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EPAR summary for the public

Alecensa

alectinib

This is a summary of the European public assessment report (EPAR) for Alecensa. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Alecensa.

For practical information about using Alecensa, patients should read the package leaflet or contact their doctor or pharmacist.

What is Alecensa and what is it used for?

Alecensa is a cancer medicine used to treat adults with a type of lung cancer called non-small-cell lung cancer (NSCLC), when the disease is advanced and has been treated before with another cancer medicine called Xalkori (crizotinib). It 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 responsible for 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. The presence of genetic defects affecting ALK ('ALK-positive' status) has to be confirmed in advance by appropriate methods.

The medicine is available as capsules (150 mg). The recommended dose is 4 capsules (600 mg) taken twice a day with food. The doctor may decide to reduce the dose or stop treatment temporarily if side effects occur. In certain cases treatment should be permanently stopped. For further information see the summary of product characteristics (also part of the EPAR).

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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.

What benefits of Alecensa have been shown in studies?

Alecensa has been investigated in two main studies involving 225 patients in whom the disease progressed despite previous treatment with crizotinib (Xalkori). In both studies, which were still ongoing at the time of Alecensa evaluation, the medicine 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 one 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). The average length of response was 14.9 months in the first study, and 15.2 months in the second study.

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, oedema (swelling, including of the ankles and feet and of the eyelids and area around the eyes), muscle pain and nausea (feeling sick). The most common severe reactions (which may affect 1 or more people in 100) were abnormal liver tests, anaemia (low levels of red blood cells), increases in the blood level of creatine phosphokinase (an enzyme in muscles which can be raised in the blood when muscles are damaged) and diarrhoea.

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

Why is Alecensa approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Alecensa's benefits are greater than its risks and recommended that it be approved for use in the EU.

Patients whose disease progresses during or shortly after treatment with Xalkori currently have very limited treatment options and therefore a high unmet clinical need. The currently available evidence was sufficient to show that Alecensa could be of benefit in these patients, although further data to confirm this are awaited. The safety profile of Alecensa was considered acceptable and in line with that of other ALK inhibitors.

Alecensa has been given 'conditional approval'. This means that there is more evidence to come about the medicine, which the company is required to provide. Every year, the European Medicines Agency will review any new information that becomes available and this summary will be updated as necessary.

What information is still awaited for Alecensa?

Since Alecensa has been granted a conditional approval, the company that markets Alecensa will provide results of a further study comparing Alecensa with Xalkori in patients with ALK-positive NSCLC who did not receive previous treatment.

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.

Other information about Alecensa

The European Commission granted a marketing authorisation valid throughout the European Union for Alecensa on 16/02/2017

The full EPAR for Alecensa can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Alecensa, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in February 2017.