

TEPEZZA

(teprotumumab)

AMGEN



Patient Guide

Important Safety Information

Hearing Problems and Serious Problems Due To High Blood Sugar Levels

Understanding the Risks of Hearing Problems, Serious Problems Due to High Blood Sugar Levels and Harm to an Unborn Baby

This guide explains the risk of hearing problems, serious problems due to high blood sugar levels and potential harm to an unborn baby that may happen with TEPEZZA treatment. Keep this guide safe to refer to at any time during or after your treatment.

TEPEZZA may cause hearing problems, or make your blood sugar levels very high, and sometimes it does not get better. If you already have hearing issues, diabetes or higher than normal blood sugar levels, these may worsen during treatment or after treatment has stopped. High blood sugar levels can cause serious health problems like diabetic ketoacidosis (DKA) or hyperosmolar hyperglycemic state (HHS). These conditions are rare but serious and therefore need immediate medical care.



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



- *Tell your healthcare provider of all medicines you are taking including insulin, diabetes medicines, 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 TEPEZZA

Talk to your doctor or nurse if you:

- Have had hearing problems or use hearing aids
- Are sensitive to loud sounds
- Have diabetes or higher than normal blood sugar levels
- Smoke
- Have had high blood pressure or blood sugar levels in the past
- Have recently been sick or had an infection
- Feel very thirsty or have trouble drinking enough water



Before starting treatment, you are advised to quit smoking. Your doctor will also assess your hearing and ensure that your blood sugar and blood pressure levels are well controlled. Tell your doctor about any existing hearing problems, use of hearing aids, sensitivity to loud noises, or history of diabetes or high blood sugar levels.

During TEPEZZA Treatment

You should avoid loud noises during treatment with TEPEZZA.



Symptoms of Hearing Problems

Look out for these symptoms:

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



Symptoms of High Blood Sugar

Look out for these symptoms:

- Feeling very thirsty and urinating more than usual
- Stomach pain
- Change in smell of urine and sweat
- Feeling sick or vomiting
- Feeling confused, sleepy, or weak
- Breathing fast or breath that smells fruity
- Severe dryness in your mouth and feeling very dehydrated

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



Hearing and Blood Sugar Level Monitoring

During your treatment with TEPEZZA, your doctor will regularly monitor your hearing and blood sugar levels. If you notice any changes in your hearing or experience symptoms of high blood sugar, tell your doctor as soon as possible so that they can perform additional tests if needed.



Stopping Treatment

Your doctor may stop your TEPEZZA treatment if you develop hearing problems or blood sugar complications that require medical treatment, interfere with your daily activities, or continue to worsen.

After TEPEZZA Treatment

Your doctor will continue to monitor your hearing and blood sugar levels for 6 months after you complete TEPEZZA treatment.

Preventing Harm to Unborn Babies

Important Pregnancy Information

- You must NOT use TEPEZZA if you are pregnant.
- TEPEZZA may cause harm your unborn baby.
- If you are pregnant, think you may be pregnant or if you are planning to have a baby, talk to your doctor for advice before starting this medicine.
- Your doctor may require you to take a pregnancy test before starting TEPEZZA treatment.
- Tell your treating doctor right away if you become pregnant while taking TEPEZZA.

Birth Control Requirements

If you are able to get pregnant, you must use effective contraception:

- Before initiating TEPEZZA treatment
- During TEPEZZA treatment
- For at least 6 months after your last dose of TEPEZZA



Discuss the appropriate contraceptive options with your doctor.



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