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Alecensa (*alectinib*)

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

What is Alecensa and what is it used for?

Alecensa is a cancer medicine used to treat a type of lung cancer called non-small-cell lung cancer (NSCLC). It is only used when the cancer is 'ALK-positive', which means that cancer cells have changes in the gene that makes a protein called anaplastic lymphoma kinase (ALK).

Alecensa is used on its own in adults with:

- advanced NSCLC that has never been treated before or has already been treated with a cancer medicine called Xalkori (crizotinib);
- NSCLC that has been removed by surgery (adjuvant treatment) and is at high risk of coming back.

Alecensa contains the active substance alectinib.

How is Alecensa used?

Alecensa can only be obtained with a prescription and treatment must be started and supervised by a doctor who is experienced in using cancer medicines. ALK positivity should be confirmed before starting treatment.

The medicine is available as capsules to be taken by mouth twice daily with food. Treatment of advanced NSCLC should be continued until the disease gets worse or unacceptable side effects occur. For adjuvant treatment, Alecensa is given for 2 years unless the cancer comes back or unacceptable side effects occur.

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

How does Alecensa work?

ALK belongs to a family of proteins 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 and stimulates the cancer cells to divide and grow

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uncontrollably. The active substance in Alecensa, alectinib, is an ALK inhibitor and works by blocking the activity of ALK, thereby reducing the growth and spread of the cancer.

What benefits of Alecensa have been shown in studies?

Alecensa has been shown to be effective in treating ALK-positive NSCLC.

Advanced NSCLC

Two main studies involved a total of 225 patients with advanced ALK-positive NSCLC in whom the disease progressed despite previous treatment with Xalkori (crizotinib), a cancer medicine that also blocks ALK. In both studies, Alecensa was not compared with any other treatment or placebo (a dummy treatment). A complete response to treatment means that the patient has no remaining signs of the cancer, whereas a partial response means that the cancer has shrunk.

In the first study, around 52% of patients given Alecensa (35 out of 67) were considered by the treating doctors to have a complete or partial response to the medicine. In the second study, this figure was 51% (62 out of 122 patients). Response was maintained for an average of approximately 15 months in both studies.

The third study involved 303 patients whose advanced ALK-positive NSCLC had not been treated before. Alecensa was compared with Xalkori. After 1 year of treatment, 68% of patients receiving Alecensa had lived without their disease getting worse compared with 49% of patients receiving Xalkori.

NSCLC that has been removed by surgery and is at high risk of coming back

In a main study involving 257 patients whose ALK-positive NSCLC was removed by surgery, 2-year treatment with Alecensa was compared to 4 cycles of platinum-based chemotherapy lasting 21 days each. Treatment was stopped earlier if the cancer came back or unacceptable side effects occurred. At the time of analysis, 88% of the patients given Alecensa were alive without their disease coming back, compared with approximately 61% of patients given platinum-based chemotherapy.

What are the risks associated with Alecensa?

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

The most common side effects with Alecensa (which may affect more than 2 in 10 people) include constipation, muscle pain, oedema (swelling), anaemia (low levels of red blood cells), high levels of bilirubin (a breakdown product of red blood cells indicating liver problems) and elevated liver enzymes.

Why is Alecensa authorised in the EU?

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

Patients whose disease progresses during or shortly after treatment with Xalkori currently have very limited treatment options and Alecensa can be of benefit in these patients. Alecensa was also better than Xalkori at treating previously untreated patients with ALK-positive NSCLC. Patients whose NSCLC was removed by surgery also benefited from treatment with Alecensa. Treatment with Alecensa for 2 years after surgery increased the time patients lived without their disease getting worse. The safety profile of Alecensa was considered acceptable.

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

The company marketing Alecensa must provide updated results of the study for adjuvant treatment, including the average time patients lived without their disease coming back and the time patients lived overall.

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

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

Other information about Alecensa

Alecensa received a marketing authorisation valid throughout the EU on 16 February 2017.

Further information on Alecensa 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 05-2024.