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Lorviqua (*lorlatinib*)

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

What is Lorviqua and what is it used for?

Lorviqua is a cancer medicine used to treat adults with non-small cell lung cancer (NSCLC) when the disease is advanced and ALK-positive, which means that the cancer cells have certain changes affecting the gene responsible for a protein called ALK (anaplastic lymphoma kinase).

Lorviqua is used on its own when the disease has not been treated before with other medicines of the same class, known as ALK tyrosine kinase inhibitors (TKIs).

Lorviqua is also used on its own when the disease has worsened despite treatment with other ALK TKIs, including alectinib, ceritinib and crizotinib.

Lorviqua contains the active substance lorlatinib.

How is Lorviqua used?

Lorviqua can only be obtained with a prescription. Treatment with Lorviqua should be started and supervised by a doctor who is experienced in using cancer medicines.

The patient's cancer should be tested before starting treatment to confirm it has the genetic change affecting ALK.

Lorviqua is available as tablets to be taken by mouth and the recommended dose is 100 mg once a day. If certain side effects develop the doctor may reduce the dose or interrupt treatment temporarily. Treatment may be stopped altogether if the disease gets worse or side effects become too severe.

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

How does Lorviqua work?

ALK belongs to a family of enzymes called receptor tyrosine kinases, which are involved in the growth of cells and the development of new blood vessels that supply them. In patients with ALK-positive NSCLC, an abnormal form of ALK is produced that causes the cancer cells to divide and grow in an uncontrolled manner.

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The active substance in Lorviqua, lorlatinib, is a tyrosine kinase inhibitor. It works by blocking the activity of ALK, thereby reducing the growth and spread of the cancer cells.

What benefits of Lorviqua have been shown in studies?

ALK-positive advanced NSCLC previously treated with an ALK TKI

Lorviqua was effective at treating ALK-positive NSCLC in one main study which included 139 patients whose disease had worsened despite treatment with either alectinib or ceritinib or with crizotinib and another ALK TKI. In this study Lorviqua was not compared with any other treatment or placebo (a dummy treatment).

Response to treatment was assessed using body scans and standardised criteria for assessing solid tumours, with complete response being when the patient had no remaining signs of the cancer. Around 43% of patients who had been previously treated with alectinib or ceritinib were considered by their doctors to have had a complete or partial response to Lorviqua.

Of the patients who had been previously treated with crizotinib and another ALK TKI, around 40% had a complete or partial response to Lorviqua.

Lorviqua was also effective when the cancer had spread to the brain. Depending on which previous treatment the patients had received, around 67% and 52% of patients treated with Lorviqua had no signs of cancer in the brain or the signs of cancer had reduced.

Previously untreated ALK-positive advanced NSCLC

One main study, involving 296 patients with ALK-positive NSCLC who had not been treated before with another ALK TKI, found that Lorviqua was more effective than crizotinib in preventing the disease from getting worse.

Patients given crizotinib got worse, on average, after around 9 months of treatment; as very few patients on Lorviqua got worse, it was not possible to calculate how many months passed before the disease worsened. The benefits of Lorviqua were further supported by study data showing that 76% of the patients given Lorviqua had a complete or partial response compared with 58% of patients receiving crizotinib. In addition, responses to Lorviqua lasted for longer compared with crizotinib.

Lorviqua was also effective in patients whose cancer had spread to the brain. Around 66% of the patients treated with Lorviqua had no signs of cancer in the brain or the signs of cancer had reduced compared with around 20% of those receiving crizotinib.

What are the risks associated with Lorviqua?

The most common side effects with Lorviqua (which may affect more than 1 in 5 people) are hypercholesterolaemia (high blood cholesterol levels), hypertriglyceridaemia (high blood levels of triglycerides, a type of fat), oedema (build-up of fluid), peripheral neuropathy (nerve damage in the hands and feet), weight gain, problems with thinking, learning and memory, tiredness, arthralgia (joint pain), diarrhoea and effects on mood. The most common serious side effects with Lorviqua (which may affect more than 1 in 100 people) are problems with thinking, learning and memory, and pneumonitis (inflammation in the lungs).

Lorviqua must not be used together with medicines known as 'strong CYP3A4/5 inducers' because the combined medicines may damage the liver and reduce the amount of Lorviqua in the blood. For the full list of side effects and restrictions with Lorviqua, see the package leaflet.

Why is Lorviqua authorised in the EU?

Lorviqua is effective at treating patients with ALK-positive NSCLC that has not been treated before or has worsened despite treatment with other ALK TKIs. Lorviqua is also effective when the cancer has spread to the brain.

Very few other treatments are available for patients with advanced ALK-positive NSCLC, and the side effects with Lorviqua are manageable.

The European Medicines Agency therefore decided that Lorviqua's benefits are greater than its risks and it can be authorised for use in the EU.

Lorviqua has been given 'conditional authorisation'. There is more evidence to come about the medicine, which the company is required to provide. Every year, the Agency will review any new information that becomes available and this overview will be updated as necessary.

What information is still awaited for Lorviqua?

Since Lorviqua has been given conditional authorisation, the company that markets Lorviqua will conduct a study with the medicine in patients whose disease has worsened after treatment with alectinib or ceritinib.

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

To further characterise the benefits of Lorviqua, the company that markets the medicine will provide the final results of the study comparing Lorviqua with crizotinib in patients with ALK-positive NSCLC who had not been treated before with another ALK TKI.

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

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

Other information about Lorviqua

Lorviqua received a conditional marketing authorisation valid throughout the EU on 6 May 2019.

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

This overview was last updated in 01-2022.