

TEPEZZA Key Product Features

INDICATION

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



RECOMMENDED DOSING¹	Intravenous infusion of 10 mg/kg for the initial dose followed by intravenous infusions of 20 mg/kg every 3 weeks. The recommended course of therapy is 8 infusions.
STORAGE AND HANDLING¹	<ul style="list-style-type: none"> • Refrigerate at 36°F to 46°F (2°C to 8°C) • Do not freeze • Store in original carton until time of use to protect from light • Discard unused portion
PACKAGING¹	Description: Single-dose vial of white to off-white lyophilized powder Each carton contains one single-dose vial of TEPEZZA 500 mg.
DIMENSIONS	1 carton (1 vial/carton): 1.38" x 2.95" x 2.36" 1 case (48 cartons/case): 10.06" x 8.94" x 6.81"
WEIGHT	1 carton (1 vial/carton): 0.11 lb 1 case (48 cartons/case): 5.87 lb
NDC NUMBER¹	10-digit: 75987-130-15 11-digit: 75987-0130-15
ORDERING INFORMATION	<p>Specialty Pharmacy: Accredo® Ophthalmic TRC: 1-877-626-1511</p> <p>Specialty Distributors: ASD Healthcare®: 1-800-746-6273 Besse® Medical: 1-800-543-2111 BioCare® SD: 1-800-304-3064 Cardinal Health™ Specialty Distribution: 1-866-476-1340 CuraScript SD®: 1-877-599-7748 McKesson Plasma and Biologics: 1-877-625-2566 McKesson Specialty Health: 1-855-477-9800 Metro® Medical: 1-800-768-2002 Oncology Supply®: 1-800-633-7555</p>

NDC, National Drug Code.

Please see Important Safety Information on next page and accompanying [Full Prescribing Information](#) or visit TEPEZZAhcp.com.

TEPEZZA
teprotumumab-trbw

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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 \geq 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](https://www.tepezzaahcp.com) for more information.

Reference: 1. TEPEZZA (teprotumumab-trbw) [prescribing information] Horizon.