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Alunbrig (*brigatinib*)

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

What is Alunbrig and what is it used for?

Alunbrig is a cancer medicine that is used to treat adults with a type of lung cancer called non-small cell lung cancer (NSCLC). It is used in patients who have not been treated before with a medicine of the ALK inhibitor class or who have been treated before with the ALK-inhibitor crizotinib.

Alunbrig is only used if the NSCLC is 'ALK-positive', which means that the cancer cells have certain changes affecting the gene that makes a protein called ALK (anaplastic lymphoma kinase).

Alunbrig contains the active substance brigatinib.

How is Alunbrig used?

Alunbrig 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 patient's cancer should be tested before starting treatment to confirm it has the gene changes affecting ALK ('ALK-positive' status).

The medicine is available as tablets (30 mg, 90 mg and 180 mg). The recommended starting dose is 90 mg taken once a day for the first 7 days and then increased to 180 mg once a day afterwards. Reduced doses are recommended in patients with severely reduced liver or kidney function. Patients with severely reduced kidney function should be closely monitored especially during the first week of treatment for symptoms of lung disease such as cough or difficulty breathing.

Treatment can continue for as long as the patient benefits from it. 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 Alunbrig, see the package leaflet or contact your doctor or pharmacist.

How does Alunbrig 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 stimulates the cancer cells to divide and grow in an

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uncontrolled fashion. The active substance in Alunbrig, brigatinib, works by blocking the activity of ALK, thereby reducing the growth and spread of the cancer.

What benefits of Alunbrig have been shown in studies?

Alunbrig has been shown to be effective in treating ALK-positive NSCLC in two main studies.

The first study involved 222 patients in whom the disease progressed despite previous treatment with crizotinib. Alunbrig 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. Out of patients who received 90 mg Alunbrig a day and increased to 180 mg after 7 days, around 56% showed a complete or partial response to the medicine. Responses were maintained on average for around 14 months.

The second study involved 275 patients who had not previously been treated with an ALK inhibitor. In this study, it took 24 months on average for the disease to get worse in patients who received Alunbrig, compared with 11 months in patients who received crizotinib.

What are the risks associated with Alunbrig?

The most common side effects with Alunbrig (which may affect more than 1 in 4 people) are hyperglycaemia (high blood sugar levels), hyperinsulinaemia (high blood insulin levels), anaemia (low red blood cell counts), nausea (feeling sick), low white blood cell counts including decreased levels of the white blood cells called lymphocytes, diarrhoea, tiredness, cough, headache, hypophosphataemia (low blood levels of phosphates), rash, vomiting, dyspnoea (difficulty breathing), hypertension (high blood pressure), myalgia (muscle pain), and blood test results indicating abnormalities of liver (increased levels of ALT and AST and alkaline phosphatase), pancreas (increased lipase and amylase), muscle function (increased CPK) or blood clotting (increased APTT).

The most common serious side effects (which may affect more than 1 in 50 people) are pneumonitis (inflammation in the lungs), pneumonia (infection of the lungs), dyspnoea and pyrexia (fever).

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

Why is Alunbrig authorised in the EU?

Alunbrig was effective in treating patients with ALK-positive NSCLC who had been previously treated with an ALK-inhibitor medicine called crizotinib or who had not been treated with an ALK-inhibitor. Once appropriate measures are taken to manage the potentially serious side effect of lung disease, the safety profile of Alunbrig is considered manageable. The European Medicines Agency decided that Alunbrig'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 Alunbrig?

The company that markets Alunbrig will submit the results of an ongoing study on the effectiveness and safety of Alunbrig in patients with ALK-positive NSCLC who have not received previous treatment targeted to ALK. It will also provide an alert card for patients summarising key safety information about the risk of lung disease with the medicine and what to do in case of signs and symptoms.

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

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

Other information about Alunbrig

Alunbrig received a marketing authorisation valid throughout the EU on 22 November 2018.

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

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