



EUROPEAN MEDICINES AGENCY  
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## Imdylltra (*tarlatamab*)

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

### What is Imdylltra and what is it used for?

Imdylltra is a medicine used to treat people with extensive-stage small cell lung cancer (SCLC) whose disease got worse during or after a first treatment with chemotherapy.

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.

Extensive-stage SCLC is rare, and Imdylltra was designated an 'orphan medicine' (a medicine used in rare diseases) on 12 January 2024. Further information on the orphan designation can be found on the EMA [website](#).

Imdylltra contains the active substance tarlatamab.

### How is Imdylltra used?

Imdylltra can only be obtained with a prescription. Treatment should be started and supervised by a doctor experienced in treating cancer.

The medicine is given by infusion (drip) into a vein over 1 hour. The first two infusions are given one week apart, followed by one infusion every 2 weeks. Treatment can continue until the disease gets worse or side effects become unacceptable.

Imdylltra can cause cytokine release syndrome (CRS), an immune reaction caused by the rapid release of inflammatory substances into the bloodstream. It can also cause immune effector cell-associated neurotoxicity syndrome (ICANS), an immune reaction that causes inflammation in the brain. To reduce these risks, people are given preventive medicines before and after the first two infusions of Imdylltra. They are also monitored for signs of CRS and ICANS, so they can be treated promptly.

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

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## **How does Imdylltra work?**

The active substance in Imdylltra, tarlatamab, is a T-cell engager, a type of antibody. Tarlatamab binds to two proteins: the DLL3 protein on cancer cells and the CD3 protein on T cells (a type of immune cell). This brings them close together and helps T cells recognise and kill the cancer cells.

## **What benefits of Imdylltra have been shown in studies?**

In a main study, Imdylltra increased the time patients with extensive-stage SCLC lived after their cancer got worse following a first treatment with platinum-based chemotherapy.

The study involved 509 adults who were given Imdylltra or standard chemotherapy (topotecan, lurbinectedin or amrubicin).

Patients treated with Imdylltra lived for an average of 13.6 months compared with an average of 8.3 months with standard treatment.

On average, the time patients lived without their disease getting worse was 4.2 months with Imdylltra compared with 3.2 months with standard treatment, on average.

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

## **What are the side effects and restrictions with Imdylltra?**

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

The most common side effects with Imdylltra (which may affect more than 1 in 10 people) include CRS, decreased appetite, fever, taste disturbance, constipation, anaemia (low levels of red blood cells), tiredness, nausea (feeling sick), asthenia (weakness), neutropenia (low levels of neutrophils), hyponatraemia (low blood sodium levels), headache and lymphopenia (low levels of lymphocytes).

Some side effects can be serious. The most frequent serious side effects with Imdylltra include CRS, fever and ICANS. CRS may affect more than 1 in 10 people, fever up to 1 in 10 people, and ICANS up to 1 in 100 people.

## **Why is Imdylltra authorised in the EU?**

Patients with extensive-stage SCLC have few treatment options and a short life expectancy. Imdylltra was shown to increase how long patients lived after their cancer had worsened following initial chemotherapy, compared with standard treatment.

CRS and ICANS are the main safety concerns with Imdylltra. Although these side effects can be serious, they are considered manageable with appropriate measures, including medication before and after the infusion and monitoring of patients for the first two doses. A patient card, together with clear warnings and recommendations in the product information support early recognition and timely management.

The European Medicines Agency decided that Imdylltra'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 Imdylltra?**

The company that markets Imdylltra will provide patients and carers with a patient card to inform them on how to recognise signs and symptoms of CRS and ICANS and to seek urgent medical attention if they develop them.

These materials may be made available by national competent authorities on their websites. A list of national repositories is available on the [EMA website](#).

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

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

## **Other information about Imdylltra**

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

Further information on Imdylltra, including the package leaflet and assessment report, can be found on the Agency's website: [ema.europa.eu/medicines/human/EPAR/imdylltra](http://ema.europa.eu/medicines/human/EPAR/imdylltra).

For information about the availability of this medicine in your country, contact your [national competent authority](#).

This overview was last updated in 05-2026.