

TEPEZZA▼ (teprotumumab)

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions to the Health Products Regulatory Authority (HPRA) using the available methods via www.hpra.ie. Adverse reactions should also be reported to Amgen Limited on +44 (0) 1223 436441 or Freephone 1800 535 160.

Healthcare Professional Guide: Safety of teprotumumab: Hearing Impairment and Embryofetal Toxicity

This guide is essential to ensure the safe use of the product and appropriate management of important selected risks and therefore it is advised to be read carefully before prescribing the medicinal product.

The information in this guide is not intended as a replacement for the Summary of Product Characteristics (SmPC).

Please read the teprotumumab SmPC in conjunction with this guide.

The teprotumumab SmPC is available on the [medicines.ie](https://www.medicines.ie) website under the following link: <https://www.medicines.ie>. To obtain additional copies of the teprotumumab SmPC and Package Leaflet, please contact Amgen UK/Ireland Medical Information on 01223 436441 or 1800 535160 (freephone) or by email to: gbinfoline@amgen.com.

The Healthcare Professional Guide fulfils the conditions of the marketing authorisation and has been approved by the competent authority.

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Contents

Introduction	3
Important Safety Information.....	4
Hearing Impairment Risk.....	4
Embryofetal Toxicity Risk	4
Monitoring and Management of Hearing Impairment Risk	5
Baseline and Ongoing Assessment for All Patients	5
Patients at Higher Risk for Hearing Impairment	6
Patient Counselling Prior to Teprotumumab Treatment	7

Introduction

This guide has been developed for healthcare professionals involved in the care of patients treated with teprotumumab to provide further information about how to minimize or prevent the following risks associated with the use teprotumumab:

- **Hearing impairment**
- **Embryofetal toxicity**

Educating patients about these factors ensures patients are enabled to make informed decisions regarding their treatment options.

Important Safety Information

Hearing Impairment Risk

- ▶ Teprotumumab therapy has been associated with hearing impairment, including symptoms such as deafness, neurosensory hypoacusis, deafness unilateral, eustachian tube dysfunction, eustachian tube patulous, hyperacusis, hypoacusis, autophony and tinnitus and tympanic membrane disorder.
- ▶ For patients with pre-existing hearing impairment, symptoms may worsen during or after treatment with teprotumumab.

Embryofetal Toxicity Risk

- ▶ Teprotumumab may cause harm to an unborn fetus and is contraindicated during pregnancy.
- ▶ Patients should inform their treating physician if they are pregnant or planning to conceive.
- ▶ If a patient becomes pregnant during treatment, the patient must notify their treating physician immediately.
- ▶ Women of childbearing potential should use effective contraception (methods that result in less than 1% pregnancy rates) prior to initiation, during treatment and for 6 months after the last infusion of teprotumumab.
- ▶ If a patient becomes pregnant while taking teprotumumab, therapy should be discontinued, and the patient advised of the potential risk to the fetus.

Monitoring and Management of Hearing Impairment Risk

Baseline and Ongoing Assessment for All Patients

- ▶ Audiometric assessments should be performed before starting treatment (first infusion), during treatment (around the third or fourth dose), and after completing teprotumumab treatment.
- ▶ Symptoms of hearing impairment should be carefully monitored, and any reported hearing issues should prompt immediate evaluation.
- ▶ If a patient experiences subjective hearing changes during treatment, additional audiometric assessments are recommended, as necessary.
- ▶ It is advised to monitor for hearing changes in all patients for 6 months after completion of treatment. Prolonged follow-up may be needed for patients who develop hearing changes, at the discretion of the treating physician.
- ▶ It should be strongly considered to discontinue teprotumumab in patients experiencing hearing loss that requires intervention, limits their ability to self-care, or is considered profound.

Patients at Higher Risk for Hearing Impairment

The information presented in this section is based on the recommendations contained within the 2021 European Group on Graves' Orbitopathy (EUGOGO) Clinical Practice Guidelines for the Medical Management of Graves' Orbitopathy.

Physicians should be particularly vigilant in monitoring hearing function in patients with the following risk factors:

- a** Pre-existing severe hearing loss and history of hearing issues
- b** Age above 65 years
- c** Significant history of smoking
- d** Systemic hypertension
- e** Diabetes mellitus
- f** Chronic exposure to high-intensity ambient noise
- g** Concomitant use of ototoxic medications, including:
 - Platinum-based anticancer agents
 - Aminoglycosides
 - Vancomycin
 - Loop diuretics

Patient Counselling Prior to Teprotumumab Treatment

Before initiating treatment, physicians should discuss the following with the patient:

Potential for Hearing Impairment

- Inform the patient about signs and symptoms of hearing loss and the importance of reporting any changes to their treating physician as soon as possible.
- Inform the patient that teprotumumab may cause hearing loss which in some cases may be permanent.
- Explain that their hearing will be assessed prior to start of first dose, around 3rd or 4th dose and after the last dose.
- Explain that their hearing will be assessed for 6 months after the last dose of teprotumumab if necessary.
- Explain that their hearing may be monitored for longer than 6 months if the patient develops changes in hearing.

Embryofetal Toxicity Risks

- Inform the patient that teprotumumab can cause harm to the unborn fetus.
- Confirm whether the patient is pregnant or planning pregnancy.
- Reinforce the need for effective contraception during treatment.
- Advise patients to notify their treating physician immediately if they become pregnant.

Patient Guide

- Each patient should receive a patient guide outlining the risks of hearing impairment and embryofetal toxicity and the package leaflet to keep as a reference throughout their treatment.