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Aumseqa (*aumolertinib*)

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

What is Aumseqa and what is it used for?

Aumseqa is a cancer medicine used on its own to treat adults with a type of lung cancer called non-small cell lung cancer (NSCLC). It is used in patients whose cancer is advanced and has certain mutations (changes) in the gene for a protein called EGFR.

It is used in adults who have not been treated before for their cancer and whose cancer cells have mutations known as EGFR exon 19 deletions or exon 21 L858R substitution.

It is also used in adults whose cancer cells have an EGFR T790M mutation.

Aumseqa contains the active substance aumolertinib.

How is Aumseqa used?

Aumseqa can only be obtained with a prescription, and treatment should be started by a doctor experienced in the use of cancer medicines.

The medicine is available as tablets to be taken by mouth once a day. Treatment should be continued for as long at the patient benefits from it or until side effects become unacceptable.

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

How does Aumseqa work?

The active substance in Aumseqa, aumolertinib, is a type of cancer medicine called a tyrosine kinase inhibitor. It blocks the activity of EGFR, which normally controls the growth and division of cells. In lung cancer, EGFR is often overactive, causing uncontrolled growth of cancer cells. By blocking EGFR, aumolertinib helps to reduce the growth and spread of the cancer.

Aumolertinib mainly targets the mutated EGFR and has less effect on normal EGFR, therefore minimising undesirable effects caused by blocking normal EGFR.

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What benefits of Aumseqa have been shown in studies?

Aumseqa was found to be effective in adults with NSCLC whose cancer cells had specific mutations in the EGFR gene in two main studies.

The first study involved 429 adults with NSCLC who had not been treated before for their cancer, whose cancer was locally advanced (had spread nearby) or metastatic (had spread to other parts of the body) and had EGFR mutations including an exon 19 deletion or exon 21 L858R substitution. Participants received either Aumseqa or gefitinib (another tyrosine kinase inhibitor targeting EGFR). Those who took Aumseqa lived for an average of 19 months before their cancer got worse, compared with about 10 months for those who received gefitinib. In addition, patients who received Aumseqa lived on average for 39 months overall compared with 31 months overall for those who received gefitinib.

The second study involved 244 patients with locally advanced or metastatic NSCLC whose cancer cells had an EGFR T790M mutation and whose cancer had progressed after previous treatment with a tyrosine kinase inhibitor targeting EGFR. Aumseqa was not compared with any other treatment or placebo (a dummy treatment). About 69% of patients (168 of 244) had a partial response to treatment (shrinkage of the tumour) and the responses lasted for an average of about 15 months.

What are the risks associated with Aumseqa?

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

The most common side effects with Aumseqa (which may affect more than 1 in 10 people) include increased levels of certain liver enzymes (which can be a sign of liver problems), hyponatraemia (low blood sodium levels), increased blood levels of creatine phosphokinase (an enzyme released into the blood when muscle is damaged), decreased white blood cell levels, decreased levels of platelets (components that help the blood to clot), upper respiratory tract (nose and throat) infections and rash.

Aumseqa must not be used in people who have certain problems with the electrical activity of their heart called congenital long QT syndrome and QT/QTc interval greater than 500 milliseconds. It must also not be used in people with a family history of sudden cardiac death or polymorphic ventricular arrhythmia (a type of heart rhythm disorder).

Why is Aumseqa authorised in the EU?

In adults with advanced NSCLC who had never been treated before, and whose cancer had exon 19 deletion or exon 21 L858R substitution, Aumseqa was shown to prolong the time patients lived without their disease getting worse, and how long they lived overall, compared to another tyrosine kinase inhibitor targeting EGFR.

In adults with advanced NSCLC whose disease had progressed after previous treatment with a tyrosine kinase inhibitor, and whose cancer had an EGFR T790M mutation, Aumseqa was shown in a study to trigger a partial but durable response to treatment in most patients. Although this study did not compare Aumseqa with another treatment, the totality of the data on Aumseqa confirmed its activity against the cancer.

In terms of safety, while the safety profile of Aumseqa appears overall in line with that of other tyrosine kinase inhibitors, certain severe side effects, including heart rhythm problems, that had not been described with this class of medicines before, were seen with Aumseqa. Standard measures, including tests before starting treatment and restrictions, are in place to minimise these risks.

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

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

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

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

Other information about Aumseqa

Aumseqa received a marketing authorisation valid throughout the EU on 12 February 2026.

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

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