EMA/3771/2023
EMEA/H/C/004650

Tremelimumab AstraZeneca (*tremelimumab*)

An overview of Tremelimumab AstraZeneca and why it is authorised in the EU

What is Tremelimumab AstraZeneca and what is it used for?

Tremelimumab AstraZeneca is a cancer medicine for treating non-small cell lung cancer (NSCLC) that has metastasised (spread to other parts of the body) in adults who have not been treated before. It is given together with durvalumab (another cancer medicine) and platinum-based chemotherapy, and is used when the cancer has shown no mutations (changes) in the so-called *EGFR* and *ALK* genes.

Tremelimumab AstraZeneca contains the active substance tremelimumab.

How is Tremelimumab AstraZeneca used?

Tremelimumab AstraZeneca can only be obtained with a prescription and treatment must be started and supervised by a doctor with experience in treating cancer.

Tremelimumab AstraZeneca is given as an infusion (drip) into a vein which lasts about an hour, in combination with durvalumab and chemotherapy. Treatment consists of a maximum of 5 doses, but may be stopped permanently if the cancer worsens or if the patient gets severe side effects.

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

How does Tremelimumab AstraZeneca work?

The active substance in Tremelimumab AstraZeneca, tremelimumab, is a monoclonal antibody (a type of protein). It is designed to attach to and block CTLA-4, a protein that controls the activity of T cells, which are part of the immune system (the body's natural defences). By blocking CTLA-4, the medicine increases the number and activity of T cells, which can then kill cancer cells. This is expected to slow down the spread of the cancer.

What benefits of Tremelimumab AstraZeneca have been shown in studies?

In a main study in patients with metastatic NSCLC, 338 patients given Tremelimumab AstraZeneca in combination with durvalumab and chemotherapy lived on average for 14 months, compared with 12 months for 337 patients given only chemotherapy. They also lived longer without their disease getting

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worse: around 6 months on average, compared with 5 months for patients who only received chemotherapy.

What are the risks associated with Tremelimumab AstraZeneca?

The most common side effects with Tremelimumab AstraZeneca in combination with durvalumab and chemotherapy (which may affect more than 2 in 10 people) are anaemia (low levels of red blood cells), nausea (feeling sick), neutropenia (low levels of neutrophils, a type of white blood cell that fights infection), tiredness, rash, thrombocytopenia (low levels of platelets in the blood) and diarrhoea.

The most common serious side effects (which may affect more than 2 in 10 people) are neutropenia and anaemia. Other serious side effects (which may affect up to 1 in 10 people) are pneumonia (infection of the lungs), thrombocytopenia, leucopenia (low levels of white blood cells), tiredness, neutropenia with fever, colitis (inflammation of the large intestine) and increased levels of liver enzymes and lipase (an enzyme that helps digest fat, mainly made in the pancreas).

Tremelimumab AstraZeneca is commonly associated with side effects related to the activity of the immune system on body organs, such as immune-mediated hypothyroidism (an underactive thyroid gland) and colitis.

For the full list of side effects and restrictions of Tremelimumab AstraZeneca, see the package leaflet.

Why is Tremelimumab AstraZeneca authorised in the EU?

Tremelimumab AstraZeneca, when given in combination with durvalumab and chemotherapy, can prolong patients' lives compared with chemotherapy only. Side effects of added Tremelimumab AstraZeneca, in particular concerning immune-mediated side effects, can be serious, and warrant caution when treating frail or elderly patients.

The European Medicines Agency decided that Tremelimumab AstraZeneca'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 Tremelimumab AstraZeneca?

The company that markets Tremelimumab AstraZeneca must provide healthcare professionals prescribing the medicine with educational materials on the side effects resulting from excessive activity of the immune system. Patients will also receive from their doctor an alert card summarising key safety information on the medicine.

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

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

Other information about Tremelimumab AstraZeneca

Tremelimumab AstraZeneca received a marketing authorisation valid throughout the EU on 20 February 2023

Further information on Tremelimumab AstraZeneca can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Tremelimumab-AstraZeneca.

This overview was last updated in 03-2023.