



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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 adults with a lung cancer called non-small-cell lung cancer (NSCLC), when the disease is advanced and has not been treated before or has been treated before with a cancer medicine called Xalkori (crizotinib).

Alecensa is used on its own and only if the NSCLC is 'ALK-positive', which means that the cancer cells have certain defects affecting the gene that makes a protein called ALK (anaplastic lymphoma kinase).

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. Genetic defects affecting ALK ('ALK-positive' status) should be confirmed in advance by appropriate methods.

The medicine is available as capsules (150 mg). The recommended usual dose is 4 capsules taken twice a day with food (1,200 mg in total). For patients with severe liver impairment the recommended dose is 3 capsules taken twice a day with food (900 mg in total). The doctor may reduce the dose or stop treatment temporarily if side effects occur. In certain cases treatment should be permanently stopped.

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 (RTKs), 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 stimulates the cancer cells to divide and grow in an uncontrolled fashion. 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.

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What benefits of Alecensa have been shown in studies?

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

Two main studies involved a total of 225 patients in whom the disease progressed despite previous treatment with Xalkori (crizotinib). In both studies Alecensa was not compared with any other treatment or placebo (a dummy treatment). Response to treatment was assessed using body scans and standardised criteria for solid tumours, with complete response being when the patient had no remaining signs of the cancer.

In the first study around 52% of patients given Alecensa (35 out of 67) were considered by the treating doctors to have shown a complete or partial response to the medicine at the time of analysis. In the second study, the complete or partial response rate at the time of analysis was 51% (62 out of 122 patients). Response was maintained for an average of 14.9 months in the first study, and 15.2 months in the second study.

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

What are the risks associated with Alecensa?

The most common side effects with Alecensa (which may affect more than 2 in 10 people) are constipation, muscle pain and oedema (swelling) including of the ankles and feet, the face, the eyelids and the area around the eyes.

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

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. The safety profile of Alecensa was considered acceptable and in line with that of other ALK inhibitors.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Alecensa have 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](https://ema.europa.eu/Find/medicine/Human%20medicines/European%20public%20assessment%20reports).

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