

press release

New fast-acting mealtime insulin, Fiasp[®], now approved and available in Canada for the treatment of diabetes

Faster absorption of insulin key for Canadians living with diabetes

MISSISSAUGA, ON, March 27, 2017 – Today, Novo Nordisk Canada Inc. announced that Fiasp[®] (insulin aspart), a faster acting mealtime insulin, is now approved and available in Canada, giving Canadians living with diabetes a new treatment option for achieving optimal mealtime glucose control.^{1,2}

Approximately 11 million Canadians live with diabetes or prediabetes and that number is set to increase to more than 13 million by 2026.³ Diabetes can lead to serious complications if left untreated or improperly managed, including heart attack, stroke, kidney failure, blindness and amputation.⁴

Achieving optimal glycemic control is recommended by Diabetes Canada to reduce the incidence and slow the progression of diabetes-related complications.⁵ Yet, limiting postprandial (post-meal) glycemic (PPG) excursions has been one of the most challenging aspects in achieving adequate glycemic control.⁶

Fiasp[®] is an innovative formulation of insulin aspart that more closely matches the natural physiological insulin response of a person without diabetes, after a meal, compared with NovoRapid[®] (conventional insulin aspart).⁷ Fiasp[®] also has the option of a flexible dosing regimen (up to two minutes before a meal and up to 20 minutes after starting a meal), without compromising overall glycemic control or safety.^{1,8}

“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[®] 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 hyperglycemia, for instance, a condition that can cause serious complications for people living with diabetes.”

Fiasp[®] is absorbed faster than NovoRapid[®] (conventional insulin aspart), appearing twice as fast in the bloodstream after injection,^{8,ix} which leads to improved glycemic control after a meal.^{1,x}

In clinical trials, Fiasp[®] demonstrated improved overall glycemic control in type 1 diabetes and comparable overall glycemic control in type 2 diabetes, versus NovoRapid[®].^{1,x} Results also showed improved mealtime glucose control in type 1 and type 2 diabetes.^{1,x} This was achieved without a significant difference in the overall rate of severe or confirmed hypoglycemia compared with NovoRapid[®].^{1,x}

“Novo Nordisk is committed to helping people living with diabetes better manage their disease, and in preventing complications that could have a detrimental impact on their health and quality of life,” said Brian Hilberdink, President, Novo Nordisk Canada Inc. “We are continuously researching innovative solutions to improve diabetes management and address critical unmet needs. We are pleased to be able to offer a new solution with the launch of Fiasp[®], one that supports people with diabetes in achieving optimal mealtime glucose control, particularly in an area that is in need of more innovative advancements.”

About Fiasp[®]

Fiasp[®] is a new, faster acting mealtime insulin, developed by Novo Nordisk with the objective of achieving a faster initial absorption, to improve glycemic control after a meal, in people with type 1 and type 2 diabetes.^{1,2} Fiasp[®] is insulin aspart, a molecule with more than 17 years of clinical experience,^{xi} 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 stability.⁹

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

Fiasp[®] was approved by Health Canada on January 6, 2017 for the treatment of adult patients with diabetes mellitus who require mealtime insulin for the control of hyperglycemia.² Fiasp[®] received marketing authorization from the European Commission on January 9, 2017. It is currently under regulatory review in Switzerland, Australia, Brazil, South Africa and Argentina.

About Novo Nordisk Canada Inc.

Novo Nordisk Canada Inc. is an affiliate of Novo Nordisk A/S, 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: hemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 42,600 employees in 75 countries, and markets its products in more than 180 countries.

Novo Nordisk's company history has deep Canadian roots, with company founders Marie and August Krogh traveling to Toronto in 1922 to meet with Banting, Best, Collip and MacLeod to discuss the insulin preparation. Novo Nordisk would become the first company in Europe to produce insulin in 1923.

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*Onset[®] 1 - Efficacy and Safety of FIASp Compared to Insulin Aspart Both in Combination with Insulin Detemir in Adults with Type 1 Diabetes

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