Tepezza (teprotumumab-trbw)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Tepezza
- **Generic name:** Teprotumumab-trbw
- **Pharmacologic class:** Human insulin-like growth factor-1 receptor inhibitor
- **Strength and Formulation:** 500mg; per vial; lyophilized pwd for IV infusion after reconstitution and dilution; preservative-free
- **Manufacturer:** Horizon Therapeutics
- **How supplied:** Single-dose vial—1
- **Legal Classification:** Rx

Tepezza


NDC-75987-130-15
TEPEZZA™
(teprotumumab-trbw)
for Injection
500 mg/vial
For Intravenous Infusion Only
Reconstitute and Further Dilute Prior to Use
Single-dose vial. Discard unused portion.
Rx Only
Store vial in original carton to protect from light.
Store unopened vial in a refrigerator at 2°C to 8°C (36°F to 46°F). Do not freeze.
No U.S. standard of potency.
See enclosed package insert for reconstitution instructions and complete information on dosage and administration.
TEPEZZA™
(teprotumumab-trbw)
for Injection
500 mg/vial
For Intravenous Infusion Only

MPR

Indication

- For the treatment of **thyroid eye disease**

MPR

Dosage and Administration

- Give 1st two infusions by IV infusion over 90mins; if tolerated, may reduce subsequent infusions to 60mins
- Initially 10mg/kg followed by 20mg/kg every 3 weeks for 7 additional infusions

Considerations for Special Populations

- **Pregnancy:** may cause fetal harm and should not be used in pregnancy; appropriate forms of contraception should be implemented prior to initiation, during treatment and for 6 months following the last dose
- **Nursing mothers**: no information regarding presence in human milk
- **Pediatric**: not established
- **Geriatric:** no overall differences in safety and efficacy observed

MPR

Warnings/Precautions

- Exacerbation of preexisting inflammatory bowel disease; if suspected, consider discontinuation
- Monitor for hyperglycemia
  - Hyperglycemic events should be controlled with medications for glycemic control, if necessary
- Preexisting diabetes
  - Should be under appropriate glycemic control before receiving Tepezza

Adverse Reactions

- **Most frequent (incidence >5%)**: muscle spasm, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dry skin, dysgeusia, headache

- **Others**: infusion-related reactions (reported in approx. 4% of patients)
  - May occur during any of the infusions or within 1.5 hours after an infusion

MPR

Mechanism of Action

- The mechanism of action of teprotumumab-trbw in patients with thyroid eye disease has not been fully characterized
- Teprotumumab-trbw binds to insulin-like growth factor-1 receptor and blocks its activation and signaling

Clinical Trials

- Two randomized, double-masked, placebo controlled studies in 171 patients with thyroid eye disease
- Patients were randomized to receive Tepezza 10mg/kg for first infusion and 20mg/kg for the remaining 7 infusions every 3 weeks for a total of 8 infusions or placebo
- Patients had clinical diagnosis of thyroid eye disease with symptoms and were euthyroid or had thyroxine and free triiodothyronine levels less than 50% above or below normal limits
- Proptosis ranged from 16-33mm and 125 patients (73%) had diplopia at baseline

MPR

Clinical Trials

- **Primary end point**: proptosis responder rate at week 24 (defined as percentage of patients with ≥2mm reduction in proptosis in the study eye from baseline, without deterioration in the non-study eye (≥2mm increase) in proptosis

- Additional evaluations included signs/symptoms of thyroid eye disease including pain, gaze evoked orbital pain, swelling, eyelid erythema, redness, chemosis, inflammation, clinical activity score and assessments of functional vision and patient appearance

MPR

Clinical Trials

- Results showed a proptosis responder rate of 71% and 83% in Tepezza-treated patients compared with 20% and 10% with placebo in Study 1 and Study 2, respectively
- Proptosis (mm) average change from baseline through week 24:
  - Study 1: -2.5 with Tepezza vs -0.2 with placebo
  - Study 2: -2.8 with Tepezza vs -0.5 with placebo
- Tepezza was also associated with improvement in the less severely impacted nonstudy eye

MPR

Clinical Trials

- Subgroup of patients evaluated for diplopia using a 4-point scale where scores ranged from 0 for no diplopia to 3 for constant diplopia
- Diplopia responder was defined as a patient with baseline diplopia >0 and a score of 0 at week 24
- Among these patients, 53% of Tepezza-treated patients (n=35/66) and 25% of placebo-treated patients (n=15/59) were diplopia responders

MPR

Clinical Trials

- Following discontinuation of treatment in Study 1, 53% of patients (n=16/30) who were proptosis responders at week 24 maintained proptosis response 51 weeks after the last Tepezza infusion

- 67% of patients (n=12/18) who were diplopia responders at week 24 maintained diplopia response 51 weeks after the last Tepezza infusion

Clinical Trials

- Examination of age and gender subgroups did not identify differences in response to Tepezza
- Reduction in proptosis was similar between smokers and non-smokers in both studies

MPR

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/tepezza/