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Summary report on authorisation dated 26 November 2025

Tepezza® (active substance: teprotumumab)

Authorisation in Switzerland: 30 April 2025

Powder for concentrate for solution for infusion to treat adults with moderate to severe thyroid eye disease (TED)

About the medicinal product

Tepezza contains the active substance teprotumumab and is a monoclonal antibody – these are proteins that bind in a targeted manner to specific structures in the body and can thereby inhibit excessive immune system reactions.

Tepezza is used for the treatment of adults with moderate to severe active thyroid eye disease (TED). This disease is also known as endocrine orbitopathy and occurs frequently in people with Graves' disease.

TED is an autoimmune disease, which means the body's own immune system mistakenly attacks the body's own tissues. This results in inflammation and swelling of the tissue behind the eyes.

Those affected often suffer from bulging eyes (proptosis), pain, swelling, sensitivity to light, and sometimes also visual impairment.

Tepezza aims to relieve the symptoms and slow progression of the disease. This treatment is aimed at patients with severe cases of TED.

Mode of action

Tepezza acts by binding in a targeted manner to a specific receptor on cells in the tissue behind the eyes, known as insulin-like growth factor-1 receptor (IGF-1R). This receptor is overactive in individuals with TED and contributes to the inflammation behind the eyes. By binding, Tepezza can prevent the activation of this receptor, thereby alleviating the inflammation. The tissue behind the eyes swells up less, reducing the symptoms of the disease, such as bulging eyes, pain, and swelling.

Administration

Tepezza is a prescription-only medicine.
Tepezza is administered as an intravenous infusion and is supplied as a powder for solution for infusion.

Each vial contains 500 mg of the active substance teprotumumab.
Treatment begins with a starting dose of 10 mg per kilogram body weight. This is followed by 7 further infusions of 20 mg per

kilogram body weight, administered at 3 week intervals.
The first 2 infusions are administered over at least 90 minutes. If no problems occur, the following infusions can be given over around 60 minutes.
Tepezza must be prepared and administered by a healthcare professional and under the supervision of a physician.

Efficacy

The efficacy of Tepezza was investigated in a number of clinical studies in patients with moderate to severe active TED.

The Phase III OPTIC (HZNP-TEP-301) study, which was pivotal for authorisation, was central.

In this study, 83 patients were treated with either Tepezza or a placebo (dummy drug) over a period of 24 weeks. The aim was to evaluate the change in proptosis (bulging eyes) and disease activity. 83% of those treated with Tepezza achieved a clinically relevant improvement in proptosis, compared with 10% in the placebo group. The clinical activity score (CAS) also improved significantly with Tepezza.

A previous Phase II study (TED01RV) in 87 subjects had already shown comparable efficacy (overall responder rate 69% with Tepezza vs. 20% with placebo).

The efficacy was also confirmed in a Phase III study in Japan (OPTIC-J) in 89 patients over a treatment duration of 24 weeks.

These studies illustrate the efficacy of Tepezza in the treatment of TED, as the progress of the eye disease was slowed and symptoms were reduced.

Precautions, undesirable effects, & risks

Tepezza must not be used in those who are hypersensitive to the active substance or any of the excipients. Tepezza must not be used during pregnancy and breastfeeding.

The most common undesirable effects (affecting more than 10% of patients) are muscle spasms, diarrhoea, hearing impairment, hair loss (alopecia), fatigue, menstrual disorders, elevated blood sugar (hyperglycaemia), headache, and nausea.

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

There is a need for an effective therapy for patients with moderate to severe active TED, as traditional treatments such as glucocorticoids may be insufficient and may be associated with adverse effects.

The Phase III OPTIC study showed that patients who received Tepezza achieved a significant reduction in bulging eyes and an improvement in disease activity.

Tepezza acts by blocking the IGF-1 receptor, thereby reducing disease progression and symptoms. Despite frequent reports of side effects such as muscle spasms and hearing impairment, the benefits outweigh these based on the proven efficacy in clinical studies.

Taking into account all risks and precautions, and based on the available data, the benefits of Tepezza outweigh the risks in patients with moderate to severe active TED. Swissmedic has therefore authorised the medicinal product Tepezza, containing the active substance teprotumumab, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Tepezza®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

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