swissmedic

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Tezspire® (active substance: tezepelumab)

First authorisation in Switzerland: 13 June 2022

Medicinal product (pre-filled syringe) for second-line treatment of severe asthma in adults

About the medicinal product

The medicinal product Tezspire, containing the active substance tezepelumab, is used in addition to other inhaled asthma medications in severe asthma in adults. It is used when the disease cannot be adequately controlled by the currently prescribed asthma medications alone (add-on treatment).

The term "asthma" refers to a group of chronic inflammatory respiratory diseases attributable to various causes, whose symptoms may vary in severity.

Mode of action

The active substance tezepelumab is a monoclonal antibody (specially developed and manufactured protein) that binds to and blocks a protein produced by the body known as thymic stromal lymphopoietin (TSLP). TSLP plays an important role in the development of inflammation in the airways, which can lead to asthma. Tezepelumab should prevent this process.

Use

Tezspire, containing the active substance tezepelumab, is a prescription-only medicine.

Tezspire is a solution for injection in a pre-filled syringe for injection under the skin. Each single-use pre-filled syringe contains 210 mg tezepelumab. The recommended dose is 210 mg Tezspire administered every four weeks. Tezspire is used for long-term treatment.

The doctor decides whether the patient is able to administer Tezspire themself or whether this should be done by a caregiver after training.

Efficacy

The efficacy of Tezspire was investigated in three pivotal studies (PATHWAY, SOURCE and NAVIGATOR). More than 1,500 patients with inadequately controlled asthma received either Tezspire or a placebo (dummy drug). The treatment duration was 48 to 52 weeks.

In the PATHWAY study, there were 0.2 asthma attacks per year in patients who received Tezspire compared to an average of 0.72 per year in patients who received the placebo. In the SOURCE study, the frequency was 1.38 asthma attacks per year in patients who received Tezspire compared to 1.82 per year in those who received the placebo. The average frequency of asthma attacks in the NAVIGATOR study was 0.93 per year in patients who received Tezspire compared to 2.1 per year in patients who received the placebo. The average frequency of asthma attacks was statistically significantly reduced during treatment with Tezspire in the PATHWAY and NAVIGATOR studies.

Further data on long-term safety and the effects of Tezspire following recent vaccination will be collected once the product has been launched on the market.

Precautions, undesirable effects & risks

Tezspire must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects are inflammation of the throat, reactions at the injection site, joint pain and rash.

All precautions, risks and other possible side effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

The studies showed that patients who received Tezspire suffered severe asthma attacks less frequently than those who received the placebo.

Taking all the risks and precautions into account, and based on the available data, the benefits of Tezspire outweigh the risks.

Swissmedic has therefore authorised the medicinal product Tezspire, containing the active substance tezepelumab, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Tezspire®

Information for patients (package leaflet): Information for patients Tezspire®

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 Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.