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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 adults and adolescents (12 years of age and older) with severe asthma. 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.

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 severe asthma.

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 the patient's level of asthma control.

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, a protein called thymic stromal lymphopoietin (TSLP) plays a role in the immune response that causes inflammation in the airway. The active substance of Tezspire, tezepelumab, is an antibody (a type of protein) that prevents TSLP from attaching to its receptor and thereby reduces airway inflammation and asthma symptoms.

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What benefits of Tezspire have been shown in studies?

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.

What are the risks associated with Tezspire?

The most common side effects with Tezspire (which may affect up to 1 in 10 people) are arthralgia (joint pain) and pharyngitis (sore throat).

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

Why is Tezspire authorised in the EU?

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

The Agency considered that Tezspire was effective at reducing severe asthma flare-ups. Regarding safety, side effects related to Tezspire were considered manageable.

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

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