

press release

Health Canada approves fast-acting mealtime insulin, Fiasp®, for children with diabetes

Health Canada also expands Fiasp® approval to include insulin infusion pumps

MISSISSAUGA, ON – March 9, 2020 - Fiasp® (insulin aspart injection), a faster acting mealtime insulin, is now approved in Canada for pediatric patients aged 2 years and above giving Canadian families managing type 1 or type 2 diabetes an effective treatment option to support optimal mealtime glucose control.¹ Health Canada has also expanded the approval of Fiasp® (10 mL vials) to include use in insulin infusion pumps for the improvement of glycemic control.



Fiasp® (insulin aspart injection) product image courtesy of Novo Nordisk Canada Inc.

Diabetes is one of the most common chronic diseases among children and youth.² Managing diabetes can be challenging for parents and caregivers given it is hard to know exactly how much or how quickly their children will eat, making mealtime insulin dosing difficult.^{3,4,5} Missed meals, illness and increased physical activity without a corresponding reduction in insulin or increase in carbohydrate consumption can lead to significant diabetes management complications for children.⁶

“Children living with diabetes face significant challenges in managing their disease. Just being a kid and factoring common daily events like mealtime, school, travel, activities, play and sick days can dramatically impact hyperglycaemia and hypoglycaemia,” said Dr. Karen McAssey, Pediatric Endocrinologist at McMaster Children’s Hospital. “As a clinician

who treats pediatric diabetes patients daily, it's essential to have effective, fast-acting mealtime insulin options to support optimal disease management and care."

Fiasp® for adult and pediatric type one and type two diabetes management -

First approved by Health Canada in January 2017 for the treatment of adult patients, Fiasp® is absorbed faster than conventional insulin aspart (e.g. NovoRapid®) appearing twice as fast in the bloodstream after injection,⁷ which leads to improved glycemic control after a meal.^{8,9} Fiasp® is now indicated for treatment of adult and pediatric patients (>2 years old) with diabetes mellitus who require mealtime insulin for the control of hyperglycemia.¹⁰

Fiasp® pump use - Fiasp® (10 mL vials) may now be used for continuous subcutaneous insulin infusion (CSII) in pump systems that are licensed in Canada for insulin infusion. An insulin pump may provide greater lifestyle flexibility and convenience particularly with regards to meal schedules and travel. Both CSII and multiple daily insulin injection therapy are effective means of implementing intensive diabetes management with the goal of achieving near-normal levels of blood glucose and improved lifestyle flexibility. Use Fiasp® in accordance with the insulin infusion pumps' instructions for use. Patients should be trained on using continuous subcutaneous insulin infusion pump therapy and to administer insulin by injection with alternate insulin therapy available in case of pump failure. Refer to the insulin infusion pump manufacturers' user manual to see if Fiasp® can be used.¹¹

"We welcome the pediatric approval of Fiasp® for younger Canadians, providing greater choice for effective disease management to support easier, healthier and safer lives for young people with type 1 diabetes," said Dave Prowten, President and CEO of JDRF Canada.

The approval of Fiasp® in pediatric patients is based on Health Canada's review of data from the onset 7 clinical trial, which confirmed the efficacy and safety of Fiasp® in children.¹² The label change for use in insulin infusion pumps is based on Health Canada's review of data from the onset 5 clinical trial, which confirmed the efficacy and safety of Fiasp® when used in insulin infusion pumps in adults with diabetes. The pump should be programmed based on guidance from healthcare providers and the pump maker's instructions.¹³

"At Novo Nordisk, we are continuously researching innovative solutions to improve diabetes management and address critical unmet needs," said Vicky Chan, Vice President, Clinical Development, Medical and Regulatory Affairs, Novo Nordisk Canada Inc. "We are pleased to offer Fiasp® – a trusted and effective mealtime glucose control treatment – to the pediatric diabetes community in Canada allowing for choice and convenience in supporting diabetes management goals."

About Fiasp®

Fiasp® is a rapid 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.¹⁴ Fiasp® is insulin aspart, a molecule with more

than 20 years of clinical experience,¹⁵ 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.¹⁶

Low blood sugar is the most common adverse effect of insulin products, including Fiasp®. If low blood sugar or high blood sugar reactions are not treated, they can cause loss of consciousness, coma or even death. Blood sugar levels should be monitored for all patients with diabetes.¹⁷

About Novo Nordisk

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines and working to prevent and ultimately cure disease. Novo Nordisk employs about 42,700 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.ca, [Twitter](#), or [YouTube](#).

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