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Tecentriq (*atezolizumab*)

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

What is Tecentriq and what is it used for?

Tecentriq is a cancer medicine for treating urothelial carcinoma (a cancer of the bladder and urinary system) and a type of lung cancer called non-small cell lung cancer.

Tecentriq is used when these cancers are advanced or have spread to other parts of the body. For urothelial carcinoma, the medicine is for patients who have tried platinum chemotherapy before or are ineligible for treatment with cisplatin. Patients with non-small cell lung cancer should first have had chemotherapy and those with certain genetic mutations (changes) that respond to targeted treatments should have those treatments before receiving Tecentriq.

Tecentriq contains the active substance atezolizumab.

How is Tecentriq used?

Tecentriq is given as an infusion (drip) into a vein every 3 weeks and treatment should continue for as long as the patient benefits from it or does not suffer from unmanageable side effects. Treatment may need to be stopped in patients experiencing certain side effects caused by the patient's own immune system (the body's defence system) including inflammationof various body organs or endocrine (glandular) disorders. For more information about using Tecentriq, see the package leaflet or contact your doctor or pharmacist.

Tecentriq can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in treating cancer.

How does Tecentriq work?

The active substance in Tecentriq, atezolizumab, is a monoclonal antibody, a type of protein designed to recognise and attach to a protein called 'programmed death-ligand 1' (PD-L1), which is present on the surface of many cancer cells.

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PD-L1 acts to switch off immune cells that would otherwise attack the cancer cells. By attaching to PD-L1 and reducing its effects, Tecentriq increases the ability of the immune system to attack the cancer cells and thereby slow down the progression of the disease.

What benefits of Tecentriq have been shown in studies?

Urothelial carcinoma

Tecentriq has been shown to reduce tumours in patients with urothelial carcinoma that is advanced or has spread. In a study of 429 patients, 23% of patients who were not eligible for platinum chemotherapy responded to Tecentriq treatment and 16% of patients who had previously had platinum chemotherapy responded (a response is a partial or complete elimination of a patient's tumours.)

Another study of 931 patients with urothelial carcinoma showed that patients given Tecentriq lived slightly longer (8.6 months) than patients given chemotherapy (8 months) although the difference could be due to chance. Response was seen even in patients whose cancer cells did not produce much PD-L1.

Non-small cell lung cancer

In patients with non-small cell lung cancer which is advanced or has spread, Tecentriq has been shown to be more effective than a comparator medicine at prolonging patients' lives. In one main study of 850 patients, those patients given Tecentriq lived on average for 14 months while those given another cancer medicine, docetaxel, lived for an average of 10 months. Similar results were seen in a second lung cancer study of 287 patients where on average patients on Tecentriq lived for 13 months compared with 10 months for patients on docetaxel.

What are the risks associated with Tecentriq?

The most common side effects with Tecentriq (which may affect more than 1 in 10 people) are tiredness, reduced appetite, nausea (feeling sick) and vomiting, difficulty breathing, diarrhoea, rash, fever, joint pain, weakness and itching. For the full list of side effects and restrictions, see the package leaflet.

Why is Tecentriq authorised in the EU?

In urothelial carcinoma, Tecentriq has been shown to reduce tumour size in patients who have tried platinum chemotherapy or who are not eligible for such treatment. Tecentriq can also improve survival by 3 or 4 months in patients with non-small cell lung cancer who have few treatment options. Furthermore, its side effects are less troublesome than standard chemotherapy treatments and are considered manageable.

What measures are being taken to ensure the safe and effective use of Tecentriq?

The company that markets Tecentriq will put in place an educational program for patients and healthcare professionals to explain that serious immune-related side effects can occur during treatment and what they should do to minimize risks. The company is also carrying out and completing studies to provide more data on the effectiveness of Tecentriq in urothelial carcinoma and on the medicine's safety.

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

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

Other information about Tecentriq

Tecentriq received a marketing authorisation valid throughout the European Union on 21 September 2017.

Further information on Tecentriq can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 03-2018.