

press release

Xultophy® approved in Canada for the treatment of adults with type 2 diabetes

Once-daily Xultophy® has been shown to help patients achieve blood glucose targets

Mississauga, April 18, 2018 — Novo Nordisk announced today that Health Canada has approved Xultophy® as an adjunct to lifestyle modifications, for the once-daily treatment of adults with type 2 diabetes mellitus to improve glycemic control in combination with metformin, with or without sulfonylurea, when these combined with basal insulin (less than 50 units daily) or liraglutide (less than or equal to 1.8 mg daily), do not provide adequate glycemic control.¹

“Living with diabetes is a complex situation in itself especially for people requiring insulin therapy. Therefore, treatment options should ideally aim to reduce complexity,” says Dr. Stewart Harris, Clinical Diabetologist and Professor at the Schulich School of Medicine and Dentistry at Western University in London, Ontario. “Xultophy®, a new insulin combination treatment therapy, not only helps people with type 2 diabetes optimize their blood glucose targets, studies have also demonstrated the added benefits of a lower risk of hypoglycemia and potential weight loss when compared to other insulin intensification approaches where hypoglycemia and weight gain poses a significant clinical barrier to successful blood glucose control. Xultophy® does this in a simple, once-daily injection using a pre-filled pen.”

Xultophy® (insulin degludec + liraglutide injection) is a fixed-ratio combination of a long-acting basal insulin (Tresiba®/insulin degludec) and a glucagon-like peptide 1 receptor agonist (GLP-1 RA) (liraglutide), in a once-daily injection. Xultophy® can be taken independent of meals, at any time of day – preferably at the same time of the day.¹

“Insulin is, and has been, the mainstay for treating patients with longstanding type 2 diabetes,” says Dr. Jan Hux, President and Chief Science Officer of Diabetes Canada. “But insulin carries the risk of causing dangerously low blood glucose levels. When insulin is used in combination with other medications that don’t carry a risk of low blood sugar levels, it can help patients with type 2 diabetes reach their blood glucose targets more safely and with less insulin than they would otherwise need.”

About the DUAL™ Clinical Development Program

The approval of Xultophy® is based on efficacy and safety data from the DUAL™ (Dual Action of Liraglutide and Insulin Degludec in Type 2 Diabetes) clinical development program. In three DUAL™ trials involving 1,393 adults with type 2 diabetes, patients who were inadequately controlled on liraglutide or basal insulin therapy and switched to Xultophy® achieved significant reductions in HbA_{1c}.¹ For adults uncontrolled on basal insulin, Xultophy® demonstrated reductions in HbA_{1c} from baseline of 1.81 per cent (vs insulin glargine) and 1.90 per cent (vs basal insulin therapies).¹

The most frequently reported adverse reactions during treatment with Xultophy® were hypoglycemia and gastrointestinal adverse reactions, of which nausea was the most frequently reported and declined as treatment continued.¹

About Xultophy®

Xultophy® is a once-daily single injection fixed-ratio combination of long-acting insulin degludec and the GLP-1RA liraglutide in one pen.

Insulin degludec lowers blood glucose by facilitating glucose uptake upon binding to insulin receptors on muscle and fat cells and simultaneously inhibiting hepatic glucose output.¹ Liraglutide stimulates insulin secretion and decreases glucagon secretion in a glucose-dependent manner.¹

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 obesity, hemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 41,700 people in 77 countries and markets its products in more than 165 countries. For more information, visit novonordisk.ca, [Twitter](#), [YouTube](#).

Further information

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References

¹ Xultophy® Product Monograph. Novo Nordisk Canada Inc. April 11, 2018.