EMA/77801/2026
EMEA/H/C/006673

Zepzelca (*lurbinectedin*)

A plain-language overview of Zepzelca and why it is authorised in the EU

What is Zepzelca and what is it used for?

Zepzelca is a medicine used to treat extensive-stage small cell lung cancer (SCLC). SCLC is a type of rapidly growing lung cancer. Extensive-stage means that the cancer has spread within the lungs or to other parts of the body.

Zepzelca is used together with another cancer medicine, atezolizumab, as maintenance (continued) treatment in adults whose cancer has not got worse after treatment with atezolizumab, carboplatin and etoposide (other cancer medicines).

Extensive-stage SCLC is rare, and Zepzelca was designated an 'orphan medicine' (a medicine used in rare diseases) on 26 February 2019. Further information on the orphan designation can be found on the EMA website.

Zepzelca contains the active substance lurbinectedin.

How is Zepzelca used?

The medicine can only be obtained with a prescription and treatment should be started and supervised by a healthcare professional experienced in using cancer medicines.

Zepzelca is given by infusion (drip) into a vein over 1 hour. It is given once every 21 days, until the disease gets worse or side effects become unacceptable.

The doctor may delay treatment if the patient's levels of neutrophils (a type of white blood cell) or platelets (components that help the blood clot) are too low. Treatment may also be delayed if the patient experiences serious side effects.

Before receiving Zepzelca, patients are given other medicines (a corticosteroid and a serotonin antagonist) to prevent them from feeling sick or vomiting. After treatment with Zepzelca, patients are given a medicine called granulocyte colony-stimulating factor (G-CSF) to prevent neutropenia (low levels of neutrophils) or febrile neutropenia (fever associated with neutropenia).

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

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How does Zepzelca work?

The active substance in Zepzelca, lurbinectedin, binds to part of the cancer cell's DNA, thereby blocking the cell's ability to make proteins needed to grow and multiply. Cancer cells have high levels of these proteins, which cause the cells to grow uncontrollably. By blocking the machinery to make these proteins, lurbinectedin reduces their level in cancer cells and slows the growth of the cancer.

What benefits of Zepzelca have been shown in studies?

In a main study involving 483 adults with extensive-stage SCLC, patients lived for an average of 13.2 months when Zepzelca was used together with atezolizumab as maintenance treatment compared with 10.6 months when atezolizumab was used alone. In addition, patients given Zepzelca plus atezolizumab lived for an average of 5.4 months without their disease getting worse, compared with 2.1 months for those given atezolizumab alone.

Studies carried out with Zepzelca are described in more detail in the medicine's assessment report.

What are the side effects and restrictions with Zepzelca?

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

The most common side effects with Zepzelca (which may affect more than 1 in 10 people) include nausea, fatigue (tiredness), anaemia (low levels of red blood cells), thrombocytopenia (low levels of blood platelets) and neutropenia.

Some side effects can be serious. The most frequent (which may affect up to 1 in 10 people) include thrombocytopenia, pneumonia (lung infection), respiratory tract infection (infection of the airways) and dyspnoea (difficulty breathing).

Zepzelca must not be used when breast-feeding.

Why is Zepzelca authorised in the EU?

Zepzelca used together with atezolizumab has been shown to increase the time patients with extensive-stage SCLC live. Although the improvement is limited, it is considered to represent a meaningful benefit for these patients, for whom the prognosis is poor. In terms of safety, the side effects with Zepzelca in combination with atezolizumab are more burdensome than those with atezolizumab alone, but are considered manageable. The European Medicines Agency therefore decided that Zepzelca'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 Zepzelca?

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

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

Other information about Zepzelca

Zepzelca received a marketing authorisation valid throughout the EU on 29 May 2026.

Further information on Zepzelca, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/zepzelca.

For information about the availability of this medicine in your country, contact your national competent authority.

This overview was last updated in 06-2026