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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 adults with squamous oesophageal cancer (cancer of the oesophagus, the passage from the mouth to the stomach) if the cancer is advanced, has spread to other parts of the body (metastatic) or cannot be removed by surgery (unresectable). It is used after cancer treatment with platinum-based medicines has not worked well enough.

Oesophageal cancer is rare, and Tevimbra was designated an 'orphan medicine' (a medicine used in rare diseases) on 13 November 2020. Further information on the orphan designation can be found on the EMA website.

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 three weeks, and treatment can continue until the disease gets worse. 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.

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What benefits of Tevimbra have been shown in studies?

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 patients treated with other cancer medicines (paclitaxel, docetaxel or irinotecan), who lived on average for 6.3 months.

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 effect with Tevimbra (which may affect more than 1 in 5 people) was anaemia (low red blood cell counts). Other common side effects (which may affect more than 1 in 10 people) include hypothyroidism (an underactive thyroid gland), cough, rash, itching, tiredness and decreased appetite.

The most common serious side effects (which may affect up to 1 in 10 people) include anaemia and pneumonia (infection of the lungs).

Why is Tevimbra authorised in the EU?

Tevimbra was effective at improving survival (how long patients lived) in patients with advanced or metastatic squamous oesophageal cancer who had previously received platinum-based chemotherapy. The side effects of this medicine were 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 09-2023.