



press release

Ozempic® (semaglutide) A New Once-Weekly GLP-1¹ Now Available and Reimbursed in Australia for People Living with Type 2 Diabetes

SYDNEY, 1ST JULY 2020 - Today, Novo Nordisk announced that Ozempic® (semaglutide), a new once-weekly GLP-1 analogue¹, will now be available and reimbursed by the Pharmaceutical Benefits Scheme (PBS), for the treatment of people with insufficiently controlled type 2 diabetes.

GLP-1 RAs, such as Ozempic®, have been recommended by the Australian Diabetes Society (ADS) for early use, after metformin to help people living with type 2 diabetes to achieve their target HbA1c.² These follow international guidelines that also recommend early use after metformin and recognise the multiple benefits that GLP-1 RAs have shown in managing type 2 diabetes including glycaemic control, weight gain and cardiovascular risk.^{3,4,5}

"Type 2 diabetes is one of the fastest growing chronic conditions in Australia⁶, driven largely by the rise in overweight and obesity⁷. Alarming, we know that less than 50% of Australian's diagnosed with type 2 diabetes, and receiving treatment, meet the HbA1c target of $\leq 7.0\%$.⁶ The PBS listing of, Ozempic®, gives us another treatment option and new opportunity to further help our patients with type 2 diabetes to achieve their blood glucose and body weight treatment targets," said Associate Professor Neale Cohen, Endocrinologist.

The launch and reimbursement of Ozempic® follows extensive clinical research conducted globally, with 400 of the global patients enrolled in Australia as part of Novo Nordisk's extensive and on-going local clinical research programmes. Ozempic® is a small,⁸ novel GLP-1 molecule with 94% homology to human GLP-1. Once weekly Ozempic® is available in two pre-filled multi dose pens, allowing for slow dose escalation. Each pen contains at least one month's supply of medication, together with needles for weekly administration¹.

The comprehensive SUSTAIN clinical trial program, with 6 phase 3a clinical trials, demonstrated in patients with type 2 diabetes treated with Ozempic® 1 mg/week in addition to anti-diabetic therapy:

- Up to 8/10 patients achieved HbA1c target $< 7\%$ ^{1,9-18}
- Up to 2/3 patients achieved weight loss $\geq 5\%$ ^{1,9-18}
- Safety and tolerability was comparable to other once-weekly GLP-1 RAs.^{10,11}

"The COVID-19 pandemic has highlighted the scale of the problem of chronic diseases like diabetes, and the urgent need for a renewed commitment to tackle them and avoid complications. Our purpose to drive change to defeat diabetes is necessary now more than ever. At Novo Nordisk, we aim to redefine success in diabetes management and believe targeting uncontrolled HbA1c and cardiovascular risk factors including weight and blood pressure is a step forward. The availability of Ozempic®, reimbursed by the PBS, reinforces our commitment to continuing to address the growing impact of diabetes with ongoing innovation," said Jeppe Theisen, Vice President and Managing Director Novo Nordisk Oceania.

PBS information: Authority Required (STREAMLINED). Type 2 Diabetes. Criteria Apply. Refer to PBS Schedule for full Authority Required Information. Available at: www.pbs.gov.au/pbs/home

Please review product information before prescribing. Full product information can be accessed at: www.novonordisk.com.au/healthcare-professionals.html

Ozempic® (semaglutide solution for injection) Minimum Product Information

Indications: treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise: (i) as monotherapy when metformin is not tolerated or contraindicated; (ii) in addition to other medicinal products for the treatment of type 2 diabetes. **Dosage and Administration:** Administered subcutaneously once-weekly on the same day each week, at any time of the day, with or without meals. Must not be administered intravenously or intramuscularly. Starting dose is 0.25 mg/week for 4 weeks, increasing to 0.5 mg/week. Can be increased to 1 mg/week to further improve glycaemic control. To reduce the risk of hypoglycaemia when used in combination with sulfonylurea (SU) or insulin, consider reducing the dose of SU or insulin. Has not been studied in children (<18 years). **Contraindications:** Hypersensitivity to semaglutide or excipients.

