin lispro Sanofi and Humalog respectively after 26 weeks; in the second study, in patients with type 2 diabetes, the corresponding figures were 0.93 versus 0.88 percentage points.

What are the risks associated with Insulin lispro Sanofi?

Insulin lispro Sanofi may cause hypoglycaemia (low blood glucose levels) and must not be given to patients whose blood glucose is already low. Severe hypoglycaemia can lead to loss of consciousness and, in very extreme cases, to death. Hypoglycaemia may be due to the medicine itself or other factors such as diet and exercise.

For the full list of all side effects and restrictions with Insulin lispro Sanofi, see the package leaflet.

Why is Insulin lispro Sanofi approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements for biosimilar medicines, Insulin lispro Sanofi has a highly similar structure, purity and biological activity to Humalog and is distributed in the body in the same way. In addition, studies show that both medicines have similar effects in reducing blood glucose levels and similar side effects. Therefore, the CHMP's view was that, as for Humalog, the benefits of Insulin lispro Sanofi outweigh its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Insulin lispro Sanofi?

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

Other information about Insulin lispro Sanofi

The European Commission granted a marketing authorisation valid throughout the European Union for Insulin lispro Sanofi on 19 July 2017.

The full EPAR for Insulin lispro Sanofi can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Insulin lispro Sanofi, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2017.