TRULICITY® (dulaglutide) PRESCRIBING INFORMATION

Presentation Dulaglutide solution for injection in a pre-filled pen. Each single-use pen contains either 0.75 mg or 1.5 mg of dulaglutide in 0.5 ml solution. Uses Dulaglutide is indicated for the treatment of adults 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 Monotherapy: Recommended dose 0.75 mg once weekly. Add-on therapy: Recommended dose 1.5 mg once weekly. For potentially vulnerable patients, 0.75 mg once weekly can be considered as a starting dose. 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 m²). Not recommended in end stage renal disease (< 15 ml/min/1.73 m²). Hepatic impairment: No dose adjustment is required. Paediatrics: The safety and efficacy of dulaglutide in children < 18 years have not been established. No data are available. Contra-indications Hypersensitivity to the active substance or to any of the excipients. Warnings and Special Precautions 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. 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 side-effects and take precautions to avoid fluid depletion. Not recommended in patients with severe gastro-intestinal disease, including severe gastroparesis. In clinical trials, 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 sodium-free (≤ 1 mmol sodium (23 mg) per 1.5 mg dose). Interactions Dulaglutide delays gastric emptying. For oral medicinal products requiring rapid gastrointestinal absorption, or prolonged release formulations, there is potential for altered drug exposure. Dulaglutide should not otherwise affect the absorption of orally administered medications. Interaction studies with specific medicinal products have been conducted. No dose adjustments of paracetamol, atorvastatin, digoxin, lisinopril, metoprolol, warfarin, oral contraceptives, or metformin (immediate release formula) are required when given together with dulaglutide. 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 distension, 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. 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 anti-drug antibodies. For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at United Kingdom: http://www.medicines.org.uk/emc/, or Ireland: http://www.medicines.ie/. Legal Category POM Marketing Authorisation Numbers and Holder EU/1/14/956/002, EU/1/14/956/007. Eli Lilly Nederland B.V., Papendorpsweg 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). An Irish price is available on request; please see section below for contact information. Date of Preparation or Last Review October 2019 Further Information is Available From Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL. Telephone: UK: + 44-(0) 1256 315000, Ireland: 01661 4377 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, or Ireland: www.hpra.ie. Adverse events and product complaints should also be reported to Lilly: please call Lilly UK on 01256 315 000, or Lilly Ireland on 01 664 0446.