Once-weekly
Tanzeum®
albiglutide
30mg, 50mg for injection

Tanzeum REMS (Risk Evaluation and Mitigation Strategy)

FDA Required REMS Safety Information

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

Potential Risk of Medullary Thyroid Carcinoma

BOXED WARNING: Risk of Thyroid C-Cell Tumors*

- Carcinogenicity of albiglutide could not be assessed in rodents, but other glucagon-like peptide-1 (GLP-1) receptor agonists have caused thyroid C-cell tumors in rodents at clinically relevant exposures. Human relevance of GLP-1 receptor agonist induced C-cell tumors in rodents has not been determined. It is unknown whether TANZEUM causes thyroid C-cell tumors, including medullary thyroid carcinoma in humans.
- TANZEUM is contraindicated in patients with a personal or family history of MTC or 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 and to report the symptoms of thyroid tumors (**e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness**) to their healthcare provider.
- Patients with thyroid nodules noted on physical examination or neck imaging should be referred to an endocrinologist for further evaluation.
- Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with TANZEUM. Such monitoring may increase the risk of unnecessary procedures, due to the low specificity of serum calcitonin testing for MTC 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.

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Risk of Acute Pancreatitis

- In clinical trials, there were more cases of acute pancreatitis among patients treated with TANZEUM than among patients treated with comparators.
- **Counsel patients** to contact their HCP promptly in the event of characteristic symptoms of acute pancreatitis: **persistent, severe abdominal pain** sometimes radiating to the back, which may or may not be accompanied by vomiting.
- If acute pancreatitis is suspected, TANZEUM should promptly be discontinued. If acute pancreatitis is confirmed, TANZEUM should not be restarted.
- TANZEUM has not been studied in patients with a history of pancreatitis to determine whether these patients are at increased risk for acute pancreatitis. Consider other anti-diabetic therapies in patients with a history of pancreatitis.

Indication

TANZEUM 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.

TANZEUM is not recommended as first-line therapy for patients inadequately controlled on diet and exercise.

What is the Tanzeum 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 TANZEUM outweigh the potential risk of medullary thyroid carcinoma and the risk of acute pancreatitis. This factsheet is required by the FDA as part of the TANZEUM REMS program. Please visit www.TANZEUMREMS.com for further information.

Adverse Events

To report adverse events among patients taking TANZEUM, contact:

- GlaxoSmithKline (the Sponsor) at 1-888-825-5249 and/or
- FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**

Please contact our Medical Information department at 1-888-825-5249 if you have any questions about this factsheet or the safe and effective use of TANZEUM.

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