TRULICITY® (dulaglutide) PRESCRIBING INFORMATION

United Kingdom (Great Britain)

Presentation Dulaglutide solution for injection in a pre-filled pen. Each single-use pen contains either 0.75 mg, 1.5 mg, 3 mg or 4.5 mg of dulaglutide in 0.5 ml solution. **Uses** Dulaglutide is indicated for the treatment of patients 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise, as monotherapy when metformin is inappropriate due to intolerance or contraindications, or in addition to other medicinal products for the treatment of diabetes. **Dosage and Administration** *Adults: Monotherapy:* Recommended dose 0.75 mg once weekly. *Add-on therapy:* Recommended dose 1.5 mg once weekly. If needed: The 1.5 mg dose can be increased after at least 4 weeks to 3 mg once weekly. The 3 mg dose can be increased after at least 4 weeks to 4.5 mg once weekly. The maximum dose is 4.5 mg once weekly. *Paediatrics:* The starting dose for paediatric patients 10 years and above is 0.75 mg once weekly. If needed, the dose can be increased to 1.5 mg once weekly after at least 4 weeks. The maximum dose is 1.5 mg once weekly. Trulicity is administered as a subcutaneous injection in the abdomen, thigh, or upper arm. It should not be administered intravenously or intramuscularly. The dose can be administered at any time of day, with or without meals. When Trulicity is added to existing metformin and/or pioglitazone therapy, the current dose of metformin and/or pioglitazone can be continued. When Trulicity is added to existing metformin and/ or sodium-glucose co-transporter 2 inhibitor (SGLT2i) therapy, the current dose of metformin and/or SGLT2i can be continued. When it is added to existing sulphonylurea or insulin therapy, a reduction in the dose of sulphonylurea or insulin may be considered to reduce the risk of hypoglycaemia. Blood glucose self-monitoring is necessary to adjust the dose of sulphonylurea or insulin, particularly when Trulicity therapy is started and insulin is reduced. A stepwise approach to insulin dose reduction is recommended. *Elderly:* No dose adjustment is required based on age. *Renal impairment:* No dose adjustment is required in mild, moderate or severe renal impairment (eGFR < 90 to ≥ 15 mL/min/1.73 m^2). Not recommended in end stage renal disease (< 15 mL/min/1.73 m^2). *Hepatic impairment:* No dose adjustment is required. *Paediatrics:* The safety and efficacy of dulaglutide in children < 10 years have not been established and no data are available. **Contraindications** Hypersensitivity to the active substance or to any of the excipients. **Warnings and Special Precautions** Traceability: In order to improve the traceability of biological medicinal products, the name and the batch number of the administered medicinal product should be clearly recorded. Dulaglutide should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Dulaglutide is not a substitute for insulin. Diabetic ketoacidosis has been reported in insulin-dependent patients after rapid discontinuation or dose reduction of insulin. Not recommended in patients with severe gastrointestinal disease, including severe gastroparesis. Dehydration, sometimes leading to acute renal failure or worsening renal impairment, has been reported in patients treated with dulaglutide, especially at the initiation of treatment. Many of the reported adverse renal events occurred in patients who had experienced nausea, vomiting, diarrhoea, or dehydration. Patients treated with dulaglutide should be advised of the potential risk of dehydration, particularly in relation to gastrointestinal adverse reactions and take precautions to avoid fluid depletion. In clinical trials and the post-marketing setting, acute pancreatitis has been reported in association with dulaglutide. Patients should be informed of the characteristic symptoms of acute pancreatitis. If pancreatitis is suspected, dulaglutide should be discontinued. If pancreatitis is confirmed, dulaglutide should not be restarted. Use of dulaglutide in combination with a sulphonylurea or insulin may increase the risk of hypoglycaemia. The risk of hypoglycaemia may be lowered by a reduction in the dose of