

press release

Fiasp® , a new, ultra-fast acting mealtime insulin is available for the treatment of diabetes in adults

Canada first country to launch Fiasp®

Bagsværd, Denmark, 27 March 2017 – Today, Novo Nordisk announced that Fiasp® , a new, fast-acting mealtime insulin for the treatment of diabetes in adults, has been launched in Canada, following the recent marketing authorisation from Health Canada on 6 January 2017.

Fiasp® is insulin aspart in an innovative formulation that more closely matches the natural physiological insulin response of a person without diabetes after a meal, compared with NovoRapid® (conventional insulin aspart)¹. Fiasp® also has the option of a flexible dosing regimen (up to 20 minutes after starting a meal), without compromising overall glycaemic control, when compared to NovoRapid® dosed at mealtime^{2,3}.

“The launch of Fiasp® in Canada represents the first new mealtime insulin in 10 years. We hope to make this innovation available to as many people with diabetes as possible worldwide,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “The goal of any insulin treatment is to match the natural physiological insulin production we see in people without diabetes, both in speed and glycaemic control. Fiasp® has narrowed the existing gap, getting us closer to that goal.”

Fiasp® is absorbed faster than NovoRapid® , appearing twice as fast in the bloodstream after injection^{1,3}, which leads to improved glycaemic control after a meal^{2,4}. In clinical trials, Fiasp® demonstrated improved overall glycaemic control in type 1 diabetes² and comparable overall glycaemic control in type 2 diabetes⁴, versus NovoRapid®. Results also showed improved mealtime glucose control in type 1 and type 2 diabetes^{2,4}. This was achieved without a significant difference in the overall rate of severe or confirmed hypoglycaemia, compared with NovoRapid®^{2,4}.

Clinical trial results showed that the faster absorption of Fiasp® , compared to NovoRapid® , was even more pronounced in those using a continuous subcutaneous insulin infusion (CSII) system (insulin pump therapy)⁵. In addition, when compared with NovoRapid® in a CSII setting in people with type 1 diabetes, Fiasp® showed no difference in pump compatibility as assessed by microscopically confirmed infusion-set occlusions,

and the treatments were equally effective in controlling glucose levels, compared to NovoRapid^{®*,†,6}.

“People living with diabetes often struggle to control blood glucose around mealtimes, which can be extremely challenging and result in debilitating diabetes-related complications,” said Dr Rémi Rabasa-Lhoret, endocrinologist at the Institut de Recherches Cliniques de Montréal and onset 1 investigator. “With the approval of a faster-acting insulin, one that is closer to the natural physiological insulin response of a person without diabetes, we can further support people in managing their blood glucose levels around meals, which may help prevent hyperglycaemia, for instance, a condition that can cause serious complications for people living with diabetes.”

Following the first country launch in Canada, Fiasp[®] will also be available in a number of European markets in the coming months.

About Fiasp^{®*}

Fiasp[®] (fast-acting insulin aspart) is a new, ultra-fast acting^{2,7,8} mealtime insulin, developed by Novo Nordisk with the objective of achieving a faster initial absorption, to improve glycaemic control after a meal, in people with type 1 and type 2 diabetes. Fiasp[®] is insulin aspart, a molecule with more than 17 years of clinical experience⁹, in an innovative formulation, in which two excipients have been added, Vitamin B3 (niacinamide) to increase the speed of absorption, and a naturally occurring Amino Acid (L-Arginine) for stability¹.

The efficacy and safety profile of Fiasp[®] was investigated in the phase 3a ‘onset’ clinical trial programme consisting of four trials, encompassing more than 2,100 people with type 1 and type 2 diabetes.

Fiasp[®] received marketing authorisation from the European Commission on 9 January 2017, covering all 28 European Union member states; approval was also obtained in Norway and Iceland. It is currently under regulatory review in Australia, Switzerland, Brazil, South Africa, Argentina and Israel.

In October 2016, a Complete Response Letter (CRL) was received from the US Food and Drug Administration (FDA) regarding the New Drug Application for fast-acting insulin aspart. Following an evaluation of the CRL, and ongoing discussions with the FDA, Novo Nordisk announced as part of the 2016 full-year results in February 2017 that a class II re-submission for fast-acting insulin aspart was expected within the next three months.

About Novo Nordisk

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: haemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 42,000 people in 77 countries and markets its products in more than 165 countries. For more information, visit novonordisk.com, [Facebook](#), [Twitter](#), [LinkedIn](#), [YouTube](#)

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This medicine is subject to additional monitoring. Healthcare professionals and patients should report any suspected adverse events due to use of this medicinal product.

* Fiasp[®] has been approved by the European Commission for CSII (insulin pump) use.

† Fiasp[®] is not approved for insulin pump use in Canada.

* Information provided about Fiasp[®] is based on the marketing authorisation received from the European Commission and these details may vary in individual markets.