Precautions: Do not use for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. Not a substitute for insulin. Patients experiencing gastrointestinal side effects should take precautions to avoid dehydration. If pancreatitis is suspected, discontinue Ozempic®; if acute pancreatitis is confirmed, Ozempic® should not be restarted. Possible increased risk of hypoglycaemia in combination with SUs or insulin. Use with caution in patients with diabetic retinopathy treated with insulin. Not recommended in patients with: NYHA class IV congestive heart failure; end-stage renal impairment. Pregnancy Category D. Discontinue use during pregnancy and breast-feeding. **Interactions:** Use with caution in combination with oral medications requiring rapid gastrointestinal absorption. **Adverse Effects:** *Very common (≥10%):* Nausea and diarrhoea, hypoglycaemia in combination with SU or insulin. *Common (≥1 to <10%):* vomiting, abdominal pain, abdominal distension, constipation, dyspepsia, gastritis, gastroesophageal reflux disease, eructation, flatulence, hypoglycaemia in combination with OADs, decreased appetite, dizziness, fatigue, diabetic retinopathy complications, cholelithiasis, increased lipase, increased amylase, weight loss. (Oct 2019)

For information on Novo Nordisk products or to report an adverse event involving a Novo Nordisk product, please contact NovoCare Customer Care Centre on 1800 668 626 (freecall) or by email at: aunrccc@novonordisk.com

Disclosure

Associate Professor Neale Cohen has served on advisory boards and provided medical education to healthcare professionals sponsored by Novo Nordisk, for which compensation was received. In relation to this Novo Nordisk media announcement, no compensation was provided to Associate Professor Neale Cohen, and the opinions expressed are their own. Associate Professor Neale Cohen has been briefed by Novo Nordisk on the approved use of this product.

-ENDS-

About Ozempic® (Semaglutide)

Ozempic® (once-weekly semaglutide) is an analogue of the naturally occurring hormone glucagon-like peptide-1 (GLP-1). It is administered in a once-weekly injection, in two prefilled multi-dose pens, to allow dose escalation monthly from 0.25mg to 0.5mg and 1.0mg.¹

It is indicated for the treatment of patients with type 2 diabetes mellitus who have inadequate glycaemic control¹⁹:

- as dual therapy in combination with metformin or a sulfonylurea where either of these is contraindicated or not tolerated;
- triple therapy in combination with metformin and a sulfonylurea

About the SUSTAIN clinical trial program^{1,9-18}

The efficacy and safety of Ozempic® 0.5mg and 1mg once-weekly were evaluated in eight randomised controlled phase 3a trials and four randomised controlled phase 3b trials, with all of these with glycaemic efficacy assessment as the primary objective. A cardiovascular outcomes trial (CVOT) has also been conducted (SUSTAIN 6) with cardiovascular outcome as the primary objective.

The trials included in total 8,124 randomised patients with type 2 diabetes (4,792 treated with semaglutide). An additional trial including 1,201 patients was conducted to compare the efficacy and safety of Ozempic® 0.5mg and 1mg once-weekly versus dulaglutide 0.75mg and 1.5mg once-weekly, respectively. Treatment with Ozempic® demonstrated statistically significant and clinically meaningful reductions in HbA1c and body weight maintained for up to 2 years compared to placebo and active control treatment (sitagliptin, insulin glargine, exenatide ER and dulaglutide).

The efficacy of Ozempic® was not impacted by age, gender, race, ethnicity, BMI at baseline, body weight (kg) at baseline, diabetes duration and level of renal function impairment.

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 43,100 people in 80 countries and markets its products in around 170 countries.

For more information, visit [novonordisk.com](https://www.novonordisk.com), [Facebook](#), [Twitter](#), [LinkedIn](#), [YouTube](#)

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Glossary

GLP-1RA: Glucagon-like-peptide-1 receptor agonist

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