

Medication Guide
TANZEUM™ (TAN-zee-um)
(albiglutide)
for injection, for subcutaneous use

Read this Medication Guide before you start using TANZEUM and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about TANZEUM?

TANZEUM may cause serious side effects, including:

- **Possible thyroid tumors, including cancer.** Tell your healthcare provider if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of thyroid cancer. In studies with rats and mice, medicines that work like TANZEUM caused thyroid tumors, including thyroid cancer. It is not known if TANZEUM will cause thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people.
- **Do not use TANZEUM if you** or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC) or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

What is TANZEUM?

TANZEUM is an injectable prescription medicine that may improve blood sugar (glucose) in adults with type 2 diabetes mellitus, and should be used along with diet and exercise.

- TANZEUM is not recommended as the first choice of medicine for treating diabetes.
- It is not known if TANZEUM can be used in people who have had pancreatitis.
- TANZEUM is not a substitute for insulin and is not for use in people with type 1 diabetes or people with diabetic ketoacidosis.
- TANZEUM is not recommended for use in people with severe stomach or intestinal problems.
- It is not known if TANZEUM can be used with mealtime insulin.
- It is not known if TANZEUM is safe and effective for use in children under 18 years of age.

Who should not use TANZEUM?

Do not use TANZEUM if:

- you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC) or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- you are allergic to albiglutide or any of the ingredients in TANZEUM. See the end of this Medication Guide for a complete list of ingredients in TANZEUM.

What should I tell my healthcare provider before using TANZEUM?

Before using TANZEUM, tell your healthcare provider if you:

- have or have had problems with your pancreas, kidneys, or liver
- have severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems with digesting food
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if TANZEUM will harm your unborn baby. Tell your healthcare provider if you become pregnant while using TANZEUM.
- are breastfeeding or plan to breastfeed. It is not known if TANZEUM passes into your breast milk. You should not use TANZEUM while breastfeeding without first talking with your healthcare provider.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. TANZEUM may affect the way some medicines work and some medicines may affect the way TANZEUM works.

Before using TANZEUM, talk to your healthcare provider about low blood sugar and how to manage it. Tell your healthcare provider if you are taking other medicines to treat diabetes including insulin or sulfonylureas.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when

you get a new medicine.

How should I use TANZEUM?

- Read the **Instructions for Use** that comes with TANZEUM.
- Use TANZEUM exactly as your healthcare provider tells you to.
- **Your healthcare provider should show you how to use TANZEUM before you use it for the first time.**
- TANZEUM is injected under the skin (subcutaneously) of your stomach (abdomen), thigh, or upper arm. **Do not** inject TANZEUM into a muscle (intramuscularly) or vein (intravenously).
- **Use TANZEUM 1 time each week on the same day each week at any time of the day.**
- You may change the day of the week as long as your last dose was given **4** or more days before.
- If you miss a dose of TANZEUM, take the missed dose of TANZEUM within **3** days after your usual scheduled day. If more than **3** days have gone by since your missed dose, wait until your next regularly scheduled weekly dose. **Do not** take 2 doses of TANZEUM within 3 days of each other.
- TANZEUM may be taken with or without food.
- TANZEUM should be injected within 8 hours after mixing your medicine.
- TANZEUM should be injected right after you attach the needle.
- **Do not** mix insulin and TANZEUM together in the same injection.
- Change (rotate) your injection site with each weekly injection. **Do not** use the same site for each injection.

Do not share your TANZEUM pen or needles with another person. You may give another person an infection or get an infection from them.

Your dose of TANZEUM and other diabetes medicines may need to change because of:

change in level of physical activity or exercise, weight gain or loss, increased stress, illness, change in diet, or because of other medicines you take.

What are the possible side effects of TANZEUM?

TANZEUM may cause serious side effects, including:

- **See “What is the most important information I should know about TANZEUM?”**
- **inflammation of your pancreas (pancreatitis).** Stop using TANZEUM and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel pain from your abdomen to your back.
- **low blood sugar (hypoglycemia).** Your risk for getting low blood sugar may be higher if you use TANZEUM with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin. Signs and symptoms of low blood sugar may include:
 - dizziness or light-headedness
 - blurred vision
 - anxiety, irritability, or mood changes
 - sweating
 - slurred speech
 - hunger
 - confusion or drowsiness
 - shakiness
 - feeling jittery
 - headache
 - fast heart beat
 - weakness
- **serious allergic reactions.** Stop using TANZEUM and get medical help right away if you have any symptoms of a serious allergic reaction including itching, rash, or difficulty breathing.
- **kidney problems (kidney failure).** In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration) which may cause kidney problems to get worse.

The most common side effects of TANZEUM may include diarrhea, nausea, reactions at your injection site, cough, back pain, cold or flu symptoms.

Talk to your healthcare provider about any side effect that bothers you or does not go away. These are not all the possible side effects of TANZEUM.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of TANZEUM.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TANZEUM for a condition for which it was not prescribed. Do not give TANZEUM to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about TANZEUM. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about TANZEUM that is written for health professionals.
For more information, go to www.TANZEUM.com or call 1-888-825-5249.

What are the ingredients in TANZEUM?

Active Ingredient: albiglutide

Inactive Ingredients: mannitol, polysorbate 80, sodium phosphate, and trehalose dihydrate. TANZEUM does not contain a preservative.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: March 2015



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