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Tepezza (*teprotumumab*)

An overview of Tepezza and why it is authorised in the EU

What is Tepezza and what is it used for?

Tepezza is a medicine used to treat adults with moderate to severe thyroid eye disease (TED, also known as Graves' eye disease), an autoimmune disease that triggers inflammation of muscles, fat, and other tissues around and behind the eyes. This can push the eyes forward causing them to bulge. An autoimmune disease is caused by the body's own defence system attacking normal tissue.

Tepezza contains the active substance teprotumumab.

How is Tepezza used?

Tepezza is given as an infusion (drip) into a vein, once every three weeks for a total of eight infusions.

Tepezza can only be obtained with a prescription. Treatment must be started and supervised by a doctor with experience in the diagnosis and treatment of TED. The medicine should be given by a healthcare professional and under the supervision of a doctor with access to appropriate support to manage possible reactions linked to the infusion.

If an allergic reaction or another type of reaction to the infusion occurs during the first two doses of Tepezza, patients should be given an antihistamine, antipyretic (to prevent fever) or corticosteroid medicine before all subsequent infusions; infusions should also be given more slowly.

For more information about using Tepezza, see the package leaflet or contact your doctor or pharmacist.

How does Tepezza work?

The way Tepezza works is not fully understood. The active substance in Tepezza, teprotumumab, is a monoclonal antibody (a type of protein) that attaches to the receptor (target) for insulin-like growth factor 1. In people with TED this receptor is present at high levels in tissues around the eyes and it is therefore thought to be involved in causing the disease symptoms. By attaching to the receptor, Tepezza blocks its activity, which is thought to help stop the development and progression of TED.

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What benefits of Tepezza have been shown in studies?

Tepezza was investigated in four main studies; three studies involved patients with active TED, and one study involved patients with chronic (long-term) TED. In all studies, treatment with Tepezza was compared with placebo (a dummy treatment) and only one eye per person (the study eye) was evaluated.

One study involved 88 patients with active TED; the main measure of effectiveness was the percentage of patients who responded to Tepezza after 24 weeks of treatment. Response was defined as a decrease of at least 2 points on the clinical activity score (CAS, a measure of disease activity), a reduction in proptosis (bulging of the eye) of at least 2 mm, and no worsening of CAS or proptosis in the non-study eye. In the study, 69% (29 out of 42) of patients given Tepezza responded to treatment, compared with 20% (9 out of 45) of patients given placebo.

A second study involving 83 patients with active TED showed that 83% (34 out of 41) of patients given Tepezza had a reduction in proptosis of at least 2 mm in the study eye after 24 weeks of treatment, compared with 10% (4 out of 42) of patients receiving placebo. In a third study involving 54 patients, these figures were 89% (24 out of 27) in patients given Tepezza and 11% (3 out of 27) in patients given placebo.

A fourth study involving 62 patients with chronic TED looked at the change in proptosis after 24 weeks of treatment; patients treated with Tepezza had an average reduction in proptosis of 2.4 mm, compared with 0.9 mm for patients given placebo.

What are the risks associated with Tepezza?

For the full list of side effects and restrictions with Tepezza, see the package leaflet.

The most common side effects with Tepezza (which may affect more than 1 in 10 people) include muscle spasms, diarrhoea, alopecia (hair loss), high blood glucose levels, tiredness, nausea (feeling sick) and headache.

Some side effects can be serious. The most important serious side effects include diabetic ketoacidosis (a dangerous condition with high blood levels of ketones), hearing problems including hearing loss, diarrhoea, reactions related to the infusion, diabetes and inflammatory bowel disease.

Tepezza must not be used during pregnancy.

Why is Tepezza authorised in the EU?

Tepezza was shown to be effective at treating patients with active TED in three main studies. The available data are also considered sufficient to support the use of Tepezza in patients with chronic TED. With regard to safety, the risks of hearing problems and of harm to the unborn baby with Tepezza are adequately addressed and are considered to be manageable with the proposed risk minimisation measures, including educational materials for patients and healthcare professionals.

The European Medicines Agency therefore decided that Tepezza’s benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Tepezza?

The company that markets Tepezza will provide educational materials for healthcare professionals and a guide for patients with information about the risk of hearing impairment, its signs and symptoms, and about the risk of harm to an unborn child with Tepezza.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Tepezza have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Tepezza are continuously monitored. Suspected side effects reported with Tepezza are carefully evaluated and any necessary action taken to protect patients.

Other information about Tepezza

Tepezza received a marketing authorisation valid throughout the EU on 19 June 2025.

Further information on Tepezza can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/tepezza

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