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 Calculations flashcard

2 Counsel

◯ **Counsel the patient on the warnings, precautions, and potential side effects of TEPEZZA.** Answer any questions.
◯ **Counsel females of reproductive potential about the need to use effective contraception.**
Tip: A Patient Access Manager (PAM) can support your patient throughout therapy.
Ask your patient to call 1-833-4MY-TED1 to enroll in Horizon Patient Services.

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 Discard the saline withdrawn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†

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.**
◯ **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.
◯ **Discard vial(s) and all unused contents.**

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 reverse and accompanying Full Prescribing Information.

INDICATION

TEPEZZA is indicated for the treatment of Thyroid Eye Disease.

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 managed with medications for glycemic control, if necessary. Monitor patients for elevated blood glucose and symptoms of hyperglycemia while on treatment with TEPEZZA. Patients with preexisting diabetes should be under appropriate glycemic control before receiving TEPEZZA.

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, and dry skin.

For additional information on TEPEZZA, please see accompanying Full Prescribing Information.

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