

Dr. Raymond Douglas: I'm Dr. Raymond Douglas. I'm a professor of ophthalmology at Cedars-Sinai Medical Center and also in private practice in Beverly Hills. I am an oculoplastic and orbital surgeon. I spend most of my time dealing with and trying to help patients with Thyroid Eye Disease and other orbital problems.

I was also the investigator on phase two and the co-principal investigator on phase three for the clinical trial looking at teprotumumab for Thyroid Eye Disease.

The most common side effects that were observed with TEPEZZA were muscle spasms. There were also other symptoms, including diarrhea, and there was also mild hair loss, and this was all over the body, and wasn't subject to one particular location.

For example, there was some thinning on scalp hair, but many patients also noted that their body hair became thinner during the course of TEPEZZA.

Hearing impairment was also noted with TEPEZZA. This was relatively mild to moderate for the patients who reported it.

One thing to consider in use of TEPEZZA is if you have a history of inflammatory bowel disease. TEPEZZA could make inflammatory bowel disease worse or the symptoms of that disease worse. It would be good to have the disease under control prior to initiation of TEPEZZA, and to certainly review the risk and benefits with your physician.

TEPEZZA can cause an increase in blood sugar, so anyone who has diabetes or maybe even pre-diabetic where this is followed with their physician, should consult their physician prior to taking TEPEZZA to know and to follow their blood glucose levels throughout treatment.

Typically, TEPEZZA infusions were very well tolerated in the clinical trial. There were three patients who had infusion reactions. These were relatively mild and well controlled, and there were no anaphylactic reactions that occurred during treatment with TEPEZZA.

INDICATION AND IMPORTANT SAFETY INFORMATION

USE:

TEPEZZA is a prescription medicine used to treat Thyroid Eye Disease.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about TEPEZZA?

Infusion reactions can happen during or within 24 hours after your infusion of TEPEZZA. If you have a reaction while receiving TEPEZZA, your doctor or nurse will slow or stop your infusion and treat your reaction. If you have a severe infusion reaction, your doctor may stop your treatment completely.

Tell your doctor or nurse right away if you have any of these symptoms during or after your treatment with TEPEZZA:

- **High blood pressure**
- **Fast heartbeat**
- **Redness of the face/Feeling hot**
- **Difficulty breathing**
- **Headache**
- **Muscle pain**

If you have inflammatory bowel disease (IBD), such as Crohn's disease or ulcerative colitis, TEPEZZA may make your IBD symptoms worse. Symptoms of worsening IBD may include: an increased number of loose stools with stomach pain or cramps, and blood in your stools. After each TEPEZZA infusion, tell your doctor right away if you have worsening IBD symptoms.

TEPEZZA may cause an increase in your blood sugar. Before starting treatment with TEPEZZA, tell your doctor if you are currently being treated for diabetes, know your blood sugar is high, or have been diagnosed with diabetes. It is important for you to take your treatments and follow an appropriate diet for glucose control as prescribed by your doctor.

Before receiving TEPEZZA, tell your doctor if you:

- Have inflammatory bowel disease (Crohn's disease or ulcerative colitis).
- Are currently being treated for diabetes, have been diagnosed with diabetes, or know your blood sugar is high.
- Are pregnant or plan to become pregnant. TEPEZZA may harm your unborn baby. Tell your doctor if you become pregnant or suspect you are pregnant during treatment with TEPEZZA.
 - Women who are able to become pregnant should use an effective form of birth control (contraception) prior to starting treatment, during treatment and for at least 6 months after the final dose of TEPEZZA.
- Are breastfeeding or plan to breastfeed. It is not known if TEPEZZA passes into your breast milk. Talk to your doctor about the best ways to feed your baby during treatment with TEPEZZA.
- Tell your doctor about all the medicines you take, including prescription and over the counter medicines, vitamins, dietary and herbal supplements. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

What are the possible side effects of TEPEZZA?

The most common side effects of TEPEZZA include muscle cramps or spasms, nausea, hair loss, diarrhea, feeling tired, high blood sugar, hearing problems, taste changes, headache, and dry skin.

This is not a complete list of all possible side effects. Tell your doctor or treatment team if you have any side effect that bothers you or that does not go away.

Please visit TEPEZZA.com for more information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/safety/medwatch, or call the FDA at 1-800-FDA-1088.