



TANZEUM REMS

FDA Required REMS Safety Information

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

Important Safety Notice

The FDA has required this safety update as part of the TANZEUM® REMS (Risk Evaluation and Mitigation Strategy) to inform healthcare providers about the following **serious risks of TANZEUM (albiglutide):**

Potential Risk of Medullary Thyroid Carcinoma (MTC)

- 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. It is unknown whether TANZEUM causes thyroid C-cell tumors, including 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.

Acute Pancreatitis

- In clinical trials, there were more cases of acute pancreatitis among patients treated with TANZEUM than among patients treated with comparators.

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

A non-promotional factsheet, reviewed by the FDA, with more detailed safety information about these risks is enclosed.

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.

Please visit www.TANZEUMREMS.com for more information.

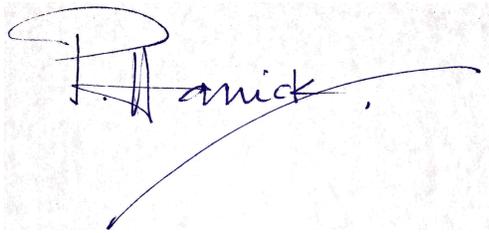
This letter does not contain the complete safety profile for TANZEUM. Please see the enclosed Prescribing Information and Medication Guide.

Reporting Adverse Events

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.

If you have any questions about the information contained in this letter or the use of TANZEUM, you may contact:

- US Medical Information Department at 1-877-356-8368

A handwritten signature in blue ink that reads "Philip Hornick". The signature is written in a cursive style with a large, stylized initial "P" and a long, sweeping underline.

Philip Hornick, MD, PhD, FESC
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Medical Affairs, North America