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EPAR summary for the public

Fiasp

insulin aspart

This is a summary of the European public assessment report (EPAR) for Fiasp. 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 Fiasp.

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

What is Fiasp and what is it used for?

Fiasp is a medicine that is used to treat 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, 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 lowest effective dose. When given by injection 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 is normally injected under the skin of the belly or upper arm.

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

For further information, see the package leaflet.

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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. By controlling the level of blood glucose, the symptoms and complications of diabetes are reduced. 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 3 main studies.

In two studies Fiasp was shown to be 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 be absorbed rapidly. The main measure of effectiveness was the medicine's ability to decrease the level in the blood of a substance called glycosylated haemoglobin (HbA_{1c}), which gives an indication of how well blood glucose is controlled over time. One study involving 1,143 patients with type 1 diabetes whose starting HbA_{1c} was around 7.6% found that after 6 months of treatment HbA_{1c} decreased 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 patients 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 patients 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 fall in HbA_{1c} after 18 weeks was 1.16 percentage points, compared with 0.22 points in those on long-acting insulin and metformin alone.

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 may occur more quickly with Fiasp than with other mealtime insulins. For the full list of all side effects and restrictions with Fiasp, see the package leaflet.

Why is Fiasp approved?

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 with Fiasp, although the total extent of the lowering effect is similar. However, it is unclear whether this would result in a difference in the risk of diabetic complications. With regard to safety 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 Agency's Committee for Medicinal Products for Human Use (CHMP) therefore decided that Fiasp's benefits are greater than its risks and recommended that it be approved 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.

Other information about Fiasp

The European Commission granted a marketing authorisation valid throughout the European Union for Fiasp on 9 January 2017.

The full EPAR for Fiasp 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 Fiasp, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01 2017.