



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/193656/2025
EMA/H/C/005919

Tevimbra (*tislelizumab*)

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

What is Tevimbra and what is it used for?

Tevimbra is a cancer medicine used to treat the following:

- Non-small cell lung cancer (NSCLC), a type of lung cancer
- Small cell lung cancer (SCLC), a type of lung cancer
- Gastric or gastroesophageal junction adenocarcinoma, a type of stomach cancer
- Oesophageal squamous cell carcinoma (OSCC), a type of oesophageal (gullet) cancer
- Nasopharyngeal carcinoma (NPC), a type of head and neck cancer.

The medicine is used in adults.

Tevimbra is mainly used when the cancer is advanced, unresectable (cannot be removed by surgery) or metastatic (has spread to other parts of the body), or when other treatments do not work.

For some cancers, Tevimbra is only given to patients whose tumours produce certain levels of a protein known as PD-L1.

In some patients with NSCLC, Tevimbra can be given before (neoadjuvant treatment) and after (adjuvant treatment) surgery.

Depending on the cancer being treated, Tevimbra can be used on its own or in combination with other cancer medicines.

Tevimbra contains the active substance tislelizumab.

How is Tevimbra used?

Treatment with Tevimbra must be started and supervised by a doctor experienced in treating cancer. The medicine can only be obtained with a prescription.

Tevimbra is given as an infusion (drip) into a vein every 3 or 6 weeks, and treatment can continue until the disease gets worse or side effects become unacceptable. The doctor may delay doses if certain side effects occur or stop treatment altogether if side effects are severe.



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

How does Tevimbra work?

The active substance in Tevimbra, tislelizumab, is a monoclonal antibody, a protein that has been designed to block a receptor (target) called PD-1 on certain cells of the immune system (the body's natural defences). Some cancers can make proteins (PD-L1 and PD-L2) that combine with PD-1 to switch off the activity of the immune cells, preventing them from attacking the cancer. By blocking PD-1, tislelizumab stops the cancer switching off these immune cells, thereby increasing the ability of the immune system to kill the cancer cells.

What benefits of Tevimbra have been shown in studies?

Non-small cell lung cancer (NSCLC)

In a study in 360 patients with a type of NSCLC known as squamous NSCLC, patients who received Tevimbra in combination with chemotherapy lived longer without their disease getting worse than those given only chemotherapy: around 7.7 months and 9.6 months, depending on the combination, compared with 5.5 months for chemotherapy alone.

In another study involving 334 patients with non-squamous NSCLC whose tumours tested strongly for PD-L1, patients who received Tevimbra with chemotherapy lived for around 14.6 months without their disease getting worse compared with 4.6 months for patients receiving chemotherapy alone. In both combination studies, patients given Tevimbra also lived longer on average.

A third study, involving 805 patients with NSCLC who had previously had chemotherapy, showed that Tevimbra alone was more effective than docetaxel. In this study, patients who received Tevimbra lived on average for around 17 months while patients treated with docetaxel lived on average for around 12 months.

A fourth study in 453 patients looked at how effective Tevimbra is when given with chemotherapy before surgery and then on its own after surgery to help prevent the cancer from coming back. After around 36 months, 32% of those who had Tevimbra had a worsening or recurrence of the cancer or had died compared with 43% of those given placebo (a dummy treatment) in place of Tevimbra. In addition, 56% of those given Tevimbra had 10% or less of viable tumour remaining compared with 15% of those given placebo.

Small Cell Lung Cancer (SCLC)

Tevimbra was shown to be effective in improving survival in a main study involving 457 adults with extensive-stage SCLC who had not been previously treated for extensive-stage SCLC. In the study, patients were given either Tevimbra or placebo (a dummy treatment), each used alongside chemotherapy medicines (platinum-based chemotherapy and etoposide). Patients given Tevimbra with chemotherapy lived on average for 15.5 months compared with 13.5 months for those given placebo with chemotherapy.

Oesophageal squamous cell carcinoma (OSCC)

A main study involved 512 adults with advanced or metastatic squamous oesophageal cancer whose disease had worsened after treatment with platinum-based chemotherapy. Patients treated with Tevimbra lived on average for 8.6 months compared with an average of 6.3 months for patients treated with other cancer medicines (paclitaxel, docetaxel or irinotecan).

Another main study in 649 patients with unresectable, locally advanced, recurrent or metastatic squamous oesophageal cancer compared treatment with Tevimbra in combination with chemotherapy with treatment with placebo plus chemotherapy. Patients treated with Tevimbra and chemotherapy lived on average for 19.1 months compared with 10.0 months for patients treated with placebo and chemotherapy. In addition, patients given Tevimbra and chemotherapy lived for 8.2 months without their disease getting worse, compared with 5.5 months for those given placebo and chemotherapy.

Gastric or gastroesophageal junction adenocarcinoma

A main study involved 997 adults with locally advanced, unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma that was HER2 negative. Patients had not received systemic treatment for their cancer before and were given Tevimbra and chemotherapy or placebo with chemotherapy. Among the 546 patients who had a PD-L1 TAP score of at least 5%, those who were treated with Tevimbra and chemotherapy lived on average for 16.4 months compared with 12.8 months for patients treated with placebo and chemotherapy. In addition, patients on Tevimbra and chemotherapy lived for 7.2 months without their disease getting worse, compared with 5.9 months for those given placebo and chemotherapy.

Nasopharyngeal carcinoma (NPC)

A main study involved 263 adults whose NPC had come back or was metastatic. As a first treatment, they were given Tevimbra or placebo, both in combination with gemcitabine and cisplatin, for 12 to 18 weeks.

Patients who were given Tevimbra lived for an average of 9.6 months without their disease getting worse, compared with 7.4 months for patients given placebo. In addition, patients treated with Tevimbra lived for an average of 45.3 months. This was 31.8 months for patients who received placebo.

What are the risks associated with Tevimbra?

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

The most common side effects with Tevimbra when given alone (which may affect more than 1 in 5 people) include anaemia (low levels of red blood cell), tiredness and raised levels of the liver enzymes aspartate aminotransferase and alanine aminotransferase (which may indicate liver damage).

The most common side effects with Tevimbra when given together with chemotherapy (which may affect more than 1 in 5 people) include neutropenia (low levels of neutrophils, a type of white blood cell), anaemia, thrombocytopenia (low blood levels of platelets, components that help the blood to clot), nausea (feeling sick), tiredness, decreased appetite, raised levels of the liver enzymes aspartate aminotransferase and alanine aminotransferase, rash and diarrhoea.

Why is Tevimbra authorised in the EU?

Tevimbra is effective at improving survival and delaying the worsening of NSCLC. It is also effective at improving survival in patients with advanced or metastatic squamous oesophageal cancer, advanced or metastatic gastric or gastro-oesophageal junction adenocarcinoma and small cell lung cancer. In patients with nasopharyngeal carcinoma, Tevimbra is effective at prolonging the time they live without their disease getting worse. The side effects of this medicine are considered manageable and comparable to those of similar cancer medicines. The European Medicines Agency therefore decided that Tevimbra'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 Tevimbra?

The company that markets Tevimbra will provide patients with an alert card to inform them about the risks of potential immune-related side effects and give instructions on when to contact their doctor if they experience symptoms.

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

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

Other information about Tevimbra

Tevimbra received a marketing authorisation valid throughout the EU on 15 September 2023.

Further information on Tevimbra can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/tevimbra.

This overview was last updated in 08-2025.