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Humalog (*insulin lispro*)

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

What is Humalog and what is it used for?

Humalog is a range of insulin medicines used to treat patients who have diabetes and need insulin to keep their blood glucose (sugar) level controlled, including patients whose diabetes has just been diagnosed.

Humalog medicines contain the active substance insulin lispro on its own or combined with protamine to make it longer acting:

- Humalog (100 units/ml): standard-strength insulin lispro (fast-acting);
- Humalog (200 units/ml): high-strength insulin lispro (fast-acting);
- Humalog Mix25 (100 units/ml): 25% insulin lispro (fast-acting) and 75% insulin lispro protamine (longer-acting);
- Humalog Mix50 (100 units/ml): 50% insulin lispro (fast-acting) and 50% insulin lispro protamine (longer-acting).

How is Humalog used?

Humalog medicines are available as solutions or suspensions for injection in vials, cartridges or prefilled pens.

The medicines are given by injection under the skin of the upper arm, thigh, buttock or abdomen (belly). Humalog 100 units/ml may also be given by continuous infusion under the skin using an insulin pump or by injection into a vein. Humalog 200 units/ml, Humalog Mix25 and Humalog Mix50 should never be given into a vein.

The dose depends on the individual patient's needs and may be reduced in patients with reduced kidney or liver function. The medicines are normally given shortly before a meal, but can be given just after a meal if necessary.

Humalog (100 or 200 units/ml) can be used with a longer-acting insulin or with sulphonylureas (a group of diabetes medicines that are taken by mouth).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Patients can inject themselves with this medicine if they have been trained appropriately.

Humalog can only be obtained with a prescription. For more information about using Humalog, see the package leaflet or contact your doctor or pharmacist.

How does Humalog work?

Diabetes is a disease in which the body does not produce enough insulin to control the level of glucose in the blood or when the body is unable to use insulin effectively. Humalog is a replacement insulin which is very similar to the insulin made by the body.

The active substance in Humalog, insulin lispro, is produced by a method known as 'recombinant DNA technology': it is made by bacteria into which a gene (DNA) has been introduced, which makes them able to produce insulin lispro.

Insulin lispro has a small difference from human insulin that allows it to be absorbed faster by the body so it can act shortly after injection. Humalog Mix25 and Humalog Mix50 contain both insulin lispro and a longer-acting form called insulin lispro protamine, which is absorbed more slowly so that it works for longer.

Humalog works in the same way as naturally produced insulin and helps glucose from the blood to enter cells. By controlling the level of blood glucose, the symptoms and complications of diabetes are reduced.

What benefits of Humalog have been shown in studies?

Humalog was originally studied in eight clinical trials including 2,951 patients with type 1 diabetes (when the body cannot produce insulin) or type 2 diabetes (when the body is unable to use insulin effectively). The effectiveness of Humalog was compared with that of Humulin R (a soluble recombinant DNA human insulin), when added to long-acting insulins given once or twice a day.

The studies measured the level of a substance in the blood called glycosylated haemoglobin (HbA1c), which gives an indication of how well the blood glucose is controlled, and 'fasting' blood glucose levels (measured when the patient had not eaten for at least eight hours). Humalog and Humulin R had a similar effect on the control of diabetes, as measured by HbA1c and fasting glucose levels.

Studies also looked at the use of Humalog in 542 patients aged between two and 19 years. The medicine's effects in the body were similar in both adults and children.

Studies on the use of Humalog in combination with sulphonylureas showed that these medicines used together reduce HbA1c more than sulphonylureas used alone.

What are the risks associated with Humalog?

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

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

Why is Humalog authorised in the EU?

Humalog has been shown to effectively reduce glucose levels and is comparable to human insulin. The European Medicines Agency decided that Humalog'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 Humalog?

When first marketing the high-strength Humalog (200 units/ml), the company provided information for patients and healthcare professionals to advise them of the 2 strengths and on how to use them safely to avoid medication errors.

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

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

Other information about Humalog

Humalog received a marketing authorisation valid throughout the EU on 30 April 1996.

Further information on Humalog can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 07-2018.