



## MEDIA RELEASE

**TRULICITY® (dulaglutide) is now indicated in adults with type 2 diabetes to reduce the risk of Major Adverse Cardiovascular Events (MACE) in patients with multiple risk factors for, or established, cardiovascular disease.<sup>1</sup>**

**12 August 2020, Sydney** – Eli Lilly Australia welcomes the Therapeutic Goods Administration's (TGA) acceptance of the expanded label indication for TRULICITY® (dulaglutide). Trulicity is now indicated as an adjunct to standard care to reduce the risk of MACE events (*cardiovascular death, non-fatal myocardial infarction, non-fatal stroke*) in adults with type 2 diabetes and multiple risk factors for, or, established cardiovascular (CV) disease.

In Australia, diabetes affects the health of at least 1.5 million people. Type 2 diabetes, a progressive condition where the body becomes resistant to the normal effects of insulin and/or gradually loses the capacity to produce enough insulin, accounts for 85-90 per cent of all cases<sup>2</sup>.

*"The burden of cardiovascular disease among people with type 2 diabetes is substantial"* notes Professor Jonathan Shaw, Deputy Director (Clinical and Population Health) at Melbourne's Baker Heart and Diabetes Institute.

*"Diabetes is a leading cause of preventable cardiovascular disease, and an independent risk factor for all manifestations of the disease. In particular, people with type 2 diabetes have higher risk of stroke, myocardial infarction, and sudden cardiac death. Studies show that 30-40% people with type 2 diabetes will die of cardiovascular disease"* he added.

The new indication reflects the differentiated patient population of REWIND<sup>3</sup>, the Trulicity® CV outcomes trial. While all participants had cardiovascular risk factors, the study consisted primarily of people without established CV disease. REWIND showed a significant reduction in risk of MACE, a composite endpoint of nonfatal myocardial infarction (heart attack), nonfatal stroke or CV death. Results demonstrated consistent MACE risk reduction with Trulicity across major demographic and disease subgroups. Trulicity's safety profile was consistent with the GLP-1 receptor agonist (RA) class<sup>1,3</sup>. The most common adverse events reported in the study were gastrointestinal events<sup>1</sup>.

Professor Shaw, the Lead Investigator of the REWIND<sup>3</sup> study in Australia further clarified: *"This trial was designed to study a broad population of people living with type 2 diabetes, reflective of those in the general population. We therefore assessed the effect of Trulicity in people with established cardiovascular disease as well as those with multiple cardiovascular risk factors."*

Professor Shaw added *"Just under a third of people with type 2 diabetes have established cardiovascular disease."*

Benjamin L. Basil, General Manager Australia & New Zealand, added, *"Lilly is dedicated to improving the lives of people living with type 2 diabetes. We introduced the world's first commercially available insulin product for the treatment of diabetes- then a fatal disease with no effective treatment options. We are continuing to help make life better for people living with type 2 diabetes."*

TRULICITY is available as a single dose, ready-to-use pre-filled pen containing dulaglutide 1.5mg per 0.5ml. Patients do not need to mix or measure the dose. TRULICITY can be administered any time of the day, with or without food<sup>4</sup>.

PBS Information: Authority Required (STREAMLINED). Type 2 diabetes. Criteria Apply. Refer to PBS Schedule for full Authority Required Information.

## TRULICITY (dulaglutide) MINIMUM PRODUCT INFORMATION

**INDICATIONS** – TRULICITY is indicated for adult patients with Type 2 diabetes as 1) an adjunct to diet and exercise to improve glycaemic control; and 2) as an adjunct to standard of care therapy to reduce the risk of major adverse cardiovascular events in those with either established cardiovascular disease or multiple risk factors for cardiovascular disease. **CONTRAINDICATIONS** – Hypersensitivity to dulaglutide or any of the excipients. **PRECAUTIONS** – should not be used in patients with Type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis; severe gastrointestinal disease – not recommended; acute pancreatitis – discontinue treatment if suspected; hypoglycaemia – combining treatment with sulfonylurea or insulin may increase risk; congestive heart failure – limited therapeutic experience; carcinogenicity – caused statistically significant dose-related increases in the incidence of thyroid C-cell tumours in rats, however, the human relevance of these findings is unknown. Use in Pregnancy Category B3. **ADVERSE EFFECTS** Clinical Trials Experience – Very Common ( $\geq 10\%$ ) gastrointestinal disorders (nausea, vomiting and diarrhoea), hypoglycaemia (in combination with insulin non-/secretagogues and/or insulin); Common ( $\geq 1$  and  $< 10\%$ ) abdominal pain, decreased appetite, dyspepsia, fatigue, hypoglycaemia (as monotherapy), immunogenicity. **DOSAGE AND ADMINISTRATION** – Dosage: Adults ( $\geq 18$  years): 1.5 mg once weekly, at any time of day, independently of meals. Elderly Patients ( $\geq 65$  years): dose adjustment not required. Children and adolescents ( $< 18$  years): safety and effectiveness have not been established. Renal Impairment: no dose adjustment is required in mild, moderate or severe renal impairment; not recommended in end-stage renal disease. Hepatic Impairment: no dose adjustment required. Administration: subcutaneous injection in the abdomen, thigh or upper arm. Should not be administered intravenously or intramuscularly. Single-use in one patient only. Discard the pen once the injection is completed. Please review full PI before prescribing. Full PI is available on request from Eli Lilly. Eli Lilly Australia Pty Ltd, 112 Wharf Road, West Ryde NSW 2114. Phone 1800 454 559. Based on PI approved 14 July 2020.

Trulicity (dulaglutide) Consumer Medicine Information-

<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2018-CMI-01316-1&d=202008051016933>

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### About Lilly

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give

back to communities through philanthropy and volunteering. Since its founding, Lilly has pioneered major breakthroughs like insulin and the polio vaccine, and has worked to make sure these discoveries reach the people around the world who need them most. For more information, visit: [www.lilly.com.au](http://www.lilly.com.au)

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PP-DG-AU-0442. Date of preparation: 06 August 2020.

### **References**

1. Trulicity (dulaglutide) Approved Product Information. 14 July 2020. (Available at: [tga.gov.au](http://tga.gov.au))
2. Diabetes Australia, 2015. Type 2 Diabetes. Available at: <https://www.diabetesaustralia.com.au/type-2-diabetes> [Accessed July 2020].
3. Gerstein HC *et al.* *Lancet* 2019;394:121–30.
4. Trulicity (dulaglutide) Consumer Medicine Information. July 2020 (Available at: [tga.gov.au](http://tga.gov.au))