



TRULICITY REMS (Risk Evaluation and Mitigation Strategy)

FDA Required TRULICITY REMS Safety Information

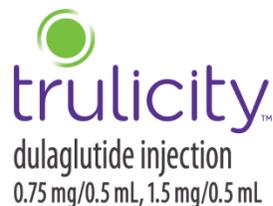
- **Potential Risk of Medullary Thyroid Carcinoma (MTC)**
- **Risk of Pancreatitis**

Potential Risk of Medullary Thyroid Carcinoma (MTC)

BOXED WARNING- Risk of Thyroid C-Cell Tumors*

- In male and female rats, dulaglutide causes a dose-related and treatment-duration-dependent increase in the incidence of thyroid C-cell tumors (adenomas and carcinomas) after lifetime exposure. It is unknown whether TRULICITY causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as the human relevance of dulaglutide-induced rodent thyroid C-cell tumors has not been determined.
- TRULICITY is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- Cases of MTC in patients treated with liraglutide, another GLP-1 receptor agonist, have been reported in the postmarketing period. The data in these reports are insufficient to establish or exclude a causal relationship between MTC and GLP-1 receptor agonist use in humans.
- **Counsel patients** regarding the potential risk for MTC with the use of TRULICITY and to report the symptoms of thyroid tumors (*e.g., a mass in the neck, dysphagia, dyspnea, or persistent hoarseness*) to their healthcare provider (HCP).
- Patients with thyroid nodules noted on physical examination or neck imaging should be further evaluated.
- Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with TRULICITY. Such monitoring may increase the risk of unnecessary procedures, due to the low test specificity for serum calcitonin and a high background incidence of thyroid disease. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated.

* The information presented in this box does not represent the complete Boxed Warning. Please see the Prescribing Information.



Risk of Pancreatitis

- Pancreatitis has been reported with the use of glucagon-like peptide-1 (GLP-1) receptor agonists. Cases of pancreatitis have been described in association with TRULICITY during clinical trials.
- **Counsel patients** to contact their HCP promptly if they experience symptoms of pancreatitis (*e.g., persistent, severe abdominal pain sometimes radiating to the back, which may or may not be accompanied by vomiting*).
- **Immediately discontinue** TRULICITY if pancreatitis is suspected. Perform confirmatory tests, and initiate appropriate management. If pancreatitis is confirmed, TRULICITY should not be restarted.
- **Consider** other antidiabetic therapies for patients with a history of pancreatitis. TRULICITY has not been studied in patients with a history of pancreatitis to determine whether these patients are at increased risk for pancreatitis.

Indication

TRULICITY (dulaglutide) is a GLP-1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

TRULICITY is not recommended as first-line therapy for patients with type 2 diabetes mellitus inadequately controlled on diet and exercise.

What is the TRULICITY REMS?

A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the FDA to manage known or potential serious risks associated with a drug product. FDA has determined that a REMS is necessary to ensure that the benefits of TRULICITY outweigh the potential risk of MTC and the risk of pancreatitis. This factsheet is required by the FDA as part of the TRULICITY REMS program.

Please visit www.TRULICITYREMS.com for further information.

Reporting Adverse Events

To report adverse events among patients taking TRULICITY, contact:

- Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979) and/or
- FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please contact The Lilly Answers Center at 1-800-545-5979 with any questions about the information in this factsheet or the safe and effective use of TRULICITY.

This factsheet does not contain the complete safety information for TRULICITY. Please refer to the Prescribing Information, including Boxed Warning, for further information.