

# press release

## Health Canada approves Saxenda® (liraglutide injection) for the treatment of obesity in adolescents aged 12- <18

**Expands indication for Saxenda®, already approved for adult weight management in Canada since 2015**

**MISSISSAUGA, ON, March 1, 2021** - Health Canada has approved a new indication for Saxenda® (liraglutide injection) for use in the treatment of obesity in adolescents (12- <18 years).<sup>1</sup> Saxenda® was first approved in 2015 for chronic weight management in adults.<sup>2</sup>

Saxenda® is now indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in pediatric patients aged 12 to less than 18 years with:

- an inadequate response to reduced calorie diet and increased physical activity alone, and
- a body weight above 60 kg (132 lbs), and
- an initial body mass index (BMI) corresponding to  $\geq 30$  kg/m<sup>2</sup> for adults (obesity) by international cut-offs.<sup>3</sup>

Over the last 30 years, obesity rates amongst children and youth in Canada have nearly tripled, and children and youth living with obesity have a high probability of remaining obese in adulthood.<sup>4</sup> However, current treatment options for this population are limited, highlighting a considerable and growing need for additional treatment strategies.<sup>5</sup>

The safety and efficacy of Saxenda® as a treatment for adolescents with obesity is supported by data from a phase 3a trial published earlier this year in the *New England Journal of Medicine*. The 56-week clinical trial investigated the effects of Saxenda® compared to placebo for weight management in 251 patients aged 12-17 living with obesity as an adjunct to lifestyle therapy, defined as counselling in healthy nutrition and physical activity for weight loss. In the trial, the primary endpoint was change from baseline in Body Mass Index (BMI) Standard Deviation Score (SDS) at week 56.<sup>6</sup>

### About Obesity

Obesity is a chronic condition that is associated with serious comorbidities including hypertension, type 2 diabetes mellitus, dyslipidemia, certain types of cancer and a decreased life expectancy. The risk of morbidity and mortality increases with the severity of obesity. It is a complex and multi-factorial disease that is influenced by genetic, physiological, environmental and psychological factors.<sup>7</sup> Just like other chronic diseases, obesity requires long-term management.<sup>8</sup>

The global increase in the prevalence of obesity is a public health issue that has severe cost implications to healthcare systems. Today, over seven million Canadian adults have obesity<sup>9</sup> and 30 per cent, or more than one in three adults, has obesity and may require medical support to manage their disease.<sup>10</sup>

### **About Adolescent Obesity**

Adolescents with obesity are also more likely to develop weight-related diseases, like diabetes and cardiovascular diseases, at a younger age.<sup>11</sup> Research shows that when both parents have excess weight, about 80 per cent of their children will have obesity.<sup>12</sup> Globally, more than 124 million children and adolescents have obesity.<sup>17</sup> In Canada over 12 per cent of children and youth are overweight or obese.<sup>13</sup>

### **About Saxenda®**

Saxenda® (liraglutide injection) is a once-daily glucagon-like peptide-1 (GLP-1) analogue with 97 per cent similarity to naturally occurring human GLP-1, a hormone that is released in response to food intake. Like human GLP-1, Saxenda® regulates appetite and lowers body weight through decreased food intake. As with other GLP-1 receptor agonists, liraglutide stimulates insulin secretion and reduces glucagon secretion in a glucose-dependent manner. These effects can lead to a reduction of blood glucose.<sup>14</sup>

Saxenda® was previously approved by Health Canada in 2015 for chronic weight management in adults with a BMI  $\geq 30$  kg/m<sup>2</sup>, or  $\geq 27$  kg/m<sup>2</sup> with one or more weight-related comorbidities, as an adjunct to a reduced-calorie diet and increased physical activity.<sup>15</sup>

Since launch in 2015, more than 1.5 million patients have been treated with Saxenda® globally.<sup>16</sup>

### **About the Phase 3 Trial**

The trial investigated the effect of Saxenda® (liraglutide 3.0 mg or maximum tolerated dose) compared to placebo for weight management in 251 adolescents (aged 12 to <18 years) living with obesity as an adjunct to lifestyle therapy.<sup>17</sup> The trial included a 12-week run-in period of lifestyle therapy, a 56-week treatment period (including dose escalation over 4 to 8 weeks) on Saxenda® or placebo and a 26-week follow-up period without Saxenda® or placebo.<sup>18</sup> All participants received lifestyle therapy beginning with the run-in period and during the 56-week treatment period and 26-week follow-up period.<sup>19</sup>

The data demonstrated a significant reduction in BMI-SDS, as well as reductions in BMI, mean body weight, and other weight-related endpoints vs. placebo in adolescents with obesity when using Saxenda® as an adjunct to lifestyle therapy. Adverse events seen in an adolescent population were similar to those observed in adults. The most common adverse reactions were gastrointestinal events, including nausea, vomiting and diarrhea.<sup>20</sup>

### **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 45,000 people in 80 countries and markets its products in around 170 countries. For more information, visit [novonordisk.ca](http://novonordisk.ca).

