trulicity®
dulaglutide once-weekly injection

Trulicity Selected Safety Information:

Indications: Trulicity is indicated in adults with type2 diabetes mellitus to improve glycaemic control as: Monotherapy When diet and exercise alone do not provide adequate glycaemic control in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications. Add-on therapy in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control (see section 5.1 for data with respect to different combinations). Cardiovascular risk reduction: Trulicity is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors. **Elderly:** No dose adjustment is required based on age. However, the therapeutic experience in patients ≥ 75 years is very limited, and in these patients 0.75 mg once weekly can be considered as a starting dose. **Renal impairment:** No dosage adjustment is required in patients with mild, moderate or severe renal impairment (eGFR <90 to ≥15 mL/min/1.73m2). There is very limited experience in patients with end stage renal disease (<15 ml/min/1.73m2), therefore Trulicity cannot be recommended in this population. **Hepatic impairment:** No dosage adjustment is required in patients with hepatic impairment. **Pediatric population:** The safety and efficacy of dulaglutide in children aged less than 18 years have not yet been established. No data are available. **Method of administration:** Trulicity is to be injected subcutaneously 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. If a dose is missed, it should be administered as soon as possible if there are at least 3 days (72 hours) until the next scheduled dose. If less than 3 days (72 hours) remain before the next scheduled dose, the missed dose should be skipped, and the next dose should be administered on the regularly scheduled day. In each case, patients can then resume their regular once weekly dosing schedule. The day of weekly administration can be changed if necessary, as long as the last dose was administered 3 or more days (72 hours) before. **Contraindications:** TRULICITY is contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) Special warnings and precautions for use Dulaglutide should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. **Summary of Adverse Reactions:** The most frequently reported adverse reactions in clinical trials were gastrointestinal, including nausea, vomiting and diarrhea. In general, these reactions were mild or moderate in severity and transient in nature. Special warnings and precautions for use Dulaglutide should not be used in patients with type1 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.

Before prescribing Trulicity, please review full prescribing information.

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For adverse events and safety reporting, please send an email: Saudi_Pharmacovigilance@lilly.com
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