swissmedic

Summary report on authorisation dated 20 March 2026

Tezspire® (active substance: tezepelumab)

Indication extension in Switzerland: 20 November 2025

Medicinal product (pre-filled syringe/pre-filled pen) for the treatment of adults with severe chronic rhinosinusitis with nasal polyps (CRSwNP)

About the medicinal product

Tezspire contains the active substance tezepelumab.

Tezspire was authorised on 13 June 2022 for the second-line treatment of severe asthma in adults.

The current indication extension means that Tezspire can now be used for the treatment of adults with severe chronic rhinosinusitis with nasal polyps (CRSwNP). This disease is characterised by a long-term inflammation of the paranasal sinuses that causes polyps to form in the nose, leading to symptoms such as the loss of the sense of smell, nasal congestion and facial pressure. Tezspire is used in addition to other treatments when the illness cannot be adequately controlled by systemic corticosteroids or surgical procedures.

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 CRSwNP. Tezepelumab is designed to prevent this process.

Administration

Tezspire is a prescription-only medicine.

Tezspire is a solution for injection in a pre-filled syringe or pre-filled pen for injection under the skin. Each pre-filled syringe or pre-filled pen contains 210 mg tezepelumab. The recommended dose is 210 mg Tezspire administered every four weeks.

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

Efficacy

In the WAYPOINT study, the efficacy of Tezspire was investigated over 52 weeks in adults with chronic rhinosinusitis with nasal polyps (CRSwNP) that could not be adequately controlled with systemic corticosteroids or surgical procedures. Every four weeks the participants received either Tezspire 210 mg or a placebo (dummy drug) in addition to their existing treatment with intranasal corticosteroids. The group treated with Tezspire showed both a reduction in nasal polyps and an improvement in nasal congestion compared to the placebo group.

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 effect (affecting more than one in ten users) is inflammation of the nose and throat.

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

Why the medicinal product has been authorised

The study showed that patients with chronic rhinosinusitis with nasal polyps (CRSwNP) treated with Tezspire experienced a reduction in nasal polyps and an improvement in nasal congestion compared to 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, in Switzerland for the treatment of adults with severe chronic rhinosinusitis with nasal polyps (CRSwNP).

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Tezspire®

Information for patients (package leaflet):

Tezspire, pre-filled syringe: Information for patients Tezspire®

Tezspire, pre-filled pen: 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 Summary report on authorisation.

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.