Infusion Checklist

TEPEZZA® teprotumumab-trbw

Patient Name: _____ **Date of Administration:** ____/____/____
First Last (MM/DD/YYYY)

Infusion Number	Dose	Duration
○ **New Start**	**10** mg/kg	**90** minutes
○ **2nd** Infusion	**20** mg/kg	**90** minutes
○ **3rd-8th** Infusion	**20** mg/kg	**60** minutes*

*If not well tolerated, the minimum infusion duration should remain at 90 minutes.

Patient's Actual Weight: _____ **kg**
Weight-Based Dose: _____ **mg**
# of Vials Required: _____
Volume of Solution to Withdraw: _____ **mL**
Saline Bag Size:
- ○ If dose is <1800 mg, use a 100-mL bag of normal saline (0.9% NaCl).
- ○ If dose is ≥1800 mg, use 250-mL bag of normal saline (0.9% NaCl).

Wastage: _____ **mg**

1 Prepare

- ○ **Prepare for the infusion** by confirming the patient's actual weight and calculating the dose, number of vials required, volume of solution to withdraw, saline bag size, and wastage.
  - See the Infusion Guide for sample calculations. For precalculated values for patients weighing 50 kg to 120 kg, see the Dosing Flashcard. A Dosing Calculator is also available at TEPEZZAhcp.com

2 Counsel

- ○ **Counsel the patient on the warnings, precautions, and potential side effects of TEPEZZA.**
  - Refer to second page of Infusion Checklist for Warnings and Precautions and Adverse Reactions
- ○ **Counsel females of reproductive potential about the need to use effective contraception.**

3 Reconstitute

- ○ **Reconstitute each vial with 10 mL of Sterile Water for Injection, USP.**
  - Ensure that the stream of diluent is not directed onto the lyophilized powder
- ○ **Gently swirl the solution by rotating the vial. Do not shake.**
  - The reconstituted solution has a volume of 10.5 mL. The final concentration is 47.6 mg/mL
- ○ **Visually inspect the solution.** Discard if any particulate matter or discoloration is observed.
  - If not used immediately, refrigerate and protect from light†

4 Dilute

- ○ **Remove the volume of saline equal to the amount of reconstituted TEPEZZA solution** to be placed into the infusion bag.
  - Use a sterile syringe and needle. Discard the saline withdrawn
- ○ **Withdraw the required volume from the TEPEZZA vial(s) based on the dose and transfer into the infusion bag.**
- ○ **Mix diluted solution by gentle inversion. Do not shake.**
  - If not used immediately, refrigerate and protect from light†
- ○ **Discard vial(s) and all unused contents.**

5 Infuse

- ○ **Allow the diluted solution to reach room temperature** prior to infusion, if previously refrigerated.
- ○ **Infuse the diluted solution** for the appropriate duration.
- ! **Do not administer as an intravenous push or bolus.**
- ! **Do not infuse concomitantly with other agents.**
- ○ **Use your normal protocol to monitor for infusion reactions.** If an infusion reaction occurs, interrupt or slow the rate of infusion and use appropriate medical management.

6 Observe and Remind

- ○ **Observe the patient** post-infusion according to the infusion order.
- ○ **Remind the patient** of their next infusion appointment.
  - TEPEZZA is given once every 3 weeks for a total of 8 infusions

†The combined storage time of reconstituted TEPEZZA solution in the vial and the diluted solution in the infusion bag is a total of 4 hours at room temperature 20°C to 25°C (68°F to 77°F) or up to 48 hours under refrigerated conditions 2°C to 8°C (36°F to 46°F) protected from light.

Please see Important Safety Information on next page and accompanying Full Prescribing Information or visit TEPEZZAhcp.com

INDICATION

TEPEZZA is indicated for the treatment of Thyroid Eye Disease regardless of Thyroid Eye Disease activity or duration.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infusion Reactions: TEPEZZA may cause infusion reactions. Infusion reactions have been reported in approximately 4% of patients treated with TEPEZZA. Reported infusion reactions have usually been mild or moderate in severity. Signs and symptoms may include transient increases in blood pressure, feeling hot, tachycardia, dyspnea, headache, and muscular pain. Infusion reactions may occur during an infusion or within 1.5 hours after an infusion. In patients who experience an infusion reaction, consideration should be given to premedicating with an antihistamine, antipyretic, or corticosteroid and/or administering all subsequent infusions at a slower infusion rate.

Preexisting Inflammatory Bowel Disease: TEPEZZA may cause an exacerbation of preexisting inflammatory bowel disease (IBD). Monitor patients with IBD for flare of disease. If IBD exacerbation is suspected, consider discontinuation of TEPEZZA.

Hyperglycemia: Increased blood glucose or hyperglycemia may occur in patients treated with TEPEZZA. In clinical trials, 10% of patients (two-thirds of whom had preexisting diabetes or impaired glucose tolerance) experienced hyperglycemia. Hyperglycemic events should be controlled with medications for glycemic control, if necessary. Assess patients for elevated blood glucose and symptoms of hyperglycemia prior to infusion and continue to monitor while on treatment with TEPEZZA. Ensure patients with hyperglycemia or preexisting diabetes are under appropriate glycemic control before and while receiving TEPEZZA.

Hearing Impairment Including Hearing Loss: TEPEZZA may cause severe hearing impairment including hearing loss, which in some cases may be permanent. Assess patients' hearing before, during, and after treatment with TEPEZZA and consider the benefit-risk of treatment with patients.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥5% and greater than placebo) are muscle spasm, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dysgeusia, headache, dry skin, weight decreased, nail disorders, and menstrual disorders.

Please see accompanying Full Prescribing Information or visit TEPEZZAhcp.com for more information.

Reference: TEPEZZA (teprotumumab-trbw) [prescribing information] Horizon.

AMGEN Rare Disease

TEPEZZA® teprotumumab-trbw