Further information: Amy Snow, 647-202-8208, [easw@novonordisk.com](mailto:easw@novonordisk.com).

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## Further information

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<sup>1</sup> Saxenda® (liraglutide), Novo Nordisk Canada Inc., Product Monograph, 26 February 2021

<sup>2</sup> Saxenda® (liraglutide), Novo Nordisk Canada Inc., Product Monograph, 26 February 2021

<sup>3</sup> Saxenda® (liraglutide), Novo Nordisk Canada Inc., Product Monograph, 26 February 2021

<sup>4</sup> Health Canada. Childhood obesity. 22 January 2019. Available at: <https://www.canada.ca/en/public-health/services/childhood-obesity/childhood-obesity.html>. Last accessed: February 2021

<sup>5</sup> Cardel M, Jastreboff A, Kelly A. Treatment of Adolescent Obesity in 2020. *JAMA*. 2019; 322:1707–1708.

<sup>6</sup> Kelly A, Auerbach P, Barrientos-Perez M. A Randomized, Controlled Trial of Liraglutide for Adolescents with Obesity. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMoa1916038>. *NEJM*. 2020;DOI: 10.1056/NEJMoa1916038

<sup>7</sup> Multimorbidity in a prospective cohort: Prevalence and associations with weight loss and health status in severely obese patients. *Obesity (Silver Spring)*. 2015 Mar;23(3):707-12. doi: 10.1002/oby.21008. Epub 2015 Feb 13. Accessed February 24, 2021

<sup>8</sup> Wharton et al. Obesity in adults: a clinical practice guideline. *CMAJ*. 2020 August 4; 192:E875-91. doi: 10.1503/cmaj.191707. Available at: <https://www.cmaj.ca/content/cmaj/192/31/E875.full.pdf>

<sup>9</sup> Statistics Canada. (2019). Overweight and obese adults, 2018.

<sup>10</sup> Obesity in Canada. Obesity Canada. <https://obesitycanada.ca/obesity-in-canada/>. Accessed July 13, 2020.

<sup>11</sup> World Health Organization. Childhood overweight and obesity. Available at: <https://www.who.int/dietphysicalactivity/childhood/en/>. Last accessed: February 2021

<sup>12</sup> Lifshitz F. Obesity in Children. *J Clin Res Pediatr Endocrinol*. 2008 Dec; 1(2): 53–60

<sup>13</sup> Pan-Canadian Public Health Network. Towards a Healthier Canada - 2015 Progress Report on Advancing the Federal / Provincial / Territorial Framework on Healthy Weights. 22 January 2016. <http://www.phn-rsp.ca/thcpr-vcpsre-2015/index-eng.php>. Last accessed: February 2021

<sup>14</sup> Saxenda® (liraglutide), Novo Nordisk Canada Inc., Product Monograph, 26 February 2021

<sup>15</sup> Saxenda® (liraglutide), Novo Nordisk Canada Inc., Product Monograph, 26 February 2021

<sup>16</sup> Novo Nordisk. Data on File.

<sup>17</sup> Kelly A, Auerbach P, Barrientos-Perez M. A Randomized, Controlled Trial of Liraglutide for Adolescents with Obesity. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMoa1916038>. *NEJM*. 2020;DOI: 10.1056/NEJMoa1916038

<sup>18</sup> Kelly A, Auerbach P, Barrientos-Perez M. A Randomized, Controlled Trial of Liraglutide for Adolescents with Obesity. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMoa1916038>. *NEJM*. 2020;DOI: 10.1056/NEJMoa1916038

<sup>19</sup> Kelly A, Auerbach P, Barrientos-Perez M. A Randomized, Controlled Trial of Liraglutide for Adolescents with Obesity. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMoa1916038>. *NEJM*. 2020;DOI: 10.1056/NEJMoa1916038

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<sup>20</sup> Kelly A, Auerbach P, Barrientos-Perez M. A Randomized, Controlled Trial of Liraglutide for Adolescents with Obesity. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMoa1916038>. *NEJM*. 2020;DOI: 10.1056/NEJMoa1916038