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Lumykras (*sotorasib*)

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

What is Lumykras and what is it used for?

Lumykras is a cancer medicine used to treat adults with non-small cell lung cancer (NSCLC) when the cancer is advanced, and its cells have a particular genetic change. The change is in the gene *KRAS* and is known as '*KRAS G12C*'. Lumykras is given when the disease has progressed after receiving systemic treatment (treatment affecting the whole body).

Lumykras contains the active substance sotorasib.

How is Lumykras used?

The medicine can only be obtained with a prescription, and treatment with Lumykras should be started 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 genetic change affecting *KRAS* (*KRAS G12C*).

Lumykras is available as tablets and is taken by mouth. The recommended dose is 960 mg once per day. Treatment is continued until the disease gets worse or side effects become too severe.

If certain side effects develop, the doctor may decide to reduce the dose to 480 mg once per day and then, if needed, to 240 mg once per day. Treatment should be stopped if side effects are too great at the lowest dose (240 mg).

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

How does Lumykras work?

Genetic changes to the *KRAS* gene can produce an altered protein that causes the uncontrolled growth of cancer cells. The active substance in Lumykras, sotorasib, attaches to this altered protein inside cancer cells. This blocks the protein from acting, interrupting the chemical messages the cancer cells need for growing and spreading, and it also encourages processes that cause the cancer cells to die.

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What benefits of Lumykras have been shown in studies?

In one main study involving 124 patients, Lumykras was effective in treating adults with NSCLC with the *KRAS G12C* genetic change whose disease had progressed after previously being treated with other cancer medicines. Lumykras was not compared with any other treatment or placebo (a dummy treatment).

Response to treatment (shrinkage in the size of the cancer) was assessed using body scans. Around 37% (46 out of 124) of the patients showed partial or complete cancer shrinkage after treatment with Lumykras. On average, responses lasted for just over 11 months.

What are the risks associated with Lumykras?

The most common side effects with Lumykras (which may affect more than 1 in 5 people) are diarrhoea, nausea (feeling sick) and tiredness. The most common severe side effects with Lumykras (which may affect up to 1 in 100 people) are increased levels of certain liver enzymes (a sign of possible liver problems) and liver injury. For the full list of side effects and restrictions of Lumykras, see the package leaflet.

Why is Lumykras authorised in the EU?

There are currently few treatment options for patients with advanced NSCLC with *KRAS G12C* mutations for whom the cancer has progressed after systemic treatment with cancer medicines, and current treatments have limited effectiveness. Although the main study did not compare Lumykras with another cancer treatment, it showed that the medicine was effective at treating the cancer including in patients whose cancer had progressed after several different treatments. In general, Lumykras' side effects were considered manageable.

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

Lumykras has been given 'conditional authorisation'. 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 overview will be updated as necessary.

What information is still awaited for Lumykras?

Since Lumykras has been given conditional authorisation, the company that markets Lumykras will provide further information from an ongoing study. The study will compare the efficacy and safety of Lumykras in treating previously treated NSCLC with *KRAS G12C* mutation with those of another cancer medicine, docetaxel.

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

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

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

Other information about Lumykras

Lumykras received a conditional marketing authorisation valid throughout the EU on 06 January 2022

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

This overview was last updated in 01-2021.