



Prescribing Information including Boxed Warning Medication Guide

TANZEUM REMS (Risk Evaluation and Mitigation Strategy)

What is the TANZEUM REMS?

A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the Food and Drug Administration (FDA) to manage known or potential serious risks associated with a drug product.

The purpose of the TANZEUM REMS is to inform healthcare providers about the following risks of TANZEUM:

Potential Risk of Medullary Thyroid Carcinoma

- 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 (MTC) in humans.
- 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 about the risk of MTC and the symptoms of thyroid tumors.

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.

A non-promotional factsheet, reviewed by the FDA, with more detailed safety information about these risks is available in the box to the right.

Materials for Healthcare Providers

 [TANZEUM REMS Safety Information for Providers Factsheet](#)

 [REMS Letter to Healthcare Providers](#)

You are encouraged to report negative side effects of prescription drugs to GlaxoSmithKline (the Sponsor) at 1-888-825-5249 and/or the FDA www.fda.gov/medwatch, or call 1-800-FDA-1088.

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