sulphonylurea or insulin. Trulicity is essentially sodium-free (< 1mmol sodium (23 mg) per dose). **Interactions** Dulaglutide delays gastric emptying. For patients receiving dulaglutide in combination with oral medicinal products with rapid gastrointestinal absorption or prolonged release, there is a potential for altered medicinal product exposure, particularly at the time of dulaglutide treatment initiation. In the clinical pharmacology studies, dulaglutide doses up to 1.5 mg did not affect the absorption of the orally administered medicinal products tested to any clinically relevant degree. No dose adjustments of paracetamol, atorvastatin, digoxin, lisinopril, metoprolol, warfarin, oral contraceptives, or metformin (immediate release formula) are required when given together with dulaglutide 1.5 mg. For the 4.5 mg dose, absence of major clinically relevant interactions was predicted by physiologically-based pharmacokinetic (PBPK) modelling simulations. For further details of these interaction studies, please see the Summary of Product Characteristics. **Fertility, pregnancy and lactation** Not recommended during pregnancy. Should not be used if breast-feeding. Effect on fertility is unknown. **Effects on ability to drive and use machines** When used in combination with a sulphonylurea or insulin, patients should be advised to take precautions to avoid hypoglycaemia while driving and using machines. **Undesirable Effects** *Very common (≥ 1/10):* Hypoglycaemia (when used in combination with insulin, glimepiride, metformin, or metformin plus glimepiride), nausea, diarrhoea, vomiting, abdominal pain. *Common (≥ 1/100 to < 1/10):* Hypoglycaemia (when used as monotherapy, in combination with metformin plus pioglitazone, or in combination with an SGLT2 inhibitor with or without metformin), decreased appetite, dyspepsia, constipation, flatulence, abdominal distention, gastro-oesophageal reflux disease, eructation, fatigue, sinus tachycardia, first-degree atrioventricular block (AVB). *Uncommon (≥ 1/1,000 to < 1/100):* Hypersensitivity, dehydration, injection site reactions, cholelithiasis, cholecystitis (the frequency of injection site reactions seen in a paediatric study was common). *Rare (≥ 1/10,000 to < 1/1,000):* Acute pancreatitis, anaphylactic reaction, angioedema. *Not Known (cannot be estimated from available data):* Non-mechanical intestinal obstruction. None of the patients with systemic hypersensitivity developed dulaglutide antidrug antibodies. The safety profile in patients treated with dulaglutide 3 mg and 4.5 mg once weekly is consistent with that described for dulaglutide doses of 0.75 mg and 1.5 mg once weekly. *For full details of these and other side-effects, please see the Summary of Product For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at : http://www.medicines.org.uk/emc/.* **Legal Category** POM **Marketing Authorisation Numbers and Holder** PLGB 14895/0259 PLGB 14895/0260 PLGB 14895/0261 PLGB 14895/0262. Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands **Cost (UK only)** £73.25 per pack of 4 single use pens (0.75 mg) £73.25 per pack of 4 single use pens (1.5 mg) £73.25 per pack of 4 single use pens (3 mg) £73.25 per pack of 4 single use pens (4.5 mg). **Date of Preparation or Last Review** May 2023 **Further Information is Available From** Eli Lilly and Company Limited, Lilly House, Basing View, Basingstoke, Hampshire, RG21 4FA. Telephone: **UK (Great Britain):** + 44-(0) 1256 315000 E-mail: ukmedinfo@lilly.com

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Adverse events and product complaints should be reported.
Reporting forms and information can be found at:
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events and product complaints should also be reported to Lilly: Please call Lilly **UK** on **01256 315 000**.

TRULICITY® (dulaglutide) PRESCRIBING INFORMATION

Ireland and United Kingdom (Northern Ireland)

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or Apple App Store, or **Ireland: www.hpra.ie**.

Adverse events and product complaints should also be
reported to Lilly: please call Lilly on
01256 315 000 (UK), or **01 664 0446 (IE)**.