

Initial REMS approved: 4/2014

Most recent modification: 07/2015

BLA STN-125431 TANZEUM®

(Albiglutide)

Glucagon-like Peptide-1 (GLP-1) Receptor Agonist

GlaxoSmithKline LLC

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL

The goal of the TANZEUM REMS is to mitigate the potential risk of medullary thyroid carcinoma and the risk of acute pancreatitis associated with TANZEUM by:

- Informing healthcare providers (HCPs) about the potential risk of medullary thyroid carcinoma associated with TANZEUM
- Informing HCPs about the risk of acute pancreatitis associated with TANZEUM

II. REMS ELEMENTS

A. Communication Plan

GSK will implement the following elements of a communication plan to healthcare providers likely to prescribe TANZEUM. The communication plan will include:

1. REMS Letters

GSK will send the *REMS Letter for Healthcare Providers* and the *REMS Letter for Professional Societies* within 60 days of initial approval, and again at 1 year after

initial approval of this REMS. The REMS Letters will address the potential risk of medullary thyroid carcinoma and the risk of acute pancreatitis.

Distribution of the REMS Letters will be via electronic mail (email) or by mail if no email contact information is available. If the first email is marked as unopened, a second email will be sent within one week. If the second email is marked as undeliverable or as unopened, a follow-up hard copy of the REMS Letter will be sent within 30 days. If a targeted healthcare provider's email address is not available or if an email is undeliverable, the letter will be sent through the mail.

A copy of (or a link to) the US Prescribing Information and Medication Guide will accompany the REMS Letters.

REMS Letter for Healthcare Providers

The intended audience for the *REMS Letter for Healthcare Providers* are healthcare providers who are likely to prescribe TANZEUM, and includes physicians, nurse practitioners, and physician assistants in the specialties of endocrinology, internal medicine, and family practice.

The *REMS Letter for Healthcare Providers* will also be available upon request through the GSK Customer Response Center and from GSK sales and medical representatives for one year after approval of the most recent REMS modification.

REMS Letter for Professional Societies

GSK will send the *REMS Letter for Professional Societies* to the following professional societies and organizations. GSK will request the letter be provided to their membership:

- American College of Physicians
- American Medical Association
- American Academy of Family Physicians
- American College of Osteopathic Family Physicians
- American College of Clinical Pharmacy
- American Pharmacists Association
- American Society of Health-System Pharmacists
- American Academy of Nurse Practitioners
- American Association of Clinical Endocrinologists
- Endocrine Society
- American Diabetes Association
- American Association of Diabetes Educators
- American Academy of Physician Assistants

- Association of Managed Care Pharmacy
- National Association of Managed Care Physicians

2. REMS Factsheet

A REMS Factsheet will be made available to healthcare providers and distributed through GSK sales and medical representatives during the first product discussion for TANZEUM with healthcare providers during the first 12 months after initial approval of this REMS.

A REMS Factsheet will be made available to healthcare providers upon request through GSK sales and medical representatives for one year after approval of the most recent REMS modification.

3. REMS Website

The TANZEUM REMS website (www.TANZEUMREMS.com) will continue for 3 years after the initial approval of the REMS. The TANZEUM REMS website will include downloadable versions of the Prescribing Information and Medication Guide, REMS *Letter for Healthcare Providers*, and the REMS Factsheet. The TANZEUM website for healthcare professionals (www.gsksource.com/tanzeum) will include a prominent REMS-specific link to the TANZEUM REMS website. All website information will be updated within 60 days post approval of the most recent modification.

The following parts of the TANZEUM REMS revised with this modification are appended:

- The *REMS Letter for Healthcare Providers* (print)
- The REMS Factsheet
- The TANZEUM REMS Website

B. Timetable for Submission of Assessments

GSK will submit REMS Assessments to FDA at 18 months, 3 years, and 7 years from the date of the approval. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. GSK will submit each assessment so that it will be received by the FDA on or before the due date.