EMA/242544/2020
EMEA/H/C/005033

Insulin aspart Sanofi (*insulin aspart*)

An overview of Insulin aspart Sanofi and why it is authorised in the EU

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

Insulin aspart Sanofi is a medicine used to control blood glucose (sugar) levels in patients from one year of age who have diabetes.

Insulin aspart Sanofi is a 'biosimilar medicine'. This means that Insulin aspart Sanofi is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Insulin aspart Sanofi is NovoRapid. For more information on biosimilar medicines, see here.

Insulin aspart Sanofi contains the active substance insulin aspart, a rapid-acting insulin.

How is Insulin aspart Sanofi used?

Insulin aspart Sanofi can only be obtained with a prescription. It is given as an injection under the skin in the upper arm, thigh, buttock or belly. Because Insulin aspart Sanofi is a fast-acting insulin, it is usually given shortly before a meal or if more appropriate, soon after a meal. Insulin aspart Sanofi is normally used in combination with a longer-acting insulin. The dose is worked out for each patient and depends on the patient's weight and blood glucose level.

A healthcare professional should explain to the patient how to use the medicine properly.

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

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

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

Laboratory studies comparing Insulin aspart Sanofi with NovoRapid have shown that the active substance in Insulin aspart Sanofi is highly similar to that in NovoRapid in terms of structure, purity and biological activity. Studies have also shown that giving Insulin aspart Sanofi produces similar levels of the active substance in the body to giving NovoRapid.

In addition, a study involving 597 patients already being treated with insulin for diabetes showed that 6-months' treatment using Insulin aspart Sanofi plus a longer-acting insulin (insulin glargine) was as effective in controlling blood sugar as a combination including NovoRapid and insulin glargine. The average HbA1c (a measurement that gives an indication of how well blood glucose levels are controlled over time) was 8.00% at the start in those treated with Insulin aspart Sanofi and 7.94% in those given NovoRapid; after 6 months it was 7.62% and 7.64% respectively.

Because Insulin aspart Sanofi is a biosimilar medicine, the studies on effectiveness and safety of insulin aspart carried out with NovoRapid do not all need to be repeated for Insulin aspart Sanofi.

What are the risks associated with Insulin aspart Sanofi?

The safety of Insulin aspart Sanofi has been evaluated, and on the basis of all the studies carried out the side effects of the medicine are considered to be comparable to those of the reference medicine NovoRapid.

The most common side effect with Insulin aspart Sanofi (which may affect more than 1 in 10 people) is hypoglycaemia (low blood glucose levels) and the medicine must not be given to people whose blood glucose level is already low.

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

Why is Insulin aspart Sanofi authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Insulin aspart Sanofi has a highly similar structure, purity and biological activity to NovoRapid and is distributed in the body in the same way. In addition, studies in patients with diabetes have shown that the safety and effectiveness of Insulin aspart Sanofi is equivalent to that of NovoRapid.

All these data were considered sufficient to conclude that Insulin aspart Sanofi will behave in the same way as NovoRapid in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was that, as for NovoRapid, the benefits of Insulin aspart Sanofi 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 Insulin aspart Sanofi?

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

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

Other information about Insulin aspart Sanofi

Insulin aspart Sanofi received a marketing authorisation valid throughout the EU on 25 June 2020.

Further information on Insulin aspart Sanofi can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/insulin-aspart-sanofi.

This overview was last updated in 06-2020.