



TEPEZZA® (teprotumumab-trbw)
Frequently Asked Questions Regarding Short-Term Supply Disruption

Horizon Therapeutics, the maker of TEPEZZA, prepared this document to address questions from the Thyroid Eye Disease (TED) community regarding the short-term disruption in TEPEZZA supply. Horizon is aware of the significant impact TED has on people living with the disease and is working diligently to limit the length of the disruption.

This disruption is the result of recent COVID-19 vaccine production orders required by the government as part of Operation Warp Speed. This has dramatically restricted production capacity at the manufacturing facility that produces TEPEZZA.

Note: If you choose to share or post these FAQs, please share the full document and not select pieces of it, in order to comply with regulatory guidelines.

Questions about TEPEZZA? Talk to Horizon Patient Services.

Call 1-833-469-8331, Mon-Fri, 8 a.m.-8 p.m. EST.

Horizon Patient Services does not provide individual patient care or medical advice.

1. What is the current status of TEPEZZA availability?

On December 17, 2020, Horizon announced that it expects a short-term disruption in TEPEZZA supply. Horizon shipped all of its remaining supply to sites of care (e.g., infusion centers, hospitals) at the end of December, and we currently anticipate that TEPEZZA will not be available for patient use beginning in early January. We expect TEPEZZA will continue to be unavailable through the first quarter of 2021.

2. What is the cause of this disruption?

This disruption is a result of recent COVID-19 vaccine production orders required by the government as part of Operation Warp Speed*. This has dramatically restricted production capacity in terms of the number of



manufacturing slots per month at the manufacturing facility that produces TEPEZZA. Of note, Horizon works with a separate company – sometimes called a “contract manufacturer” – to complete the last step in the manufacturing process for TEPEZZA, which is to fill/finish the vials with the medicine. It is very common for biopharmaceutical companies to work with an outside company to complete this step. Some of the companies that manufacture COVID-19 vaccine and therapeutics use the same contract manufacturer as Horizon. In order to increase capacity for vaccine production, Operation Warp Speed has required that Horizon’s previously contracted TEPEZZA drug product manufacturing slots be canceled and provided to other companies to increase vaccine production. Because of this, TEPEZZA manufacturing slots have been significantly reduced and therefore our ability to produce enough TEPEZZA to meet patient demand has been disrupted.

**NOTE: Operation Warp Speed was initiated by the U.S. government to facilitate and accelerate the development, manufacturing and distribution of COVID-19 vaccines, therapeutics and diagnostics.*

3. Was it Horizon’s decision to stop manufacturing TEPEZZA in order to increase vaccine production?

No, this was not Horizon’s decision. The decision was made by Operation Warp Speed, through authority granted by invoking the Defense Production Act of 1950. We have had ongoing open dialogue with the U.S. Food and Drug Administration (FDA) and other government agencies to work through potential solutions, as well as elevate the significant burden of TED on patients and the importance of TEPEZZA to people who have been prescribed the medicine by their doctors. We will continue to do all that we can to end the short-term disruption in supply.

4. Does Horizon make a COVID-19 vaccine?

No, Horizon does not make a COVID-19 vaccine. The partner company that we use to manufacture TEPEZZA is the same partner company that other biopharmaceutical companies use to manufacture COVID-19 vaccine and therapeutics.



5. What is Horizon doing to end the TEPEZZA disruption?

Due to losing manufacturing space, Horizon now has a fewer number of manufacturing slots at its contract manufacturer for TEPEZZA. We have one manufacturing slot where we used to have several per month (a slot is a dedicated space for production of a medicine). Horizon will be increasing its ability to produce more medicine than is currently approved by the U.S. Food and Drug Administration (FDA) for each of its manufacturing slots. This increase requires approval by the FDA. Horizon will submit data to support this change in manufacturing process to the FDA in January. The FDA will then decide if the data are sufficient for FDA approval of the increased manufacturing capacity.

Separately, Horizon is planning to bring on an additional drug product manufacturer to help maintain adequate product inventory. However, this takes some lead time, as there is a process to obtain regulatory approvals for a new manufacturer.

6. How long is this supply disruption expected to continue?

The length of the disruption will depend on:

- The successful completion of our efforts to increase manufacturing using our limited slots.
- Decisions by the FDA regarding this increased scale manufacturing process of TEPEZZA.

Horizon expects to submit data in January from the first increased scale manufacturing lot to the FDA for its review and approval. It will be the FDA's decision whether these data are sufficient for FDA approval of the increased manufacturing capacity.

7. How has Horizon managed distribution of remaining TEPEZZA supply?

Horizon encourages sites of care (e.g., infusion centers, hospitals, etc.) to prioritize remaining product for those who already started treatment. Horizon suggests that each site of care continue treating patients as scheduled, until they no longer have any remaining medicine. Sites of care will run out of medicine at different times, depending on how much they have in stock and



how many patients they have scheduled. Once a site of care runs out of medicine, they will not be able to order more for their patients until this temporary disruption in supply has been resolved. The TEPEZZA supply disruption could last through the first quarter of 2021.

8. Were certain sites of care able to order mass shipments?

In an effort to evenly distribute remaining medicine across the hundreds of sites of care that administer TEPEZZA, Horizon has closely monitored orders being placed by the sites of care to help prevent any of the sites from receiving more medicine than they typically order.

9. How do I know if my next treatment will continue as scheduled?

You may contact your site of care or your doctor to determine whether your next treatment will continue as scheduled. You can also talk with your Horizon Patient Access Manager (PAM) for support.

