

TEPEZZA▼ (teprotumumab)

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. Side effects can be reported directly to Health Products Regulatory Authority (HPRA) using the available methods via www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Amgen Limited on +44 (0) 1223 436441 or Freephone 1800 535 160.

Patient Guide: Understanding the Risks of Hearing Problems and Harm to an Unborn Baby

This guide explains the risk of hearing problems and potential harm to an unborn baby that may happen with teprotumumab treatment. Keep this guide safe to refer to at any time during or after your treatment.

The information in this guide is not intended to take the place of discussions with your doctor or other healthcare professionals.

For complete information on the side effects of teprotumumab, you should read the Package Leaflet.

If you have any questions about teprotumumab, please speak to your doctors or nurses, or refer to the Package Leaflet on the [medicines.ie](http://www.medicines.ie) website under the following link: <https://www.medicines.ie>. To obtain additional copies of the Package Leaflet, please contact Amgen UK/Ireland Medical Information on 01223 436441 or 1800 535160 (freephone) or by email to gbinfoline@amgen.com.

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

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Important Safety Information

Hearing Problems

- Teprotumumab may cause hearing problems, including severe hearing loss, which may be permanent. If you already have hearing issues, these might get worse during treatment or after treatment has stopped.
- Tell your healthcare provider of all medicines you are taking including over the counter and herbal products.
- If you start any new medicines while on treatment, be sure to tell your healthcare provider right away.

Before Starting Teprotumumab

Talk to your doctor or nurse if you:

- Have had hearing problems or use hearing aids
- Are sensitive to loud sounds
- Have diabetes or pre-diabetes
- Smoke
- Have had high blood pressure in the past

You should quit smoking before starting treatment, and your doctor may need to check your blood pressure before and during Teprotumumab.

Signs of Hearing Problems

Look out for these signs:

- Partial or total loss of hearing
- Ringing or buzzing in your ears
- Feeling like your ears are blocked or have pressure
- Hearing your own voice louder than normal
- Sounds seem muffled or unclear

If you notice any of these, tell your doctor right away.

You should avoid loud noises during treatment with teprotumumab.

Hearing Checkups

Your doctor will check your hearing at these times:

- Before you start teprotumumab
- During treatment
- After treatment is finished

If you have hearing problems during treatment, your doctor may recommend more hearing tests to check on you.

After Treatment Monitoring

Your doctor will check your hearing for 6 months after you finish teprotumumab.

Stopping Treatment

Your doctor might stop your teprotumumab treatment if you develop hearing problems that:

- Need medical treatment
- Make daily tasks harder
- Keep getting worse

Preventing Harm to Unborn Babies

Teprotumumab and Pregnancy

- Do NOT use teprotumumab if you are pregnant
- Teprotumumab can harm your unborn baby
- If you think you may be pregnant, are pregnant or planning to have a baby, talk to your doctor or nurse before starting this medicine.
- Tell your treating doctor right away if you become pregnant while taking teprotumumab.

Important Safety Information

Birth Control While Using Teprotumumab

If you can get pregnant, you must use an effective method of birth control:

- While taking teprotumumab
- For at least 6 months after your last dose

Talk to your doctor about the best birth control options for you.