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Fiasp (*insulin aspart*)

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

What is Fiasp and what is it used for?

Fiasp is a medicine that is used to treat children from one year of age and adults with diabetes. It contains the active substance insulin aspart, a rapid-acting insulin.

How is Fiasp used?

Fiasp is a solution for injection available in vials, cartridges or pre-filled pens and can only be obtained with a prescription. It is usually injected under the skin of the belly or upper arm immediately before a meal, although it may be given up to 20 minutes after starting a meal if necessary. The dose depends on the patient's blood glucose, which should be tested regularly to find the dose that gives good control of blood sugar. When injected under the skin, Fiasp should be used in combination with an intermediate- or long-acting insulin that is given at least once a day.

Fiasp can also be used in a pump system for continuous insulin infusion under the skin or alternatively, it can be injected into a vein but only by a doctor or a nurse.

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

How does Fiasp work?

Diabetes is a disease in which blood glucose is high, either because the body cannot produce insulin (type 1 diabetes) or because the body does not make enough insulin or cannot use it effectively (type 2 diabetes). The replacement insulin in Fiasp acts in the same way as the body's own insulin and helps glucose enter cells from the blood. This controls the level of blood glucose and reduces the symptoms and complications of diabetes. Insulin aspart enters the bloodstream faster than human insulin after injection and therefore works more quickly.

What benefits of Fiasp have been shown in studies?

The benefits of Fiasp in reducing blood glucose as part of diabetes treatment have been shown in 4 main studies.

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In two studies Fiasp was at least as effective as another insulin, NovoRapid. Both Fiasp and NovoRapid contain insulin aspart but Fiasp contains some different ingredients intended to help it to be absorbed rapidly. The main measure of effectiveness was the medicine's ability to decrease the level in the blood of glycosylated haemoglobin (HbA_{1c}), a substance which indicates how well blood glucose is controlled over time. One study involving 1,143 adults with type 1 diabetes whose starting HbA_{1c} was around 7.6% found that after 6 months of treatment HbA_{1c} fell by 0.32 percentage points with a mealtime dose of Fiasp, compared with 0.17 points with the other insulin. In the second study involving 689 adults with type 2 diabetes, the fall after 6 months of treatment (from a starting value of 7.96% and 7.89% respectively) was 1.38 points with Fiasp and 1.36 points with the comparator.

A third study involving 236 adults with type 2 diabetes and a starting HbA_{1c} of around 7.9% found that adding mealtime Fiasp to treatment with a long-acting insulin and the diabetes medicine metformin improved blood glucose control. (There was no direct comparison between Fiasp and another mealtime insulin in this study.) In patients given Fiasp the HbA_{1c} fell after 18 weeks by 1.16 percentage points, compared with 0.22 points in those on long-acting insulin and metformin alone.

A fourth study in 777 adolescents and children from 2 years of age with type 1 diabetes and a starting HbA_{1c} of around 7.6% compared Fiasp (given at mealtime or 20 minutes after the start of the meal) with NovoRapid (given at mealtime). In this study, Fiasp was at least as effective as the comparator: there was almost no change in HbA_{1c} in patients given Fiasp at mealtime (0.05 percentage points) and a similar slight increase in those given Fiasp after a meal or NovoRapid at mealtime (0.35 and 0.23 percentage points respectively).

What are the risks associated with Fiasp?

The most common side effect with Fiasp (which may affect more than 1 in 10 people) is hypoglycaemia (excessively low blood sugar). Hypoglycaemia can occur more quickly with Fiasp than with other mealtime insulins. For the full list of side effects and restrictions of Fiasp, see the package leaflet.

Why is Fiasp authorised in the EU?

A clinically relevant benefit in lowering blood glucose has been shown in studies with Fiasp.

Compared with the already authorised insulin aspart medicine NovoRapid, the lowering of blood glucose develops earlier in adults given Fiasp, although the total extent of the lowering effect is similar. However, it is unclear whether this changes the risk of diabetic complications. The overall rate and severity of side effects was comparable with NovoRapid, although hypoglycaemia occurred more often in the first 2 hours after a dose of Fiasp. The benefits of Fiasp were also shown in children. Although Fiasp was not studied in children below 2 years of age, it is also expected to have a beneficial effect in younger children. The slightly higher risk of hypoglycaemia at night in children treated with Fiasp is addressed in the product information and is considered manageable.

The European Medicines Agency therefore decided that Fiasp's benefits 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 Fiasp?

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

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

Other information about Fiasp

Fiasp received a marketing authorisation valid throughout the EU on 9 January 2017.

Further information on Fiasp can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/fiasp.

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