



GSK
5 Crescent Drive
Philadelphia PA
19112
www.gsk.com

TANZEUM (albiglutide) Discontinuation — Q&A

On July 26, 2017, GSK announced plans to discontinue the manufacturing and sale of TANZEUM (albiglutide) (30 mg and 50 mg for injection) by July 2018.

This was a difficult decision for all of us at GSK. Given the availability of multiple treatment options for patients with type 2 diabetes, it has become harder and harder to make the impact we anticipated for patients. We believe patients can be well served by other companies that offer alternative treatments and also have ongoing investments in patient education and support services.

We are announcing this decision well in advance of July 2018 to ensure that you have plenty of time to have a discussion with your doctor to determine what alternative treatment might be the most appropriate for you.

As with any medicine, it is very important that you do not stop taking TANZEUM without first speaking to your doctor.

ACTIONS YOU SHOULD TAKE:

Set up an appointment with your doctor to discuss your type 2 diabetes and learn more about alternative treatment options which might be right for you.

1. Why has GSK decided to discontinue manufacturing TANZEUM after announcing in November that you would keep the product on the market in the US?

In 2016, we announced an end to our direct sales force promotion for TANZEUM in the US. While we continued to invest in a small marketing effort, we have seen a steady decline in the sales of TANZEUM. In the current marketplace, it has been harder and harder to make the type of impact we would want for patients. Given the availability of multiple different treatment options for patients with type 2 diabetes, we have decided to cease manufacture and supply for TANZEUM and expect all supplies to be depleted by July 2018.

2. Has this decision been taken due to a safety concern with the medicine?

No, this decision has not been taken due to any safety concern.

3. What should I do if I'm a patient with type 2 diabetes currently taking TANZEUM?

You should speak to your doctor about which alternative treatment options may be right for you.

4. What alternatives to TANZEUM are available?

There are several alternative therapies available. You should speak to your doctor to discuss transitioning to an alternative treatment option by the end of June 2018.

5. Why might I continue to see advertising for TANZEUM (in magazines, online, etc)?

GSK will stop any ongoing promotional efforts. However, given the lead time to stop some of these programs, it is possible that you may continue to see some of the advertising until the cancellation process has completed.

TANZEUM.com will remain available to provide information about TANZEUM through July 2018.

If you have additional questions, please call the GSK Customer Response Center at 1-888-825-5249.

Please see "What Is TANZEUM?" and Important Safety Information for TANZEUM on page 2.

Please see full Prescribing Information, including Boxed Warning and Medication Guide, for TANZEUM on www.gsksource.com.

What is TANZEUM (albiglutide)?

TANZEUM is an injectable prescription medicine that may improve blood sugar (glucose) in adults with type 2 diabetes, and should be used along with diet and exercise. TANZEUM is not recommended as the first medication to treat diabetes. TANZEUM has not been studied in people who have had pancreatitis. TANZEUM is not a substitute for insulin and is not for people with type 1 diabetes or 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 or if TANZEUM is safe and effective for use in children under 18 years of age.

Important Safety Information for TANZEUM

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 MTC or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2. 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.

Do not use TANZEUM if you are allergic to albiglutide or any of the ingredients in TANZEUM.

Before using TANZEUM, tell your healthcare provider about your medical conditions, including 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.

Tell your healthcare provider if you are pregnant or plan to become pregnant. It is not known if TANZEUM will harm your unborn baby. Tell your healthcare provider if you are breastfeeding or plan to breastfeed. It is not known if TANZEUM passes into your breast milk.

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.

TANZEUM may cause serious side effects, including:

- possible thyroid tumors, including cancer.
- 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; sweating; confusion or drowsiness; headache; blurred vision; slurred speech; shakiness; fast heartbeat; anxiety, irritability, or mood changes; hunger; feeling jittery; and weakness.
- serious allergic reactions. Stop using TANZEUM and get medical help right away if you have any symptoms of a serious allergic reaction, including: swelling of your face, lips, tongue or throat; problems breathing or swallowing; severe rash or itching; fainting or feeling dizzy; very rapid heartbeat.
- kidney injury. Worsening kidney function and kidney injury have happened in people with kidney problems and in people without kidney problems, who have taken TANZEUM. Diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration) which may cause kidney function to get worse. Tell your healthcare provider if you have diarrhea, nausea, or vomiting. Drink plenty of fluids to help reduce your risk of dehydration during treatment with TANZEUM.

The most common side effects of TANZEUM may include: upper respiratory tract infection; diarrhea; nausea; reactions at your injection site; cough; back pain; joint pain; inflammation of the sinuses; 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.

Please see full Prescribing Information, including Boxed Warning and Medication Guide, for TANZEUM on www.gsksource.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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Produced in USA. 832488R0 February 2018