10. What should I do if I have started therapy with TEPEZZA and have not completed all eight infusions?

Patients who have already started therapy with TEPEZZA may speak with their doctor about how to manage their care during this disruption. Of note, your doctor will not be able to answer questions about TEPEZZA supply, but he or she can discuss other potential ways to manage your TED during this supply disruption.

11. What should I do if my doctor decided to start me on TEPEZZA, but I have yet to start therapy?

Patients who are waiting to begin therapy with TEPEZZA can speak with their doctor about how to manage their care during this disruption. Of note, your doctor will not be able to answer questions about TEPEZZA supply, but he or she can discuss other potential ways to manage your TED during this supply disruption.



12. How can patients who have started or are waiting to start TEPEZZA therapy get in touch with Horizon?

You can contact your Horizon Patient Access Manager (PAM) by calling 1-833-469-8331 Monday-Friday, 8 a.m. to 8 p.m. EST. PAMs are trained professionals who understand your condition and what you may be going through. They can provide ongoing updates regarding the status of the short-term supply disruption and help answer questions that you may have.

13. What is TEPEZZA?

TEPEZZA is the first and only medicine FDA-approved to treat TED. Unlike other medicines you and your doctor may have tried, TEPEZZA treats the cause of TED. When you have TED, a switch behind your eye, called a receptor, is turned on that causes redness and swelling. This can also make your eyes bulge. TEPEZZA is the only medicine that blocks this receptor to treat TED at its source. Learn more at www.TEPEZZA.com.

14. In what form is TEPEZZA made available?

TEPEZZA is an IV (intravenous) treatment given once every three weeks for a total of eight treatments. This means it is delivered through a needle that is placed in your arm. The first and second treatments will last about 90 minutes. The remaining six treatments will take about 60 minutes each, but could be longer depending on how you respond to the medicine.

15. What is Thyroid Eye Disease?

Thyroid Eye Disease (TED) is a vision-threatening autoimmune disease that often occurs in people living with Graves' disease; however, it is a different disease that must be managed separately. Common symptoms of TED include double vision, bulging eyes, dry eyes, eye pain, eyelid redness and swelling, teary eyes, light sensitivity and vision changes.

16. Is there a way for me to voice my concern about this disruption in the availability of TEPEZZA?

If you have concerns or would like to share information about your experience, there are patient advocacy organizations that can provide support:

- Prevent Blindness: (800) 331-2020 or info@preventblindness.org



- American Autoimmune Related Diseases Association (AARDA): info@aarda.org
- Lupus and Allied Diseases Association (LADA): info@ladainc.org
- Vision Health Advocacy Coalition (VHAC): info@visionhealthadvocacy.org

You can also phone or send an email to the FDA Office of the Ombudsman: (301) 796-8530 or ombuds@oc.fda.gov.

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TEPEZZA is a prescription medicine used to treat Thyroid Eye Disease.

IMPORTANT SAFETY INFORMATION

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

Infusion reactions can happen during or within 24 hours after your infusion of TEPEZZA. If you have a reaction while receiving TEPEZZA, your doctor or nurse will slow or stop your infusion and treat your reaction. If you have a severe infusion reaction, your doctor may stop your treatment completely.

Tell your doctor or nurse right away if you have any of these symptoms during or after your treatment with TEPEZZA:

- High blood pressure
- Fast heartbeat
- Redness of the face/Feeling hot
- Difficulty breathing
- Headache
- Muscle pain

If you have inflammatory bowel disease (IBD), such as Crohn's disease or ulcerative colitis, TEPEZZA may make your IBD symptoms worse. Symptoms of worsening IBD may include: an increased number of loose stools with stomach pain or cramps, and blood in your stools. After each TEPEZZA infusion, tell your doctor right away if you have worsening IBD symptoms.

TEPEZZA may cause an increase in your blood sugar. Before starting treatment with TEPEZZA, tell your doctor if you are currently being treated for diabetes, know your

blood sugar is high, or have been diagnosed with diabetes. It is important for you to take your treatments and follow an appropriate diet for glucose control as prescribed by your doctor.

Before receiving TEPEZZA, tell your doctor if you:

- Have inflammatory bowel disease (Crohn’s disease or ulcerative colitis).
- Are currently being treated for diabetes, have been diagnosed with diabetes, or know your blood sugar is high.
- Are pregnant or plan to become pregnant. TEPEZZA may harm your unborn baby. Tell your doctor if you become pregnant or suspect you are pregnant during treatment with TEPEZZA.
 - Women who are able to become pregnant should use an effective form of birth control (contraception) prior to starting treatment, during treatment and for at least 6 months after the final dose of TEPEZZA.
- Are breastfeeding or plan to breastfeed. It is not known if TEPEZZA passes into your breast milk. Talk to your doctor about the best ways to feed your baby during treatment with TEPEZZA.
- Tell your doctor about all the medicines you take, including prescription and over the counter medicines, vitamins, dietary and herbal supplements. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

What are the possible side effects of TEPEZZA?

The most common side effects of TEPEZZA include muscle cramps or spasms, nausea, hair loss, diarrhea, feeling tired, high blood sugar, hearing problems, taste changes, headache, and dry skin.

This is not a complete list of all possible side effects. Tell your doctor or treatment team if you have any side effect that bothers you or that does not go away.

Please visit TEPEZZA.com for more information.

You should report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/safety/medwatch, or call the FDA at [1-800-FDA-1088](tel:1-800-FDA-1088).