

Summary report on authorisation dated 23 March 2026

## Zepzelca<sup>®</sup> (active substance: lurbinectedin)

Indication extension in Switzerland: 20 November 2025

**Powder for concentrate for solution for infusion for the maintenance treatment, in combination with atezolizumab, of adult patients with extensive-stage small-cell lung cancer (ES-SCLC) without CNS metastases**

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### About the medicinal product

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The medicinal product Zepzelca contains the active substance lurbinectedin.

Zepzelca has already been authorised by Swissmedic, on 7 March 2023, for the second-line treatment of adults with metastatic small-cell lung cancer (SCLC).

The current indication extension means that Zepzelca can now be used in combination with atezolizumab (immunotherapy) for the maintenance treatment of adult patients with extensive-stage small-cell lung cancer (ES-SCLC)<sup>1</sup> without CNS metastases<sup>2</sup>. The disease must not have progressed after first-line induction therapy with atezolizumab in combination with platinum-based chemotherapy (carboplatin and etoposide).

The indication extension for Zepzelca was authorised in connection with "Project Orbis".

Project Orbis is a programme for promising cancer treatments coordinated by the FDA, the US regulatory authority. It provides a framework for the concurrent submission and review of cancer medicines by several international partner authorities in various countries. The ultimate aim is to give patients faster access to innovative cancer treatments. In addition to the FDA, the authorisation authorities in Australia (TGA), Brazil (ANVISA), Israel (MOH), Canada (HC), Singapore (HSA), Switzerland (Swissmedic), and the United Kingdom (MHRA) are currently represented in Project Orbis.

Further details of the international collaboration of Project Orbis are published on the Swissmedic website: [Project Orbis \(swissmedic.ch\)](https://www.swissmedic.ch)

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<sup>1</sup> Extensive-stage small cell lung cancer (ES-SCLC) is a very advanced form of the disease in which the tumour has spread beyond one side of the lung, e.g. to the other side of the lung, lymph nodes or other organs.

<sup>2</sup> CNS metastases are secondary growths of a tumour in the central nervous system (CNS). The central nervous system includes the brain and spinal cord.

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## Mode of action

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The active substance lurbinectedin is a cytotoxin (cell poison) and an alkylating agent. Alkylating agents bind to specific structures of the DNA. In doing so, they impair certain

cell processes such as growth and replication, ultimately resulting in cell death of the cancer cells.

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## Use

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Zepzelca, containing the active substance lurbinectedin, is a prescription-only medicine.

Zepzelca is available in a vial containing 4 mg lurbinectedin. The powder is dissolved before use. The solution contains 0.5 mg/mL

lurbinectedin. This solution is injected into the veins.

The recommended dose is 3.2 mg/m<sup>2</sup> body surface area administered over a period of 1 hour every 21 days.

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## Efficacy

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The efficacy of Zepzelca in combination with atezolizumab as maintenance therapy was investigated in the IMforte trial, which enrolled adult patients with extensive-stage small-cell lung cancer (ES-SCLC), whose disease had not progressed after first-line induction therapy with atezolizumab, carboplatin and etoposide and who had an ongoing response or stable disease.

The trial participants received either Zepzelca plus atezolizumab or atezolizumab on its own as maintenance therapy. The primary endpoints, assessed by an independent review facility (IRF), were progression-free survival (PFS)<sup>3</sup> and overall survival (OS)<sup>4</sup>.

The median<sup>5</sup> PFS was 5.4 months with the treatment of Zepzelca and atezolizumab, compared to 2.1 months with the atezolizumab treatment on its own. The probability of disease progression or death was reduced by 46% in the main analysis.

The median OS was 13.2 months with the treatment of Zepzelca and atezolizumab, compared to 10.6 months with the atezolizumab treatment on its own. The probability of death was reduced by 27% in the main analysis.

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## Precautions, undesirable effects, & risks

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Zepzelca must not be used in those with moderate or severe liver failure or in those who are hypersensitive to the active substance or any of the excipients.

The most frequent undesirable effects are neutropenia, lymphopenia and leukopenia

(lack of different types of white blood cells), anaemia (lack of red blood cells), loss of appetite, nausea, vomiting, constipation and diarrhoea, and fatigue.

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<sup>3</sup> Progression-free survival (PFS): Period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

<sup>4</sup> Overall survival (OS) refers to the period between the start of treatment and the death of the patient.

<sup>5</sup> Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always less than the median, the other half are always greater.

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All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

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## Why the medicinal product has been authorised

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The prognosis for patients with extensive-stage small-cell lung cancer (ES-SCLC) after first-line treatment remains poor. An initial response to the combination of platinum-based chemotherapy and atezolizumab is often followed by relapses or disease progression.

The above-mentioned IMforte trial shows that the maintenance therapy with Zepzelca plus atezolizumab significantly improves progression-free survival and overall survival. Although the combination was associated with higher toxicity, the safety profile showed low rates of treatment-related dis-

continuations and fatalities, and is acceptable in view of the demonstrated efficacy and the severity of the disease.

Taking all the risks and precautions into account, and based on the available data, the benefits of the indication extension for Zepzelca outweigh the risks. Swissmedic has therefore authorised the medicinal product Zepzelca, containing the active substance lurbinectedin, in combination with atezolizumab, in Switzerland for the maintenance treatment of adult patients with extensive-stage small-cell lung cancer (ES-SCLC) without CNS metastases.

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## Further information on the medicinal product

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Information for healthcare professionals: [Information for healthcare professionals Zepzelca®](#)

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.