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Loqtorzi (*toripalimab*)

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

What is Loqtorzi and what is it used for?

Loqtorzi is a cancer medicine used in adults to treat:

- nasopharyngeal cancer (cancer of the nasopharynx, where the throat and nose connect) that is recurrent (has come back) and cannot be treated with surgery or radiotherapy or is metastatic (has spread to other parts of the body). It is used together with cisplatin and gemcitabine, other cancer medicines (also known as chemotherapy);
- oesophageal squamous cell cancer, a type of cancer affecting the oesophagus (the passage from the mouth to the stomach). It is used when the cancer is advanced and cannot be removed by surgery or if it is recurrent or metastatic. It is used together with the chemotherapy medicines cisplatin and paclitaxel.

Loqtorzi contains the active substance toripalimab.

How is Loqtorzi used?

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

Loqtorzi is given once every 3 weeks as an infusion (drip) into a vein. The infusion lasts 60 minutes for the first dose and, providing the medicine is well tolerated, 30 minutes for subsequent doses.

Treatment should continue for up to 24 months. The doctor may delay doses if certain side effects occur or stop treatment altogether for certain severe side effects or if the disease gets worse.

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

How does Loqtorzi work?

The active substance in Loqtorzi, toripalimab, is a monoclonal antibody, a type of protein that has been designed to attach to a receptor called PD-1 found on cells of the immune system called T cells. Cancer cells can produce proteins (PD-L1 and PD-L2) that attach to this receptor and switch off the activity of the T cells, preventing them from attacking the cancer. By attaching to the receptor, toripalimab

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prevents PD-L1 and PD-L2 from switching off the T cells, thereby increasing the ability of the immune system to kill cancer cells.

What benefits of Loqtorzi have been shown in studies?

A main study involved 289 adults with metastatic or recurrent locally advanced (spread to nearby tissue) nasopharyngeal cancer who had not received treatment for their recurrent or metastatic disease. They received either Loqtorzi or placebo (a dummy treatment), each given together with gemcitabine and cisplatin. People who received Loqtorzi lived on average for 21.4 months without the disease getting worse, compared with 8.2 months for those who received placebo. In addition, people who received placebo lived for an average of 33.7 months; this time could not be calculated for people who received Loqtorzi because fewer people had died during the follow-up period.

A second main study involved 514 adults with recurrent or metastatic oesophageal squamous cell cancer who had not received systemic (whole-body) treatment for their recurrent or metastatic disease. The study compared the effect of Loqtorzi with that of placebo, each given together with paclitaxel and cisplatin. People who received Loqtorzi lived for an average of 17.7 months, while those who received placebo lived on average for 12.9 months. The average time people lived before their disease got worse was 5.7 months with Loqtorzi and 5.5 months with placebo.

What are the risks associated with Loqtorzi?

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

Loqtorzi is commonly associated with side effects related to the activity of the immune system which may cause inflammation of body organs and tissues and can be serious. Most will go away with appropriate treatment or on stopping Loqtorzi.

The most common side effects with Loqtorzi in combination with platinum-based chemotherapy, such as cisplatin, (which may affect more than 1 in 10 people) include anaemia (low levels of red blood cells), leucopenia (low levels of white blood cells), neutropenia (low levels of neutrophils, a type of white blood cell), thrombocytopenia (low levels of blood platelets, components that help the blood to clot), nausea (feeling sick), vomiting, decreased appetite, rash, tiredness, abnormal liver function tests, hypothyroidism (an underactive thyroid gland), constipation, neuropathy (nerve damage), colitis (inflammation in the large bowel), fever, cough, pruritus (itching), decreased creatinine clearance (a sign of kidney problems) and hyponatraemia (low blood sodium levels).

Why is Loqtorzi authorised in the EU?

In people with nasopharyngeal cancer or oesophageal squamous cell cancer that has come back or spread, Loqtorzi has been shown to be effective at increasing the time they live before their disease gets worse, although for oesophageal cancer the difference was small. It has also been found to increase the overall time people with these cancers live.

The side effects of Loqtorzi are similar to those of other cancer medicines that target PD-1 and are considered manageable with appropriate measures.

The European Medicines Agency therefore decided that Loqtorzi’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 Loqtorzi?

The company that markets Loqtorzi will provide an alert card for patients with information on the risks of the medicine, as well as instructions on when to contact their doctor if they have symptoms of immune-related side effects.

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

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

Other information about Loqtorzi

Loqtorzi received a marketing authorisation valid throughout the EU on 19 September 2024.

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

This overview was last updated in 09-2024.