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Tezspire (*tezepelumab*)

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

What is Tezspire and what is it used for?

Tezspire is a medicine used to treat:

- severe asthma in adults and adolescents (12 years of age and older). It is used as an additional treatment in adults and adolescents with severe asthma that is not adequately controlled by a combination of high-dose corticosteroids taken by inhalation plus another asthma medicine;
- severe chronic (long-term) rhinosinusitis with nasal polyps (inflamed lining of the nose and sinuses with growths in the nose) in adults. Tezspire is used with a corticosteroid given into the nose when treatment with a corticosteroid given by mouth or injection and/or surgery, does not work well enough.

Tezspire contains the active substance tezepelumab.

How is Tezspire used?

Tezspire can only be obtained with a prescription, and treatment should be initiated by a doctor with experience in diagnosing and treating the conditions that Tezspire is used to treat.

Tezspire is injected under the skin every 4 weeks. This medicine is used for long-term treatment. Every year the doctor will decide whether to continue treatment, based on how well the patient's condition is controlled.

The patient or their caregiver may inject the medicine themselves after they have received training.

Tezspire should not be used to treat asthma attacks. Patients should contact their doctor if their asthma remains uncontrolled or worsens after starting this medicine.

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

How does Tezspire work?

In patients with asthma and chronic rhinosinusitis with nasal polyps, a protein called thymic stromal lymphopoietin (TSLP) plays a role in the immune response that causes inflammation in the airways. The active substance in Tezspire, tezepelumab, is an antibody (a type of protein) that prevents TSLP

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

from attaching to its receptor (target). This reduces inflammation in the airways and the lining of the nose and sinuses which improves disease symptoms.

What benefits of Tezspire have been shown in studies?

Asthma

Two main studies including over 1,500 adults and adolescents with inadequately controlled asthma showed that Tezspire was effective in reducing the number of severe asthma flare-ups.

In the first study, patients given Tezspire had on average 0.93 asthma flare-ups per year after one year of treatment compared with 2.10 in patients given placebo (a dummy treatment). In the second study, patients taking Tezspire had an average of 0.20 flare-ups per year after one year, compared with 0.72 in patients who received placebo.

Chronic rhinosinusitis with nasal polyps

A main study involving 410 adults with chronic rhinosinusitis with nasal polyps showed that Tezspire was more effective than placebo at reducing the size of the polyps and improving symptoms of the condition. The main measures of effectiveness were the nasal polyp score, which measures the size of polyps (each nostril is rated from 0, no polyps, to 4, complete blockage), as well as the average change in patient's nasal congestion score. The nasal congestion score assesses how symptoms impact daily life; scores range from 0 (no symptoms) to 3 (severe congestion). After 1 year of treatment, adults given Tezspire had an average reduction of around 2.5 in their nasal polyp score compared with an average reduction of around 0.4 for those given placebo. After 1 year of treatment, adults given Tezspire had an average reduction of around 1.7 in their nasal congestion score compared with an average reduction of around 0.7 for those given placebo.

What are the risks associated with Tezspire?

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

The most common side effects with Tezspire (which may affect up to 1 in 10 people) when used for the treatment of asthma include arthralgia (joint pain) and pharyngitis (sore throat). The most common side effect with Tezspire (which may affect up to 1 in 10 people) when used for the treatment of chronic rhinosinusitis is pharyngitis (sore throat).

Why is Tezspire authorised in the EU?

The Agency considered that Tezspire was effective at reducing severe asthma flareups and improving symptoms of chronic rhinosinusitis with nasal polyps, as well as the size of the polyps. Regarding safety, side effects related to Tezspire were considered manageable.

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

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

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

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

Other information about Tezspire

Tezspire received a marketing authorisation valid throughout the EU on 19 September 2022.

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

This overview was last updated in 10-2025.