swissmedic

Summary report on authorisation dated 5 December 2025

Tevimbra® (active substance: tislelizumab)

Indication extension in Switzerland: 3 July 2025

Concentrate for solution for infusion, in combination with platinum- and fluoropyrimidine-based chemotherapy, for the first-line treatment of adults with HER-2-negative, locally advanced, unresectable or metastatic adenocarcinoma of the stomach or gastro-oesophageal junction, whose tumours express PD-L1 with a tumour area positivity (TAP) score of ≥ 5 %

About the medicinal product

Tevimbra contains the active substance tislelizumab.

Tevimbra is used together with specific chemotherapies (platinum- and fluoropyrimidine-based active substances) for the first-line treatment of adults suffering from advanced, unresectable or already spread (metastatic) stomach cancer or a tumour at the junction between the oesophagus and stomach (gastro-oesophageal junction).

The treatment is considered as an option if the tumour does not carry the so-called "HER2-receptor" (is HER2-negative), but a specific surface feature known as a PD-L1 protein is detectable in at least 5 % of the tumour tissue (TAP score ≥ 5 %).

Tevimbra was first authorised by Swissmedic on 11 April 2024, with a subsequent indication extension on 3 July 2025 for the first-line treatment, in combination with platinum-based chemotherapy, of adults with unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma, whose tumours express PD-L1 with a TAP score of ≥ 5 %.

Mode of action

The active substance in Tevimbra, tislelizumab, is a monoclonal antibody (immunologically active protein) that binds to a specific protein known as PD-1 (programmed cell death receptor-1) and thereby prevents it from binding to the PD-ligand (programmed cell death-ligand). As a result, the immune response is inhibited, and the growth of the cancer can be delayed or stopped.

Administration

Tevimbra is a prescription-only medicinal product that is available as a concentrate for solution for infusion. The recommended dose of Tevimbra is 200 mg and is administered every 3 weeks as an intravenous infusion (into the veins).

Efficacy

The efficacy of Tevimbra in combination with chemotherapy was compared in the pivotal trial BGB-A317-305 with that of placebo (dummy drug) in combination with chemotherapy in patients with previously untreated, locally advanced or metastatic gastric or gastro-oesophageal junction adenocarcinoma. Of the total of 997 study participants, 546 had a PD-L1 score of ≥ 5 %.

The study revealed that the treatment with Tevimbra in combination with chemotherapy significantly prolonged overall survival (OS)[1] compared to placebo in combination with chemotherapy in patients with a PD-L1 score of ≥ 5 %. The patients who received Tevimbra had a median[2] OS of 16.4 months compared to 12.8 months in those in the placebo group.

In patients with low or no PD-L1 expression, the addition of Tevimbra to the chemotherapy showed no clear benefit.

The benefit of the treatment with Tevimbra in patients with a PD-L1 score of ≥ 5 % was also evident in the prolongation of progression-free survival (PFS)[3] by 7.2 months compared to 5.9 months in the placebo group.

Precautions, undesirable effects, & risks

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

The most frequent adverse effects (affecting more than 1 in 10 patients) are reduced counts of white blood cells (leukocytes, neutrophils) and platelets (thrombocytes) in the blood, reduced lymphocyte count, low haemoglobin (blood pigment), lack of thyroid hormones (hypothyroidism), lower potassium and sodium levels, increased potassium levels, diarrhoea, cough, stomatitis (inflammation of the lining of the mouth), increased levels of aspartate aminotransferase, alanine aminotransferase[4], alkaline phosphatase and bilirubin[5], lower albumin levels, elevated creatine kinase (heart and skeletal muscle enzyme), elevated creatinine (kidney function indicator), rash, fatigue and fever.

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

[1] Overall survival: Overall survival (OS) refers to the period between the start of treatment and the death of the patient.

[2] Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always less than the median, the other half are always greater.

[3] PFS: progression-free survival. Period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

[4] Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) are enzymes produced mainly in the liver. Elevated levels of activity of these enzymes in the blood may indicate liver-related diseases.

[5] Bilirubin forms as a result of the breakdown of the blood pigment haemoglobin, and an elevated bilirubin level in the blood may be a sign of liver damage.

Why the medicinal product has been authorised

Locally advanced, unresectable or metastatic adenocarcinoma of the stomach or gastro-oesophageal junction is difficult to treat and has a high mortality rate. Existing treatments are often inadequate, particularly for HER2-negative forms, which do not respond to conventional treatments. Tevimbra, in combination with platinum- and fluoropyrimidine-based chemotherapy, offers a new treatment option. Studies have shown that this medicinal product improves overall survival in affected patients, particularly in those with a PD-L1 expression ≥ 5 %.

Taking all the risks and precautions into account, and based on the available data, the benefits of this indication extension for Tevimbra outweigh the risks. Swissmedic has therefore extended the authorisation for use in Switzerland of the medicinal product Tevimbra, containing the active substance tislelizumab, for the first-line treatment, in combination with platinum- and fluoropyrimidine-based chemotherapy, of adults with locally advanced, unresectable or metastatic HER-2-negative adenocarcinoma of the stomach or gastro-oesophageal junction, whose tumours express PD-L1 with a tumour area positivity (TAP) score of ≥ 5 %.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Tevimbra®

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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